FEDERAL REGISTER

Vol. 78 Friday

No. 249 December 27, 2013

OFFICE OF THE FEDERAL REGISTER

FEDERAL REGISTER

Vol. 78 Friday,
No. 249 December 27, 2013

Pages 78693–79282

OFFICE OF THE FEDERAL REGISTER

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2012–0020]

RIN 3150–AJ10

List of Approved Spent Fuel Storage Casks: Transnuclear, Inc. Standardized NUHOMS® Cask System

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of January 7, 2014, for the direct final rule that was published in the **Federal Register** on October 24, 2013. This direct final rule amended the NRC's spent fuel storage regulations by revising the Transnuclear, Inc. Standardized NUHOMS® Cask System listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 11 to Certificate of Compliance (CoC) No. 1004.

DATES: The effective date of January 7, 2014, is confirmed for the direct final rule published October 24, 2013 (78 FR 63375).

ADDRESSES: Please refer to Docket ID NRC–2012–0020 when contacting the NRC about the availability of information for this direct final rule. You may access publicly-available information related to this direct final rule by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0020. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Gregory Trussell, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6445, email: *Gregory.Trussell@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

On October 24, 2013 (78 FR 63375), the NRC published a direct final rule amending its regulations at § 72.214 of Title 10 of the *Code of Federal Regulations* (10 CFR) by revising the Transnuclear, Inc. Standardized NUHOMS® Cask System listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 11 to CoC No. 1004. Amendment No. 11 added a new transfer cask, the OS197L, for use with the 32PT and 61BT dry shielded canisters, and converted the CoC No. 1004 Technical Specifications to the format in NUREG–1745, "Standard Format and Content for Technical Specifications for 10 CFR Part 72 Cask Certificates of Compliance." In addition, the amendment made several other changes as described in Section III, "Discussion of Changes," section of the direct final rule.

II. Public Comments on the Companion Proposed Rule

In the direct final rule, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on January 7, 2014. The NRC received one public comment on the companion proposed rule (78 FR 63408), from Mr. Richard Ochs (ADAMS Accession No. ML13320A027). Mr. Ochs stated his concern that the neutron emissions inside the outer shell of nuclear waste storage containers are dangerous to living organisms, including insects, microbes, bacteria or virus that attach to dust that passes through the screened windows in the outer steel covers of storage containers. Specifically, Mr. Ochs raises a concern based on the emergence of Lyme's Disease in Lyme, Connecticut, which he asserts occurred following an unintended release of radioactive gas from the nearby Millstone Nuclear Reactor. According to his comment, "[T]he Deer Tick has carried a spirochete bacteria for millions of years, but after the Millstone release, that spirochete was mutated, causing the emergence of Lyme's Disease."

The NRC staff reviewed this comment and concluded that this comment is not a significant adverse comment as defined in NUREG–BR–0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook" (ADAMS Accession No. ML052720461), as it is beyond the scope of this rulemaking. Instead, this comment raises a generic concern regarding the use of any spent fuel storage casks and is not specific to any issue or concern with the amendment to the cask certificate that is the subject of this rulemaking effort.

Moreover, the NRC staff has concluded that there would be no significant environmental impacts as confirmed in Section VII, "Finding of No Significant Environmental Impact: Availability," of the direct final rule. This comment does not challenge that finding because, as the Environmental Assessment explained, this amendment to the rule will not result in any significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. This amendment continues to ensure that the Commission's regulations regarding dose rates, found in 10 CFR Part 20, are maintained. A challenge to those dose rates, or the method by which the Commission

establishes those dose rates, would be most appropriately addressed as a petition for rulemaking pursuant to 10 CFR 2.802. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 20th day of December 2013.

For the Nuclear Regulatory Commission.

Helen Chang,

Acting Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 2013–31080 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1238

[No. 2013–N–19]

Orders: Supplemental Orders on Reporting by Regulated Entities of Stress Testing Results as of September 30, 2013

AGENCY: Federal Housing Finance Agency.

ACTION: Orders.

SUMMARY: In this document, the Federal Housing Finance Agency (FHFA) provides notice that it issued Orders to supplement its Orders dated November 26, 2013, with respect to reporting under section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).

DATES: Each Order is effective on the date signed.

FOR FURTHER INFORMATION CONTACT: Naa Awaa Tagoe, Senior Associate Director, Office of Financial Analysis, Modeling and Simulations, (202) 649–3140, *naaawaa.tagoe@fhfa.gov;* Stefan Szilagyi, Examination Manager, FHLBank Modeling, FHLBank Risk Modeling Branch, (202) 649–3515, *stefan.szilagy@fhfa.gov;* or Mark D. Laponsky, Deputy General Counsel, Office of General Counsel, (202) 649–3054 (these are not toll-free numbers), *mark.laponsky@fhfa.gov.* The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

FHFA is responsible for ensuring that the regulated entities operate in a safe and sound manner, including the maintenance of adequate capital and internal controls, that their operations and activities foster liquid, efficient, competitive, and resilient national housing finance markets, and that they carry out their public policy missions through authorized activities. *See* 12 U.S.C. 4513. These Supplemental Orders are being issued under 12 U.S.C. 4514(a), which authorizes the Director of FHFA to require by Order that the regulated entities submit regular or special reports to FHFA and establishes remedies and procedures for failing to make reports required by Order. The Supplemental Orders provide to the regulated entities two additional appendices of scenario assumptions to be used for stress testing.

II. Orders

For the convenience of the affected parties, the text of the Supplemental Orders, without appendices, follows below in its entirety. You may access these Orders with Appendices 11 and 12 from FHFA's Web site at *http://www.fhfa.gov/Default.aspx?Page=440.* The Supplemental Orders and Summary Instructions and Guidance will be available for public inspection and copying at the Federal Housing Finance Agency, Eighth Floor, 400 Seventh St. SW., Washington, DC 20024. To make an appointment, call (202) 649–3804.

The text of the Supplemental Orders is as follows:

Federal Housing Finance Agency

Order Nos. 2013–OR–B–3, 2013–OR–FNMA–3, and 2013–OR–FHLMC–3

SUPPLEMENTAL ORDER ON REPORTING BY REGULATED ENTITIES OF STRESS TESTING RESULTS AS OF SEPTEMBER 30, 2013

Whereas, section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act") requires certain financial companies with total consolidated assets of more than $10 billion, and which are regulated by a primary Federal financial regulatory agency, to conduct annual stress tests to determine whether the companies have the capital necessary to absorb losses as a result of adverse economic conditions;

Whereas, FHFA's rule implementing section 165(i)(2) of the Dodd-Frank Act is codified as 12 CFR part 1238 and requires that "[e]ach regulated entity must file a report in the manner and form established by FHFA." 12 CFR § 1238.5(b);

Whereas, on November 26, 2012, FHFA issued an Order to each regulated entity accompanied by appendices numbered 1 through 10 and amended Summary Instructions and Guidance relating to the performance of stress tests as of September 30, 2013, and the reporting of the results of such tests;

Whereas, FHFA's Acting Director has determined that it is appropriate to supplement the appendices to the November 26, 2013 Orders with two additional appendices;

Whereas, section 1314 of the Safety and Soundness Act, 12 U.S.C. § 4514(a) authorizes the Director of FHFA to require regulated entities, by general or specific order, to submit such reports on their management, activities, and operations as the Director considers appropriate.

Now therefore, it is hereby ordered as follows:

Each regulated entity shall report to FHFA and to the Board of Governors of the Federal Reserve System the results of stress testing as required by 12 CFR § 1238, in the form and with the content described therein and in the Summary Instructions and Guidance accompanying the November 26, 2013 Orders, and using the scenarios provided in Appendices 1 through 10 to those Orders and Appendices 11 and 12 that accompany this Order.

This Order is effective immediately.

Signed at Washington DC, this 13th day of December, 2013.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

Dated: December 13, 2013.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2013–30567 Filed 12–26–13; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0365; Directorate Identifier 2012–NM–223–AD; Amendment 39–17704; AD 2013–25–08]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding airworthiness directive (AD) 2009–24–09 for all Airbus Model A330–200 and –300 series airplanes, and Model A340–200 and –300 series airplanes. AD 2009–24–09 required a repetitive inspection program on certain check valves in the hydraulic systems that includes, among other things, inspections for lock wire presence and integrity, traces of seepage or black deposits, proper torque, alignment of the check valve and manifold, installing new lock wire, and corrective actions if needed. This new AD expands the applicability, reduces the compliance time, changes torque values of the check valve tightening, and requires a repetitive inspection program for certain check valves in the

hydraulic systems on airplanes that have had a certain modification embodied during production or in-service. This AD was prompted by multiple reports of hydraulic line check valves loosening. We are issuing this AD to detect and correct such check valve loosening, which could result in hydraulic leaks, possibly leading to the loss of all three hydraulic systems and consequent loss of control of the airplane.

DATES: This AD becomes effective January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of December 14, 2009 (74 FR 62208, November 27, 2009).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2013-0365;* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to the specified products. The NPRM was published in the **Federal Register** on May 8, 2013 (78 FR 26716), and proposed to supersede AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009). The NPRM proposed to correct an unsafe condition for the specified products. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2012–0244R1, dated January 25, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> An A330 operator experienced a yellow hydraulic circuit low level due to a loose check valve, Part Number (P/N) CAR401. During the inspection on the other two hydraulic systems, the other three check valves P/N CAR401 were also found to be loose with their lock wire broken in two instances. Airbus A340 aeroplanes are also equipped with P/N CAR401 high pressure manifold check valves.
>
> Additional cases of P/N CAR401 check valve loosening have been reported on aeroplanes having accumulated more than 1,000 [total] flight cycles (FC). The check valve fitted on the Yellow hydraulic system is more affected, due to additional system cycles induced by cargo door operation.
>
> This condition, if not detected and corrected, could result in hydraulic leaks, possibly leading to the loss of all three hydraulic systems and consequent loss of control of the aeroplane.
>
> To address this unsafe condition, EASA issued Emergency AD 2009–0223–E (*http://ad.easa.europa.eu/blob/easa_ad_2009_0223E_superseded.pdf/EAD_2009-0223-E_1*) [which corresponds to FAA AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)] to require an inspection programme to detect any check valve loosening and if necessary, to apply the applicable corrective actions.
>
> EASA AD 2010–0145 (*http://ad.easa.europa.eu/blob/easa_ad_2010_0145_Superseded.pdf/AD_2010-0145_1*), which superseded EASA EAD 2009–0223–E retaining its requirements, was issued to expand the applicability to the newly certified models A330–223F and A330–243F.
>
> Prompted by further reported in-service events of check valve P/N CAR401 loosening before reaching the threshold of 700 FC, EASA AD 2011–0139 (*http://ad.easa.europa.eu/blob/easa_ad_2011_0139_superseded.pdf/AD_2011-0139_1*), which superseded EASA AD 2010–0145, retaining its requirements, was issued to:
>
> —Extend the requirement to identify the P/N CAR401 check valves to all aeroplanes, and to
>
> —reduce the inspection threshold for aeroplanes fitted with check valve P/N CAR401, either installed in production through Airbus modification 54491, or installed in service through Airbus Service Bulletin (SB) A330–29–3101 or Airbus SB A340–29–4078.
>
> EASA AD 2012–0070 (*http://ad.easa.europa.eu/blob/easa_ad_2012_0070_Correction_superseded.pdf/AD_2012-0070_1*), which superseded EASA AD 2011–0139, retaining its requirements, was issued to require an increased torque value of the check valve tightening and High Pressure (HP) manifold re-identification.
>
> Since EASA AD 2012–0070 was issued, additional in-service events have been reported on aeroplanes fitted with check valves on which the increased torque value had been applied. Based on those events, it has been concluded that the action to re-torque the check valves with an increased value is not a satisfactory terminating action for addressing the issue of those check valves.
>
> For the reasons described above, this new [EASA] AD partially retains the requirements of EASA AD 2012–0070, which is superseded. Additionally, for aeroplanes equipped with P/N CAR401 on which the increased torque value has been applied, this new [EASA] AD requires repetitive inspections of the check valves and HP manifolds. Finally, this [EASA] AD also requires application of a lower torque value when a check valve P/N CAR401 is installed on an aeroplane.
>
> This [EASA] AD is considered to be an interim action and further AD action may follow.
>
> Note: the reporting and the torque value increase requirements for check valves P/N CAR401 of EASA AD 2012–0070 are no longer part of this new [EASA] AD.

You may obtain further information by examining the MCAI in the AD docket. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0365-0003.*

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received.

Request To Change Compliance Time

US Airways requested that we change the compliance time in paragraph (j) of the NPRM (78 FR 26716, May 8, 2013) to 1,000 flight hours after the effective date of the AD, or within 1,000 flight hours after the date of issuance of the original export certificate of airworthiness, whichever occurs later. US Airways stated that this will provide an inspection threshold for new airplane deliveries.

We disagree with changing the compliance time to base it, in part, on the date of issuance of the original export certificate of airworthiness. In developing appropriate compliances time for this final rule, we considered the safety issue as well as the recommendations of the manufacturer, the availability of necessary repair parts, and the practical aspect of accomplishing the required inspection within an interval of time that corresponds to the normal maintenance schedules of most affected operators. In addition, the compliance time of "Within 1,000 flight hours after the effective date of this AD" specified in paragraph (j) of this final rule corresponds with the compliance time given in the MCAI. We have not changed this final rule in this regard.

Change Made to This Final Rule

We reformatted paragraph (n) of this final rule, and removed an unnecessary sentence that appeared at the end of paragraph (n)(2) of the NPRM (78 FR 26716, May 8, 2013).

Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes:

- Are consistent with the intent that was proposed in the NPRM (78 FR 26716, May 8, 2013) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (78 FR 26716, May 8, 2013).

Costs of Compliance

We estimate that this AD affects 67 airplanes of U.S. registry.

The actions that are required by AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009), and retained in this AD take about 8 work-hours per product, at an average labor rate of $85 per work hour. Based on these figures, the estimated cost of the currently required actions is $680 per product.

We estimate that it will take about 2 work-hours per product to comply with the new requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $11,390, or $170 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2013-0365;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009), and adding the following new AD:

2013–25–08 Airbus: Amendment 39–17704. Docket No. FAA–2013–0365; Directorate Identifier 2012–NM–223–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective January 31, 2014.

(b) Affected ADs

This AD supersedes AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009).

(c) Applicability

This AD applies to Airbus Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; and Model A340–211, –212, –213, –311, –312, and –313 airplanes; certificated in any category; all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Reason

This AD was prompted by multiple reports of hydraulic line check valves loosening. We are issuing this AD to detect and correct such check valve loosening, which could result in hydraulic leaks, possibly leading to the loss of all three hydraulic systems and consequent loss of control of the airplane.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Retained Actions

This paragraph restates the requirements of paragraph (g) of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009). Except for Model A330–223F and A330–243F airplanes: Do the actions required by paragraphs (g)(1) and (g)(2) of this AD.

(1) For airplanes that do not have Airbus Modification 54491 embodied in production, or Airbus Service Bulletin A330–29–3101 or Airbus Service Bulletin A340–29–4078 embodied in service: Within 100 flight cycles or 28 days after December 14, 2009 (the effective date of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)), whichever occurs first, inspect the check valves on the blue, green, and yellow hydraulic systems to identify their part numbers (P/Ns), in accordance with the instructions of Airbus All Operators Telex (AOT) A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Accomplishment of the inspection required by paragraph (h) of this AD terminates the requirements of this paragraph.

(i) If check valves having P/N CAR401 are installed on all three hydraulic systems, before further flight, do the actions specified in paragraph (g)(2)(i) of this AD. After accomplishing the actions required by paragraph (g)(2)(i) of this AD, do the actions specified in paragraphs (g)(2)(ii) and (g)(2)(iii) of this AD at the applicable compliance times specified in those paragraphs. Accomplishment of the inspection required by paragraph (i) of this AD terminates the requirements of this paragraph.

(ii) If check valves having P/N CAR401 are not installed on all three hydraulic systems, no further action is required by this paragraph until any check valve having P/N CAR400 is replaced with a check valve having P/N CAR401. If any check valve having P/N CAR400 is replaced by a check valve having P/N CAR401, before further flight, do the inspection specified in paragraph (g)(1) of this AD to determine if all three hydraulic systems are equipped with check valves having P/N CAR401. Accomplishment of the inspection required by paragraph (h) of this AD terminates the requirements of this paragraph.

(2) For airplanes on which Airbus Modification 54491 was embodied in production, or Airbus Service Bulletin A330–29–3101 or Airbus Service Bulletin A340–29–4078 was embodied in service, do the actions specified in paragraphs (g)(2)(i), (g)(2)(ii), and (g)(2)(iii) of this AD.

(i) Except as required by paragraph (g)(1)(i) of this AD, at the applicable times specified in paragraphs (g)(2)(i)(A) and (g)(2)(i)(B) of this AD, as applicable: Do the inspection program (detailed inspection of the lock wire for presence and integrity, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) on yellow and blue high pressure manifolds, install new lock wires, and do all applicable corrective actions, in accordance with the instructions of paragraph 4.1.1 of Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Do all applicable corrective actions before further flight. Accomplishment of the inspection required by paragraph (h)(1) of this AD terminates the requirements of this paragraph.

(A) For airplanes on which Airbus Modification 54491 has been embodied in production: At the later of the times specified in paragraphs (g)(2)(i)(A)(*1*) and (g)(2)(i)(A)(*2*) of this AD.

(*1*) Before the accumulation of 1,000 total flight cycles since first flight but no earlier than the accumulation of 700 total flight cycles since first flight.

(*2*) Within 100 flight cycles or 28 days after December 14, 2009 (the effective date of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)), whichever occurs first.

(B) For airplanes on which Airbus Service Bulletin A330–29–3101 or A340–29–4078 was embodied in service: At the later of the times specified in paragraphs (g)(2)(i)(B)(*1*) and (g)(2)(i)(B)(*2*) of this AD.

(*1*) Within 1,000 flight cycles since the embodiment of Airbus Service Bulletin A330–29–3101 or A340–29–4078 but no earlier than 700 flight cycles after the embodiment of Airbus Service Bulletin A330–29–3101 or A340–29–4078.

(*2*) Within 100 flight cycles or 28 days after December 14, 2009 (the effective date of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)), whichever occurs first.

(ii) Within 900 flight hours after accomplishment of paragraph (g)(2)(i) of this AD, do the inspection program (detailed inspection of the lock wire for presence and integrity, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) and install a new lock wire on the green high pressure manifold; and do an inspection (detailed inspection for traces of seepage or black deposits, and detailed inspection to determine alignment of the check valve and manifold) on the yellow and blue high pressure manifolds, and do all applicable corrective actions; in accordance with the instructions of paragraph 4.1.2 of Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Do all applicable corrective actions before further flight. Accomplishment of the inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

(iii) Within 900 flight hours after accomplishment of paragraph (g)(2)(ii) of this AD, and thereafter at intervals not to exceed 900 flight hours, do the inspection program (detailed inspection for traces of seepage or black deposits, and detailed inspection to determine alignment of the check valve and manifold) on the green, yellow, and blue high pressure manifolds, and do all applicable corrective actions, in accordance with the instructions of paragraph 4.1.3 of Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Do all applicable corrective actions before further flight. Accomplishment of the inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

(h) New Inspection and Actions

For airplanes equipped with check valves having P/N CAR400; and for airplanes equipped with check valves having P/N CAR401, except for airplanes on which Airbus Modification 201384 has been embodied during production, or on which Airbus Service Bulletin A330–29–3119 (for Model A330–200, –200F, and –300 series airplanes) or Airbus Service Bulletin A340–29–4091 (for Model A340–200 and –300 series airplanes) has been embodied in service: Within 900 flight hours after the effective date of this AD, inspect the check valves on the blue, green, and yellow hydraulic systems to identify their part numbers, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011 (for Model A330–200, –200F and –300 series airplanes); or Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011 (for Model A340–200 and –300 series airplanes). Accomplishment of the actions required by this paragraph terminates the requirements specified in paragraphs (g)(1) and (g)(1)(ii) of this AD.

(1) If check valves having P/N CAR401 are installed on all three hydraulic systems: Before further flight, do the inspection program (detailed inspection for red mark presence and alignment integrity of the check valve and manifold, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) on yellow and blue high pressure manifolds, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011 (for Model A330–200, –200F, and –300 series airplanes); or Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011 (for Model A340–200 and –300 series airplanes). Accomplishment of the actions required by this paragraph terminates the requirements specified in paragraph (g)(2)(i) of this AD.

(2) If check valves having P/N CAR401 are not installed on all three hydraulic systems, no further action is required by this paragraph until any check valve having P/N CAR400 is replaced with a check valve having P/N CAR401. If any check valve having P/N CAR400 is replaced by a check valve having P/N CAR401: Before further flight after such replacement, do the actions specified in paragraph (h) of this AD, to determine if all three hydraulic systems are equipped with check valves having P/N CAR401. If check valves having P/N CAR401 are installed on all three hydraulic systems: Before further flight, do the actions specified in paragraphs (h)(1) and (i) of this AD.

(i) New Repetitive Inspection Program and Corrective Actions

Within 900 flight hours after accomplishment of paragraph (h)(1) of this AD, do the inspection program (detailed inspection for red mark presence and alignment integrity of the check valve and manifold, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) on the green, yellow, and blue system check valves, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011 (for Model A330–200, –200F, and –300 series airplanes); or Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011 (for Model A340–200 and –300 series airplanes). Repeat the inspection program thereafter at intervals not to exceed 900 flight hours. Do all applicable corrective actions before further flight. Accomplishment of the actions required by this paragraph terminates the requirements specified in paragraphs (g)(1)(i), (g)(2)(ii), and (g)(2)(iii) of this AD.

(j) New Repetitive Inspection for Certain Airplanes

For airplanes equipped with check valves having P/N CAR401 and on which Airbus Modification 201384 has been embodied during production, or on which Airbus Service Bulletin A330–29–3119 (for Model A330–200, –200F, and –300 series airplanes); or Airbus Service Bulletin A340–29–4091 (for Model A340–200 and –300 series airplanes) has been embodied in service: Within 1,000 flight hours after the effective date of this AD, do a general visual

inspection of the green, yellow, and blue high pressure manifolds and check valves having P/N CAR401 for any sign of rotation of the check valve head, and for any signs of hydraulic fluid leakage or seepage (including black deposits), in accordance with the instructions of Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012. Repeat the inspection thereafter at interval not to exceed 900 flight hours.

(k) New Corrective Action for Certain Airplanes

If, during any inspection required by paragraph (j) of this AD, any sign of rotation of the check valve head is found, or any sign of hydraulic fluid leakage or seepage (including black deposits) is found: Before further flight, do all applicable corrective actions, in accordance with the instructions of Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012.

(l) No Terminating Action

Accomplishment of the corrective actions required by this AD does not constitute terminating action for the repetitive inspections required by this AD.

(m) Replacement Check Valve Torque Value

As of the effective date of this AD, at each replacement of a check valve with a check valve having P/N CAR401, apply a torque of 141 to 143 newton metre (N.m) (103.98 to 105.45 pounds-foot (lbf.ft)) during installation.

(n) Credit for Previous Actions

(1) This paragraph restates the credit specified in paragraph (g)(2)(iv) of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009). This paragraph provides credit for actions required by paragraph (g)(2)(i) of this AD, if those actions were performed before December 14, 2009 (the effective date of AD 2009–24–09), using the applicable service information specified in paragraphs (n)(1)(i) and (n)(1)(ii) of this AD.

(i) Airbus AOT A330–29A3111, dated September 2, 2009 (for Model A330–200 and –300 series airplanes), which is not incorporated by reference in this AD.

(ii) Airbus AOT A340–29A4086, dated September 2, 2009 (for Model A340–200 and –300 series airplanes), which is not incorporated by reference in this AD.

(2) This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using the applicable service information specified in paragraphs (n)(2)(i) through (n)(2)(iv) of this AD.

(i) Airbus AOT A330–29A3111, dated September 2, 2009 (for Model A330–200 and –300 series airplanes), which is not incorporated by reference in this AD.

(ii) Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes).

(iii) Airbus AOT A340–29A4086, dated September 2, 2009, (for Model A340–200 and –300 series airplanes), which is not incorporated by reference in this AD.

(iv) Airbus AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes).

(o) No Reporting

Although the service information specified in paragraphs (o)(1) through (o)(5) of this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(1) Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012.

(2) Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011.

(3) Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011.

(4) Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009.

(5) Airbus AOT A340–29A4086, Revision 1, dated October 8, 2009.

(p) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD. AMOCs approved for AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009), are approved as AMOCs for the corresponding provisions of this AD, except AMOC ANM–116–11–172 is not approved as an AMOC for the corresponding provisions of this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(q) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information European Aviation Safety Agency Airworthiness Directive 2012–0244R1, dated January 25, 2013, for related information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0365-0003.*

(2) Service information identified in this AD that is not incorporated by reference may be obtained at the addresses specified in paragraphs (r)(5) and (r)(6) of this AD.

(r) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on January 31, 2014.

(i) Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012.

(ii) Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011.

(iii) Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011.

(4) The following service information was approved for IBR on December 14, 2009 (74 FR 62208, November 27, 2009).

(i) Airbus Alert Operators Telex A330–29A3111, Revision 1, dated October 8, 2009. Only the first page of this document contains the document number, revision level, and date; no other pages of this document contain this information.

(ii) Airbus Alert Operators Telex A340–29A4086, Revision 1, dated October 8, 2009. Only the first page of this document contains the document number, revision level, and date; no other pages of this document contain this information.

(5) For service information identified in this AD, contact Airbus SAS—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com*; Internet *http://www.airbus.com.*

(6) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on November 26, 2013.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–29998 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0603; Directorate Identifier 2009–SW–079–AD; Amendment 39–17706; AD 2013–25–10]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain serial-numbered Bell Helicopter Textron Canada Limited (BHTC) Model 206L, 206L–1, 206L–3, and 206L–4 helicopters with a certain tailboom upper left attachment fitting (fitting). This AD requires inspecting the fitting for a crack and other conditions. This AD was prompted by the manufacturer revising and extending the 100 hour time-in-service (TIS) inspection requirements for the fitting. The actions of this AD are intended to detect a crack, loose rivet, corrosion, or any other damage, which could lead to loss of the tailboom and subsequent loss of control of the helicopter.

DATES: This AD is effective January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of January 31, 2014.

ADDRESSES: For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272, or at *http://www.bellcustomer.com/files/*. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the foreign authority's AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sharon Miles, Aerospace Engineer, FAA, Regulations and Policy Group, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone: (817) 222–5110; email: *sharon.y.miles@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

On July 12, 2013, at 78 FR 41886, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to add an AD that would apply to BHTC Model 206L, 206L–1, 206L–3, and 206L–4 helicopters with an upper left attachment fitting part number 206–032–409–001 installed. The NPRM proposed to require within 100 hours TIS and thereafter at intervals not exceeding 110 hours TIS, inspecting the upper left tailboom attachment fitting for a crack, corrosion, damage, or a loose rivet. If there is a crack or corrosion or damage beyond acceptable limits, the NPRM proposed to require replacing the upper left tailboom attachment fitting. If there is corrosion or damage within acceptable limits, the NPRM proposed to require repairing the fitting. If there is a loose rivet, the NPRM proposed to require replacing the loose rivet. The proposed requirements were intended to detect a crack, loose rivet, corrosion, or any other damage, which could lead to loss of the tailboom and subsequent loss of control of the helicopter.

The NPRM was prompted by AD No. CF–2009–41, dated November 16, 2009, issued by Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada. TCCA issued AD No. CF–2009–41 to correct an unsafe condition for certain 206L series helicopters, specifically: Model 206L, serial number (S/N) 45004 through 45153, and 46601 through 46617; Model 206L–1, S/N 45154 through 45790; Model 206L–3, S/N 51001 through 51612; and Model 206L–4, all S/Ns. TCCA advises that AD No. CF–2009–41 was prompted by a new airworthiness limitation for the fitting that requires an inspection of fitting part number 203–032–409–001 at each 100-hour or annual inspection. The TCCA AD requires inspecting the fitting, and replacing or repairing it if necessary, in accordance with the Accomplishment Instructions of BHTC Alert Service Bulletin (ASB) 206L–09–158, Revision A, dated August 31, 2009 (ASB 206L–09–158 Revision A). TCCA further states that incorporating this inspection into the applicable maintenance manual revision constitutes terminating action to TCCA AD No. CF–2009–41. The actions in TCCA AD No. CF–2009–41 are intended to detect a crack in a tailboom attachment fitting, which could result in loss of the tailboom and subsequent loss of control of the helicopter.

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM (78 FR 41886, July 12, 2013).

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, TCCA, its technical representative, has notified us of the unsafe condition described in the TCCA AD. We are issuing this AD because we evaluated all information provided by TCCA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the TCCA AD

The TCCA AD requires a recurring inspection every 100 hours, while this AD requires the inspection at intervals not to exceed 110 hours to align with the Bell ASB.

Related Service Information

We reviewed ASB 206L–09–158, Revision A for certain serial-numbered Model 206L, L–1, L–3, and L–4 helicopters with certain tailboom assemblies installed. The ASB requires an inspection of the fitting for a crack, loose rivets, corrosion, and damage at each 100-hour or annual inspection. If there is a crack, the ASB specifies replacing the fitting with an airworthy fitting. If there is a loose rivet, the ASB specifies replacing the rivet with an airworthy rivet. If the fitting has corrosion or mechanical damage, the ASB specifies determining if the corrosion or mechanical damage is within acceptable limits. If the corrosion or mechanical damage is within acceptable limits, the ASB specifies repairing the damage in accordance with the instructions contained in the ASB. If the damage is not within acceptable limits, the ASB specifies replacing the fitting with an airworthy

fitting. TCCA classified this ASB as mandatory and issued AD No. CF–2009–41 to ensure the continued airworthiness of these helicopters.

Since that time, BHTC has issued ASB 206L–09–158, Revision B, dated June 1, 2011, for all Model 206L series helicopters. Revision B of the ASB changes the recurring inspection interval from every 100 flight hours to every 110 flight-hours.

Costs of Compliance

We estimate that this AD affects 783 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. At an average labor rate of $85 per work-hour, inspecting the fitting requires about 1 work-hour, for a cost per helicopter of $85 and a total cost to U.S. operators of $66,555 per inspection cycle.

We estimate the following costs to do any necessary repairs or replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these repairs or replacements. Repairing a damaged fitting requires about 8 work-hours and required parts cost about $10, for a cost per helicopter of $690. Replacing a fitting which is damaged beyond the allowable repair limits requires about 8 work-hours and required parts cost about $793, for a cost per helicopter of $1,473. Replacing a loose rivet requires about 1 work-hour, and required parts cost about $1, for a cost per helicopter of $86.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on helicopters identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2013–25–10 Bell Helicopter Textron Canada (BHTC): Amendment 39–17706; Docket No. FAA–2013–0603; Directorate Identifier 2009–SW–079–AD.

(a) Applicability

This AD applies to BHTC Model 206L, 206L–1, 206L–3, and 206L–4 helicopters with an upper left attachment fitting part number 206–032–409–001 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in a tailboom attachment fitting, which could result in loss of the tailboom and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective January 31, 2014.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) At the next 100-hour inspection, and thereafter at intervals not to exceed 110 hours time-in-service, inspect each tailboom upper left attachment fitting (fitting) for a crack, a loose rivet, corrosion, or damage as depicted in Figure 2 of BellAlert Service Bulletin 206L–09–158, Revision B, dated June 1, 2011 (ASB 206L–09–158).

(2) If there is a crack, corrosion, or damage beyond the acceptable limits of Figure 2 of ASB 206L–09–158, before further flight, replace the fitting with an airworthy fitting.

(3) If there is corrosion or damage within the acceptable limits of Figure 2 of ASB 206L–09–158, before further flight, repair the fitting as described in the Accomplishment Instructions, Part I, paragraphs 5.b.(1) through 5.b.(6), of ASB 206L–09–158.

(4) If there is a loose rivet, before further flight, replace the loose rivet with an airworthy rivet.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Sharon Miles, Aerospace Engineer, FAA, Regulations and Policy Group, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone: (817) 222–5122; fax: (817) 222–5961; email: *sharon.y.miles@faa.gov*.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

The subject of this AD is addressed in Transport Canada Civil Aviation (TCCA) AD No. CF–2009–41, dated November 16, 2009. You may view the TCCA AD at *http://www.regulations.gov* in Docket No. FAA–2013–0603.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 5302: Rotorcraft Tailboom.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Bell Alert Service Bulletin 206L–09–158, Revision B, dated June 1, 2011.

(ii) Reserved.

(3) For Bell service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272, or at *http://www.bellcustomer.com/files/*.

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Fort Worth, Texas, on December 5, 2013.

Kim Smith,

Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–30186 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0421; Directorate Identifier 2013–NM–003–AD; Amendment 39–17701; AD 2013–25–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–300, –400, and –500 series airplanes. This AD was prompted by fuel system reviews conducted by the manufacturer. This AD requires, depending on airplane configuration, replacing fuel pump power control relays with new relays having a ground fault interrupter (GFI) feature, installing ground studs and a bonding jumper, doing certain bonding resistance measurements, and changing the GFI relay position. This AD also requires revising the maintenance program to incorporate certain airworthiness limitations. We are issuing this AD to prevent damage to the fuel pumps caused by electrical arcing that could introduce an ignition source in the fuel tank, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

DATES: This AD is effective January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 31, 2014.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Georgios Roussos, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6482; fax: 425–917–6590; email: *georgios.roussos@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. The NPRM published in the **Federal Register** on May 16, 2013 (78 FR 28764). The NPRM proposed to require, depending on airplane configuration, replacing fuel pump power control relays with new relays having a ground fault interrupter (GFI) feature, installing ground studs and a bonding jumper, doing certain bonding resistance measurements, and changing the GFI relay position. The NPRM also proposed to require revising the maintenance program to incorporate certain airworthiness limitations.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal (78 FR 28764, May 16, 2013) and the FAA's response to each comment.

Support for the NPRM

Boeing concurred with the content of the proposed rule.

Request To Include Certain Instructions and Delete Certain Step

All Nippon Airways (ANA) requested that we include instructions for the removal and installation of certain relay sockets, and for removal of paint on the mounting panel under Step 5 of Figure 5 of Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012. ANA stated that without removal of the paint on the mounting panel, the required bonding resistance measurements cannot be obtained. In addition, ANA requested that we delete step 6 of Figure 5 of Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012, which describes removal of paint around the relay cutout. ANA stated that paint removal around the relay cutout is not needed since the relay sockets are mounted to the cutout area of the panel and the relays are a spacer-mounted type.

We disagree with providing additional instructions that would expand the scope of this final rule, requiring additional notice and comment. We find that delaying this action would be inappropriate in light of the urgency of the identified unsafe condition. Operators should note that a general AMOC, which was requested by Boeing on behalf of all operators, has been issued for AD 2011–12–09, Amendment 39–16716 (76 FR 33988, June 10, 2011). The AMOC provides essentially the same relief as that requested by the commenter. Once this final rule is effective, we may issue a similar AMOC. Any person may request approval of an alternative method of compliance (AMOC) under the provisions of paragraph (l) of this AD for procedures that help them meet the bonding resistance requirements. We have not changed this final rule in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD

as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (78 FR 28764, May 16, 2013) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (78 FR 28764, May 16, 2013).

Costs of Compliance

We estimate that this AD affects 14 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace fuel pump power control relays, install ground studs and a bonding jumper, and do certain bonding resistance measurements, and change the GFI relay position, depending on airplane configuration.	Up to 31 work-hours × $85 per hour = $2,635.	Up to $21,338 ..	Up to $23,973 ..	Up to $335,622.
Maintenance program revision	1 work-hour × $85 per hour = $85.	$0	$85	$1,190.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2013–25–05 The Boeing Company: Amendment 39–17701; Docket No. FAA–2013–0421; Directorate Identifier 2013–NM–003–AD.

(a) Effective Date

This AD is effective January 31, 2014.

(b) Affected ADs

Certain requirements of this AD terminate certain requirements of AD 2011–12–09, Amendment 39–16716 (76 FR 33988, June 10, 2011).

(c) Applicability

This AD applies to The Boeing Company Model 737–300, –400, and –500 series airplanes; certificated in any category; identified as Groups 5, 6, 7, and 9 in Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 2822, Fuel boost pump.

(e) Unsafe Condition

This AD was prompted by fuel system reviews conducted by the manufacturer. We are issuing this AD to prevent damage to the fuel pumps caused by electrical arcing that could introduce an ignition source in the fuel tank, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Installation of Ground Studs and Bonding Jumper and Fuel Boost Pump Relays Replacement

For airplanes in Groups 5, 6, 7, and 9, Configuration 1, as identified in Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012 (airplanes on which Boeing Alert Service Bulletin 737–28A1212 was not done): Within 60 months after the effective date of this AD, install ground studs and a bonding jumper, replace fuel boost pump relays, and do certain bonding resistance measurements, in accordance with Part 1 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012. Doing the actions required by this paragraph terminates the requirements of paragraph (g) of AD 2011–12–09, Amendment 39–16716 (76 FR 33988, June 10, 2011), for airplanes in Groups 5, 6, 7, and 9, Configuration 1 only, provided that the requirements of paragraph (g) of this AD are done at the time given in AD 2011–12–09.

(h) Ground Studs and Bonding Jumper Installation and GFI Relay Position Change

For airplanes in Groups 5, 6, 7, and 9, Configuration 2, as identified in Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012 (airplanes on which Boeing Alert Service Bulletin 737–28A1212, dated July 23, 2009 was done): Within 60 months after the effective date of this AD, install ground studs and a bonding jumper, change the GFI relay position, and do certain bonding resistance measurements, in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012. Doing the actions required by this paragraph terminates the requirements of paragraph (h) of AD 2011–12–09, Amendment 39–16716 (76 FR 33988,

June 10, 2011), for airplanes in Groups 5, 6, 7, and 9, Configuration 2 only, provided that the requirements of paragraph (h) of this AD are done at the time given in AD 2011–12–09.

(i) Ground Fault Interrupt (GFI) Relay Position Change

For airplanes in Groups 5, 6, 7, and 9, Configuration 3, as identified in Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012 (certain airplanes on which Boeing Alert Service Bulletin 737–28A1212, Revision 1, dated August 27, 2010 was done): Within 60 months after the effective date of this AD, change the GFI relay position and do certain bonding resistance measurements, in accordance with Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012.

(j) Maintenance Program Revision

Concurrently with accomplishing the actions required by paragraph (g), (h), or (i) of this AD, or within 30 days after the effective date of this AD, whichever occurs later: Revise the maintenance program by incorporating Airworthiness Limitation 28–AWL–22 of Boeing 737–100/200/200C/300/400/500 AWL and Certification Maintenance Requirements (CMRs), Document D6–38278–CMR, Revision August 2012. The initial compliance time for the actions specified in AWL 28–AWL–22 of Boeing 737–100/200/200C/300/400/500 AWL and Certification Maintenance Requirements (CMRs), Document D6–38278–CMR, Revision August 2012, is within 1 year after accomplishing the installation required by paragraph (g), (h), or (i) of this AD, or within 1 year after the effective date of this AD, whichever occurs later.

(k) No Alternative Actions, Intervals, and/or Critical Design Configuration Control Limitations (CDCCLs)

After accomplishing the revision required by paragraph (j) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l) of this AD.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(m) Related Information

For more information about this AD, contact Georgios Roussos, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6482; fax: 425–917–6590; email: *georgios.roussos@faa.gov.*

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737–28A1212, Revision 2, dated October 18, 2012.

(ii) Airworthiness Limitation 28–AWL–22 of Boeing 737–100/200/200C/300/400/500 AWL and Certification Maintenance Requirements (CMRs), Document D6–38278–CMR, Revision August 2012. Page 1.0–33, where Airworthiness Limitation 28–AWL–22 is listed, is dated May 2009.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on December 4, 2013.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–29670 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0706; Directorate Identifier 2013–NM–067–AD; Amendment 39–17708; AD 2013–25–12]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model DC–9–10, DC–9–30, and DC–9–40 series airplanes. This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the aft pressure bulkhead web area is subject to widespread fatigue damage (WFD). This AD requires modifying the aft pressure bulkhead. The modification includes inspecting for cracks around the rivet holes, and repair of any cracking. We are issuing this AD to prevent fatigue cracking of the aft pressure bulkhead, which could result in reduced structural integrity of the airplane.

DATES: This AD is effective January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 31, 2014.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0706; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Eric Schrieber, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: (562) 627–5348; fax: (562) 627–5210; email: *eric.schrieber@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to the specified products. The NPRM published in the **Federal Register** on September 11, 2013 (78 FR 55662). The NPRM proposed to require modifying the aft pressure bulkhead. The modification includes inspecting for cracks around the rivet holes, and repair of any cracking.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (78 FR 55662, September 11, 2013) or on the determination of the cost to the public.

Change Made to this AD

We have revised the service information citations throughout this final rule to correctly identify the manufacturer name specified on the service information.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD with the change described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (78 FR 55662, September 11, 2013) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (78 FR 55662, September 11, 2013).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Costs of Compliance

We estimate that this AD affects 6 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification (includes inspection)	542 work-hours × $85 per hour = $46,070	$4,680	$50,750	$304,500

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2013–25–12 The Boeing Company: Amendment 39–17708; Docket No. FAA–2013–0706; Directorate Identifier 2013–NM–067–AD.

(a) Effective Date

This AD is effective January 31, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model DC–9–11, DC–9–12, DC–9–13, DC–9–14, DC–9–15, and DC–9–15F airplanes, DC–9–31, DC–9–32, DC–9–32 (VC–9C), DC–9–32F, DC–9–33F, DC–9–34, DC–9–34F, and DC–9–32F (C–9A, C–9B) airplanes, and DC–9–41 airplanes, certificated in any category, identified in McDonnell Douglas DC–9 Alert Service Bulletin A53–144, Revision 2, dated February 23, 1984.

(d) Subject

Joint Aircraft System Component (JASC) Code 5312, Fuselage Main Bulkhead.

(e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the fuselage bulkhead web area is subject to widespread fatigue damage (WFD). We are issuing this AD to prevent fatigue cracking of the bulkhead, which could result in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Modification

For airplanes on which the modification (AD4 rivets replaced with AD5 rivets) required by AD 85–01–02 R1, Amendment 39–5241 (51 FR 6101, dated February 20, 1986), has not been done: Before the accumulation of 72,000 total flight cycles, or within 18 months after the effective date of this AD, whichever occurs later, modify the aft pressure bulkhead by removing all affected AD4 rivets and doing either a fluorescent penetrant or eddy current inspection around the rivet holes for cracks, repairing any cracking, and installing five-leaf doublers with AD5 rivets, in accordance with the Accomplishment Instructions of McDonnell Douglas DC–9 Alert Service Bulletin A53–144, Revision 2, dated February 23, 1984; except as required by paragraph (h) of this AD.

Note 1 to paragraph (g) of this AD: Information on additional procedures for the modification can be found in Notes 4, 5, and 6, as applicable, of paragraph 1.D., "Compliance" of McDonnell Douglas DC–9 Alert Service Bulletin A53–144, Revision 2, dated February 23, 1984.

(h) Exception to Service Information

If any crack is found during any inspection required by this AD, and McDonnell Douglas DC–9 Alert Service Bulletin A53–144, Revision 2, dated February 23, 1984, specifies to contact the manufacturer for appropriate action: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) No Reporting Required

Sheet 1 of Service Sketch 3109, and Sheet 7 of Service Sketch 3110B of McDonnell Douglas DC–9 Alert Service Bulletin A53–144, Revision 2, dated February 23, 1984; specify reporting the details of any cracks found; however, this AD does not require reporting.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the Los Angeles ACO, send it to the attention of the person identified in paragraph (k) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by Structures Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

(k) Related Information

For more information about this AD, contact Eric Schrieber, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: (562) 627–5348; fax: (562) 627–5210; email: *eric.schrieber@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the **Federal Register** approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) McDonnell Douglas DC–9 Alert Service Bulletin A53–144, Revision 2, dated February 23, 1984.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on December 10, 2013.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–30779 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0416; Directorate Identifier 2012–NM–144–AD; Amendment 39–17707; AD 2013–25–11]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2010–24–07 for all Airbus Model A318 series airplanes, Model A319 series airplanes, Model A320 series airplanes, and Model A321 series airplanes. AD 2010–24–07 required repetitive inspections of the 80VU rack lower lateral fittings for damage, repetitive inspections of the 80VU rack lower central support for cracking, and corrective action if necessary. AD 2010–24–07 also specified optional terminating action for the repetitive inspections. This new AD reduces the inspection compliance time, adds an inspection of the upper fittings and shelves of the 80VU rack, and adds airplanes to the applicability. This AD was prompted by reports of worn lower lateral fittings of the 80VU rack. We are issuing this AD to detect and correct damage or cracking of the 80VU fittings and supports, which could lead to possible disconnection of the cable harnesses to one or more computers, and if occurring during a critical phase of flight, could result in reduced control of the airplane.

DATES: This AD becomes effective January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of January 11, 2011 (75 FR 75878, December 7, 2010).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2013-0416;* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1405; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to the specified products. The NPRM was published in the **Federal Register** on May 14, 2013 (78 FR 28152), and proposed to supersede AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010). The NPRM proposed to correct an unsafe condition for the specified products. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2012–0134, dated July 18, 2012 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> Damage to the lower lateral fittings of the 80VU rack, typically elongated holes, migrated bushes, and/or missing bolts have been reported on in-service aeroplanes. The 80VU rack contains computers for flight controls, communication and radio-navigation. In addition, damage to the lower

central support fitting (including cracking) has been reported.

Failure of the 80VU fittings, in combination with a high load factor or strong vibration, could lead to failure of the rack structure and/or computers or rupture/disconnection of the cable harnesses to one or more computers located in the 80VU rack. Even though the computer functions are duplicated across other racks, multiple system failures or (partial) disconnection of systems, if occurring during a critical phase of flight, could result in reduced control of the aeroplane.

To address this potential unsafe condition, EASA issued AD 2007–0276 to require repetitive inspections of the lower lateral 80VU fittings and the lower central 80VU support and, depending on findings, the accomplishment of corrective actions. [EASA] AD 2007–0276 was revised to introduce a reinforced lower central support as an optional terminating action for the repetitive inspections.

Since issuance of EASA AD 2007–0276R1 [*http://ad.easa.europa.eu/blob/easa_ad_2007_0276_R1_superseded.pdf/AD_2007–0276R1_1*] [which corresponds to FAA AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010)], and prompted by in-service experience, the previous inspection programme has been reassessed. New conditions of inspection for a new finding on the lower central fitting attachment (crack in the lower of the lateral flanges), and a new visual inspection of the upper fittings and shelves of the 80VU are introduced by this inspection programme. In addition, the replacement of a cracked lateral fitting or central support with a lateral fitting or central support having the same part number is no longer preferable as corrective action. Instead, the installation of the reinforced lower central support is now defined as optional terminating action for the repetitive inspections required by this [EASA] AD.

For the reasons described above, this [EASA] AD supersedes EASA AD 2007–0276R1 and requires implementation of an amended inspection programme with a reduced inspection threshold.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0416-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comments received.

Request to Change Compliance Time

United Airlines (UAL) requested that we change the compliance time for the corrective actions specified in paragraphs (m), (o), and (p) of the NPRM (78 FR 28152, May 14, 2013) from "before further flight" to the following.

- Within one deferral flight cycle, or the applicable time given in Paragraph E.(2), "Accomplish Timescale," of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012, whichever is later.
- Within 50 flight cycles or at the applicable time given in Paragraph E.(2), "Accomplish Timescale," of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012, whichever is later.

UAL stated that the first option would give operators a chance to fly a ferry flight to a more equipped resourced base maintenance station, and that the second option would give operators an option to create a short-term deferred item to plan for its accomplishment by creating a formal maintenance task with planned allocated resources.

UAL stated that due to the inspection threshold and repeat interval of 500 flight cycles, it is concerned that the inspection will take place at mainly airplane line maintenance stations, with significant exposure to possible damage conditions that require correction before further flight. UAL commented that typical airplane line stations might not have the resources, materials, and equipment to perform this type of modification, repair, and access. UAL also stated that certain corrective actions require approximately 57 work-hours, which would lead to lengthy out-of-service time and costs to the airline.

We do not agree with UAL's request to extend the compliance time. The FAA AD provides a provision for operators to apply for a special flight permit in accordance with 14 CFR 21.197, which allows operators to fly airplanes to a base where repairs, alterations, or maintenance can be performed. These airplanes may not fully meet applicable airworthiness requirements, but are capable of safe flight for reasons stated in 14 CFR 21.197. In developing an appropriate compliance time for this final rule, we considered the urgency associated with the subject unsafe condition, the availability of required parts, and the practical aspect of accomplishing the required corrective actions. Some safety issues are more time-sensitive than others, so we consider the overall risk to the fleet, including the severity of the failure and the likelihood of the failure's occurrence in establishing the compliance time in this final rule. The commenter has not provided sufficient substantiation for revising the corrective action compliance time for repairing certain damage conditions that will meet an acceptable level of safety to mitigate risk to the fleet.

Under the provisions of paragraph (s) of this AD, we will consider requests for approval of an extension of the compliance time if sufficient data are submitted to substantiate that the new compliance time would provide an acceptable level of safety. We have not changed this final rule in this regard.

Additional Changes to This AD

We have revised paragraph (o)(1) of this final rule to include the option of contacting the EASA (or its delegated agent) for repair instructions.

Paragraph (p) of the NPRM (78 FR 28152, May 14, 2013) incorrectly referred to "paragraphs (m) and (o) of this AD" for certain special detailed inspections. Those special detailed inspections are specified in paragraphs (l) and (n) of this AD. We have revised paragraph (p) of this AD to refer to paragraphs (l) and (n) of this AD.

Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these changes:

- Are consistent with the intent that was proposed in the NPRM (78 FR 28152, May 14, 2013) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (78 FR 28152, May 14, 2013).

Costs of Compliance

We estimate that this AD affects about 755 products of U.S. registry.

The actions that are required by AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010), and retained in this AD, take about 82 work-hours per product, at an average labor rate of $85 per work hour. Required parts cost about $2,592 per product. Based on these figures, the estimated cost of the currently required actions is $9,562 per product.

We estimate that it takes about 5 work-hours per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Where the service information lists parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD on U.S. operators to be $320,875, or $425 per product.

In addition, we estimate that any necessary follow-on actions would take about 189 work-hours and require parts costing $7,047, for a cost of $23,112 per product. Where the service information lists required parts costs that are

covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2013-0416;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the MCAI, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010), and adding the following new AD:

2013–25–11 Airbus: Amendment 39–17707. Docket No. FAA–2013–0416; Directorate Identifier 2012–NM–144–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective January 31, 2014.

(b) Affected ADs

This AD supersedes AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010).

(c) Applicability

This AD applies to Airbus Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; certificated in any category; all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings; and Code 53, Fuselage.

(e) Reason

This AD was prompted by reports of worn lower lateral fittings of the 80VU rack. We are issuing this AD to detect and correct damage or cracking of the 80VU fittings and supports, which could lead to possible disconnection of the cable harnesses to one or more computers, and if occurring during a critical phase of flight, could result in reduced control of the airplane.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Retained Repetitive Inspections of the 80VU Rack Lower Lateral Fittings

This paragraph restates the requirements of paragraph (g) of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010). Except for Model A318–121 and –122 airplanes, and except for airplanes on which Airbus Modification 34804 has been embodied in production, or on which Airbus Service Bulletins A320–25–1557 and A320–53–1215 have been done in service, prior to the accumulation of 24,000 total flight cycles, or within 500 flight cycles after January 11, 2011 (the effective date of AD 2010–24–07), whichever occurs later: Do a special detailed inspection of the 80VU rack lower lateral fittings for damage (e.g., broken fitting, missing bolts, migrated bushings, material burr, or rack in contact with the fitting) of the 80VU rack lower lateral fittings, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 02, dated November 5, 2008. Repeat the inspection thereafter at the interval specified in paragraph (g)(1) or (g)(2) of this AD, as applicable. Modifying the 80VU lower lateral fittings, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–25–1557, Revision 02, dated November 5, 2008, terminates the inspection requirements of this paragraph. Doing the initial inspection specified in paragraph (l) of this AD terminates the requirements of this paragraph.

(1) For airplanes on which the 80VU rack lower lateral fittings have not been replaced in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 02, dated November 5, 2008: Repeat the inspection thereafter at intervals not to exceed 4,500 flight cycles.

(2) For airplanes on which the 80VU rack lower lateral fittings have been replaced in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 02, dated November 5, 2008: Do the next inspection within 24,000 flight cycles after doing the replacement and repeat the inspection thereafter at intervals not to exceed 4,500 flight cycles.

(h) Retained Corrective Actions With Additional New Corrective Actions

This paragraph restates the requirements of paragraph (h) of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010), with new corrective actions. If any damage is found during any inspection required by paragraph (g) of this AD, do all applicable corrective actions (inspection and/or repair), in accordance with the Accomplishment Instructions and timeframes in Airbus Mandatory Service Bulletin A320–25A1555, Revision 02, dated November 5, 2008; or in accordance with and at the time specified in paragraph (q) of this AD. As of the effective date of this AD, if any

damage is found, do all applicable corrective actions in accordance with and at the times specified in paragraph (q) of this AD.

(i) Retained Repetitive Inspections of the 80VU Rack Lower Central Support

This paragraph restates the requirements of paragraph (i) of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010). Except for airplanes on which Airbus Modification 34804 has been embodied in production or on which Airbus Service Bulletins A320–25–1557 and A320–53–1215 have been done in service, prior to the accumulation of 24,000 total flight cycles, or within 500 flight cycles after January 11, 2011 (the effective date of AD 2010–24–07), whichever occurs later: Do a special detailed inspection of the 80VU rack lower central support for cracking, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 02, dated November 5, 2008. Repeat the inspection thereafter at the interval specified in paragraph (i)(1) or (i)(2) of this AD, as applicable. Replacing the pyramid fitting on the 80VU rack with a new, reinforced fitting, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1215, dated November 5, 2008, terminates the inspection requirements of this paragraph. Doing the initial inspection specified in paragraph (n) of this AD terminates the requirements of this paragraph.

(1) For airplanes on which the 80VU rack lower central support has not been repaired or replaced using Airbus Mandatory Service Bulletin A320–25A1555 or Airbus Service Bulletin A320–25–1557: Repeat the inspection thereafter at the interval specified in paragraph (i)(1)(i) or (i)(1)(ii) of this AD, as applicable.

(i) For airplanes on which the lower central support has accumulated 30,000 total flight cycles or more: At intervals not to exceed 500 flight cycles.

(ii) For airplanes on which the lower central support has accumulated fewer than 30,000 total flight cycles: At intervals not to exceed 4,500 flight cycles, without exceeding 30,750 total flight cycles on the support for the first repetitive inspection.

(2) For airplanes on which the 80VU rack lower central support has been repaired or replaced using Airbus Mandatory Service Bulletin A320–25A1555 or Airbus Service Bulletin A320–25–1557: Do the next inspection within 24,000 flight cycles after the repair or replacement and thereafter repeat the inspection at the interval specified in paragraph (i)(1)(i) or (i)(1)(ii) of this AD, as applicable.

(j) Retained Corrective Actions for Paragraph (i) of This AD

This paragraph restates the requirements of paragraph (j) of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010). If any crack is found during any inspection required by paragraph (i) of this AD: Before further flight, replace the pyramid fitting on the 80VU rack with a new, reinforced fitting, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1215, dated November 5, 2008. Doing this replacement terminates the inspection requirements of paragraph (i) of this AD.

(k) Retained Optional Terminating Action

This paragraph restates the requirements of paragraph (k) of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010). Doing the actions specified in paragraphs (k)(1) and (k)(2) of this AD terminates the repetitive inspections required by this AD.

(1) Replacing the pyramid fitting on the 80VU rack with a new, reinforced fitting, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1215, dated November 5, 2008.

(2) Modifying the 80VU lower lateral fittings, in accordance with Airbus Service Bulletin A320–25–1557, Revision 02, dated November 5, 2008.

(l) New Requirement of This AD: Repetitive Inspection of Lower Lateral Support Fittings

Except for airplanes on which Airbus Modification 34804 has been embodied in production, or on which the 80VU rack lower lateral support has been modified, as specified in the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25–1557, dated June 14, 2007; Revision 01, dated February 7, 2008; or Revision 02, dated November 5, 2008: At the latest of the applicable times specified in paragraphs (l)(1) through (l)(4) of this AD, do a special detailed (borescope) inspection of the 80VU rack lower lateral fittings for damage (e.g., broken fitting, missing bolts, migrated bushings, material burr, or rack in contact with the fitting), in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012. Repeat the inspection thereafter at intervals not to exceed 500 flight cycles until the terminating action specified in paragraph (k) of this AD is done. Doing the initial inspection specified in this paragraph terminates the requirements of paragraph (g) of this AD.

(1) Before the accumulation of 20,000 total flight cycles from the airplane first flight, or within 750 flight cycles after the effective date of this AD, whichever occurs later, without exceeding 24,000 total flight cycles.

(2) Within 20,000 flight cycles after the most recent repair or replacement of the 80VU rack lower lateral fittings was done, as specified in the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, dated June 24, 2007; Revision 01, dated February 18, 2008; or Revision 02, dated November 5, 2008.

(3) Within 500 flight cycles after the effective date of this AD, without exceeding 4,500 flight cycles after the most recent inspection of the 80VU rack lower lateral fittings was done, as specified in the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, dated June 14, 2007; Revision 01, dated February 18, 2008; or Revision 02, dated November 5, 2008.

(4) Within 500 flight cycles after the effective date of this AD.

(m) New Requirement of This AD: Corrective Action for Damage of Lower Lateral Support Fittings

If any damage is found during any inspection required by paragraph (l) of this AD: At the applicable time given in paragraph E.(2)., "Accomplishment Timescale," in Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012, accomplish the applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012; except where this service information specifies to contact Airbus for further instructions, before further flight, contact either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent) for instructions; and do those instructions.

(n) New Requirement of This AD: Repetitive Inspection on Lower Central Support

Except for airplanes on which Airbus Modification 34804 has been embodied in production, or on which the 80VU rack lower central support has been modified, as specified in the Accomplishment Instructions of Airbus Service Bulletin A320–53–1215, dated November 5, 2008: At the latest of the applicable times specified in paragraphs (n)(1) through (n)(6) of this AD, do a special detailed (borescope) inspection of the 80VU rack lower central support for cracking, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012. Repeat the inspection thereafter at intervals not to exceed 500 flight cycles until the terminating action specified in paragraph (k) of this AD is done. Doing the initial inspection specified in this paragraph terminates the requirements of paragraph (i) of this AD.

(1) Before the accumulation of 20,000 total flight cycles from the airplane first flight, or within 750 flight cycles after the effective date of this AD, whichever occurs later, without exceeding 24,000 total flight cycles.

(2) Within 20,000 flight cycles after the most recent repair or replacement of the 80VU rack lower central support was done, as specified in the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, dated June 14, 2007; Revision 01, dated February 18, 2008; or Revision 02, dated November 5, 2008.

(3) Within 20,000 flight cycles after modification of the 80VU rack lower central support was done, as specified in the Accomplishment Instructions of Airbus Service Bulletin A320–25–1557, dated June 14, 2007; or Revision 01, dated February 07, 2008.

(4) For airplanes on which, as of the effective date of this AD, the 80VU rack lower central support has accumulated fewer than 30,000 total flight cycles: Within 500 flight cycles after the effective date of this AD, without exceeding 4,500 flight cycles after the most recent inspection of the 80VU rack lower central support was done, as specified in the Accomplishment Instructions of Airbus Mandatory Service

Bulletin A320–25A1555, dated June 24, 2007; Revision 01, dated February 18, 2008; or Revision 02, dated November 5, 2008.

(5) For airplanes on which, as of the effective date of this AD, the 80VU rack lower central support has accumulated 30,000 total flight cycles or more: Within 500 flight cycles after the most recent inspection of the 80VU rack lower central support was done, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, dated June 14, 2007; Revision 01, dated February 18, 2008; or Revision 02, dated November 5, 2008.

(6) Within 500 flight cycles after the effective date of this AD.

(o) New Requirement of This AD: Corrective Action for Damage to Lower Central Support

If any cracking is found during any inspection required by paragraph (n) of this AD: Before further flight do the actions in paragraph (o)(1) or (o)(2) of this AD.

(1) If kits 25A1555A01 thru A05 are available, contact the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent); for instructions and do the repair.

(2) Do the actions specified in paragraph (k)(1) and (k)(2) of this AD.

(p) New Requirement of This AD: Repetitive Inspection of Upper Fittings and Shelves

Concurrently with each special detailed inspection required by paragraphs (l) and (n) of this AD: Do a general visual inspection for damage (cracking or deformation) of the upper fittings and shelves of the 80VU rack, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012. If any damage is found: Before further flight, repair the damage using a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA (or its delegated agent).

(q) New Requirement of This AD: Corrective Action for Previous Findings

For airplanes that have been inspected before the effective date of this AD as specified in Airbus Service Bulletin A320–25A1555, dated June 14, 2007; Airbus Mandatory Service Bulletin A320–25A1555, Revision 01, dated February 18, 2008; or Airbus Mandatory Service Bulletin A320–25A1555, Revision 02, dated November 5, 2008; and on which damage of the fittings was found, except for airplanes specified in paragraph (q)(1) or (q)(2) of this AD: At the applicable time given in paragraph E.(2)., "Accomplishment Timescale," of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012, accomplish the applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012, except where this service information specifies to contact Airbus for further instructions, before further flight, contact either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA (or its delegated agent); for instructions and follow those instructions. Accomplishing the actions required by this paragraph terminates the requirements of paragraph (h) of this AD.

(1) Airplanes on which Airbus Modification 34804 has been embodied in production.

(2) Airplanes on which the terminating action specified in paragraph (k) of this AD has been done.

(r) Credit for Previous Actions

This paragraph restates the credit given in paragraph (l) of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010).

(1) This paragraph provides credit for actions required by paragraphs (g), (h), and (i) of this AD, if those actions were performed before January 11, 2011 (the effective date of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010)), using the service bulletins specified in paragraph (r)(1)(i) or (r)(1)(ii) of this AD.

(i) Airbus Mandatory Service Bulletin A320–25A1555, Revision 01, dated February 18, 2008, which is not incorporated by reference in this AD.

(ii) Airbus Service Bulletin A320–25A1555, dated June 14, 2007, which is not incorporated by reference in this AD.

(2) This paragraph provides credit for actions required by paragraphs (g) and (k)(2) of this AD, if those actions were performed before January 11, 2011 (the effective date of AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010)), using the service bulletins specified in paragraph (r)(2)(i) or (r)(2)(ii) of this AD.

(i) Airbus Service Bulletin A320–25–1557, dated June 14, 2007, which is not incorporated by reference in this AD.

(ii) Airbus Service Bulletin A320–25–1557, Revision 01, dated February 7, 2008, which is not incorporated by reference in this AD.

(s) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1405; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD. AMOCs approved previously for AD 2010–24–07, Amendment 39–16526 (75 FR 75878, December 7, 2010), are approved as AMOCs for the corresponding provisions of this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they were approved by the State of Design Authority (or its delegated agent, or the Design Approval Holder with a State of Design Authority's design organization approval, as applicable). For a repair method to be approved, the repair approval must specifically refer to this AD. You are required to ensure the product is airworthy before it is returned to service.

(t) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information European Aviation Safety Agency Airworthiness Directive 2012–0134, dated July 18, 2012, for related information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0416-0002.*

(2) Service information identified in this AD that is not incorporated by reference may be obtained at the addresses specified in paragraphs (u)(5) and (u)(6) of this AD.

(u) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on January 31, 2014.

(i) Airbus Mandatory Service Bulletin A320–25A1555, Revision 03, dated February 28, 2012.

(ii) Reserved.

(4) The following service information was approved for IBR on January 11, 2011 (75 FR 75878, December 7, 2010).

(i) Airbus Mandatory Service Bulletin A320–25A1555, Revision 02, excluding Appendix 1, dated November 5, 2008.

(ii) Airbus Service Bulletin A320–25–1557, Revision 02, dated November 5, 2008.

(iii) Airbus Service Bulletin A320–53–1215, dated November 5, 2008.

(5) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; Internet *http://www.airbus.com.*

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on December 4, 2013.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–30066 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0340; Directorate Identifier 2010–SW–081–AD; Amendment 39–17630; AD 2013–21–06]

RIN 2120–AA64

Airworthiness Directives; Eurocopter Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Eurocopter Deutschland GmbH (Eurocopter) Model EC135 P1, EC135 P2, EC135 P2+, EC135 T1, EC135 T2, EC135 T2+, and MBB–BK 117 C–2 helicopters with a certain external mounted hoist system (hoist) with boom support assembly (boom) installed. This AD requires inspecting the boom for a crack and, if a crack exists, replacing the boom with an airworthy boom. Until the boom is inspected, this AD requires, before further flight, and thereafter before the first flight of each day, checking the hoist for a crack. This AD was prompted by cracks found on the boom during a pre-flight check of a hoist on an MBB–BK 117 C–2 helicopter. The actions of this AD are intended to detect a crack and prevent failure of the boom, loss of the boom and attached loads, and subsequent loss of helicopter control.

DATES: This AD is effective January 31, 2014.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of January 31, 2014.

ADDRESSES: For service information identified in this AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.eurocopter.com/techpub*, and contact UTC Aerospace Systems (formerly the Goodrich Corporation), 2727 East Imperial Highway, Brea, CA 92821; telephone (714) 984–1461; fax 714–984–1675, or at *www.goodrich.com*. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the foreign authority's ADs, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Matt Wilbanks, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *matt.wilbanks@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

On April 15, 2013, at 78 FR 22209, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Eurocopter Model EC135 P1, EC135 P2, EC135 P2+, EC135 T1, EC135 T2 and EC135 T2+ helicopters with a Goodrich Corporation (Goodrich) hoist with a boom, Part Number (P/N) 44301–500, 44307–500, or 44307–500–1 installed, and Model MBB–BK 117 C–2 helicopters with a Goodrich hoist with boom P/N 44307–500 installed. The NPRM proposed to require dye penetrant inspecting the boom for a crack and, if a crack exists, replacing the boom with an airworthy boom. Until the inspection is completed, the NPRM proposed to require, before the first flight of each day, a visual check of the hoist for a crack. The NPRM proposed to allow an owner/operator (pilot) holding at least a private pilot certificate to conduct that check. The performance of the check would be required to be entered into the aircraft's maintenance records showing compliance with this AD in accordance with applicable regulations. This authorization marks an exception to our standard maintenance regulations. The proposed requirements were intended to detect a crack and prevent failure of the boom, loss of the boom and attached loads, and subsequent loss of helicopter control.

The NPRM was prompted by AD No. 2010–0154, dated August 13, 2010, issued by the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued AD No. 2010–0154 to correct an unsafe condition for Eurocopter Model MBB–BK 117 C–2, EC135, and EC635 series helicopters. EASA AD No. 2010–0154 supersedes EASA AD No. 2009–0093–E, dated April 17, 2009. EASA advises that cracks were detected on the boom, P/N 44307–500, during a pre-flight check of the hoist on a Model MBB–BK 117 C–2 helicopter. EASA advises that this condition, if not detected and corrected, would impair the structural strength of the boom and could lead to failure of the boom. EASA advises that this could result in the loss of the boom and attached loads. According to EASA, boom P/Ns 44301–500 and 44307–500–1 are of similar design to P/N 44307–500, and therefore are also subject to this unsafe condition. As a result, EASA issued Emergency AD No. 2009–0093–E to require repetitive visual checks of the affected boom and removal or replacement of the boom when cracks are found.

EASA advises that since AD No. 2009–0093–E was issued, further technical investigation determined that torque values that were too high have been applied. EASA advises that Goodrich Corporation, the manufacturer of the affected booms, had developed an inspection that would determine the need for further action. As a result, EASA superseded its AD to include a new inspection to detect damage, by issuing EASA AD No. 2010–0154. EASA AD states that if no damage is found during this new inspection, that constitutes terminating action.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM (78 FR 22209, April 15, 2013).

FAA's Determination

These helicopters have been approved by the aviation authority of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with Germany, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air

safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the EASA AD

The EASA AD requires you to notify and return parts to the manufacturer, and this AD does not. The EASA AD also applies to the Eurocopter EC635 series military helicopters, while this AD does not because these models are not type certificated in the United States.

Related Service Information

Eurocopter has issued Emergency Alert Service Bulletin (EASB) No. EC135–85A–036, Revision 2, dated June 23, 2010, and EASB No. MBB BK117 C–2–85A–024, Revision 1, dated June 23, 2010, which specify a visual check of the boom for cracks, and removing or replacing the boom before the next flight if there is a crack. The EASBs also require compliance with the visual and dye penetrant inspection procedures specified in Goodrich Corporation Service Bulletin 44307–500–03, Revision 2, dated April 30, 2010. EASA classified these EASBs as mandatory, and issued EASA AD No. 2010–0154, dated August 13, 2010, to ensure the continued airworthiness of these helicopters.

Costs of Compliance

We estimate that this AD affects 350 helicopters of U.S. Registry and a labor rate of $85 per work-hour. Based on these estimates, we expect the following costs:

- We estimate that the cost of the daily visual check is minimal.
- We estimate that removing the hoist and boom assembly, performing the dye penetrant inspection, and reinstalling the equipment requires 1.5 work hours. No parts are needed, for a total cost of about $128 per helicopter and $44,800 for the U.S. fleet.
- Replacing the hoist and boom assembly, if needed, requires about a 0.33 work-hour for a labor cost of about $28. Parts cost $10,833 for a total cost of $10,861 per helicopter.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on helicopters identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2013–21–06 Eurocopter Deutschland GmbH Helicopters: Amendment 39–17630; Docket No. FAA–2013–0340; Directorate Identifier 2010–SW–081–AD.

(a) Applicability

This AD applies to Eurocopter Deutschland GmbH (Eurocopter) Model EC135 P1, EC135 P2, EC135 P2+, EC135 T1, EC135 T2, and EC135 T2+ helicopters with a Goodrich Corporation (Goodrich) external mounted hoist system (hoist) with boom support assembly (boom) Part Number (P/N) 44301–500, 44307–500, or 44307–500–1 installed, and Model MBB–BK 117 C–2 helicopters with a Goodrich hoist with boom P/N 44307–500 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in the boom. This condition could result in loss of the boom and attached loads, and subsequent loss of helicopter control.

(c) Effective Date

This AD becomes effective January 31, 2014.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Before further flight, and thereafter before the first flight of each day until you have performed the inspection required by paragraph (e)(2) of this AD, clean the hoist and visually check for a crack, paying particular attention to the areas that are circled as depicted in Figure 1 to paragraph (e) of this AD. The actions required by this paragraph may be performed by the owner/operator (pilot) holding at least a private pilot certificate, and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1)–(4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

BILLING CODE 4910–13–P

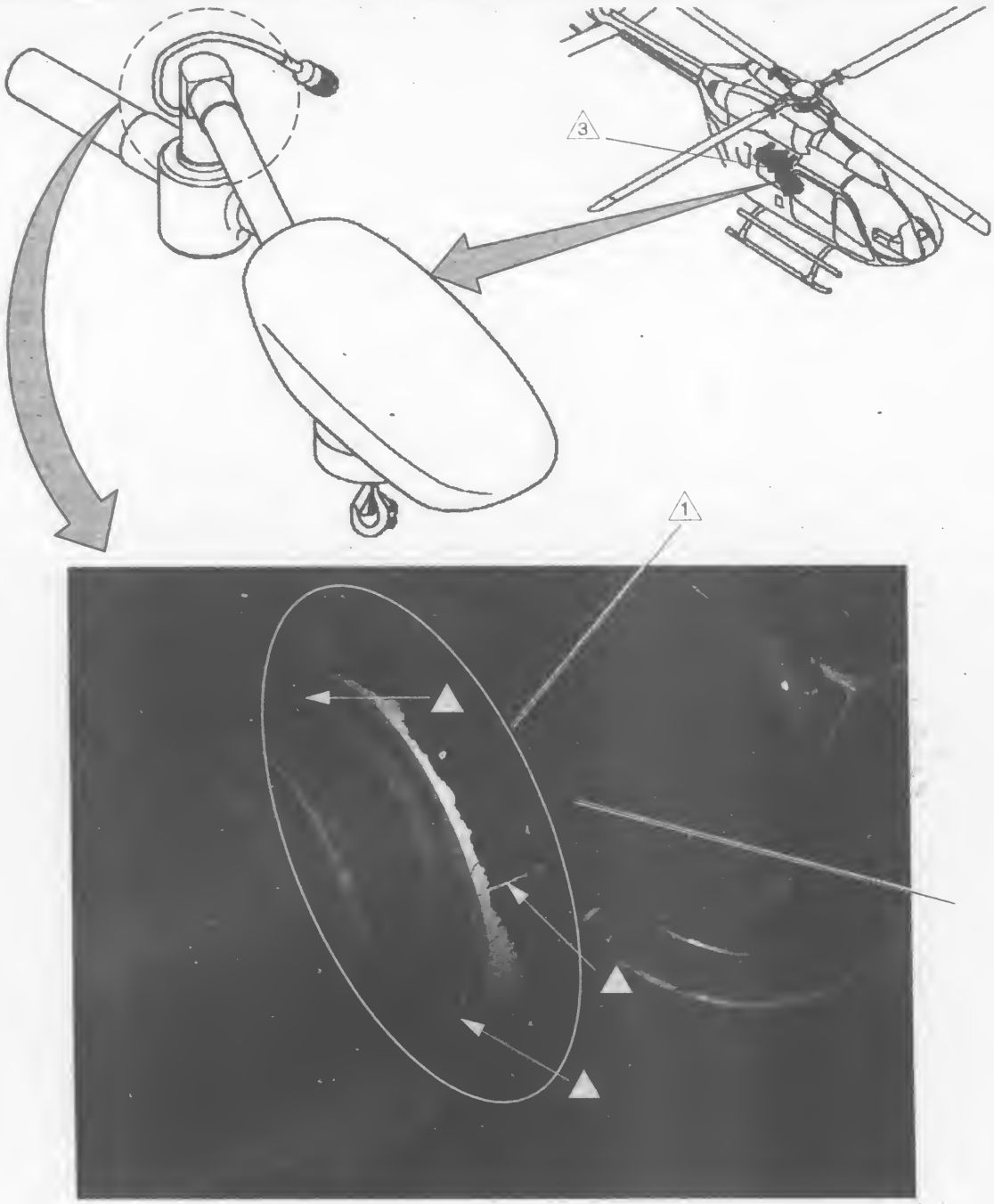


Figure 1 to Paragraph (e)

BILLING CODE 4910–13–C

(2) Within 30 days, perform a dye penetrant inspection of the boom in accordance with the Accomplishment Instructions, Section 2.D, of the Goodrich Service Bulletin 44307–500–03, Revision 2, dated April 30, 2010 (SB).

Note 1 to paragraph (e)(2) of this AD: A copy of the SB is attached to Eurocopter Emergency Alert Service Bulletin (EASB) EC135–85A–036, Revision 2, and Eurocopter EASB MBB BK117 C–2–85A–024, Revision 1, both dated June 23, 2010.

(3) If a crack exists in the boom, replace the cracked boom with an airworthy boom before further flight.

(f) Special Flight Permits

Special flight permits would be allowed provided the hoist is disabled during the ferry flight.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Wilbanks, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *matt.wilbanks@faa.gov*.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

(1) Eurocopter EASB EC135–85A–036, Revision 2, and Eurocopter EASB MBB BK117 C–2–85A–024, Revision 1, both dated June 23, 2010, which are not incorporated by reference, contain additional information about the subject of this AD. For Eurocopter service information identified in this AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.eurocopter.com/techpub*. You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2010–0154, dated August 13, 2010, which supersedes EASA AD No. 2009–0093–E, dated April 17, 2009. You may view the EASA ADs on the Internet at *http://www.regulations.gov* in Docket No. FAA–2013–0340.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 5345, Fuselage, Equipment Attach Fittings.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Goodrich Service Bulletin 44307–500–03, Revision 2, dated April 30, 2010.

(ii) Reserved.

(3) For Goodrich service information identified in this AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.eurocopter.com/techpub*, and contact the UTC Aerospace Systems (formerly the Goodrich Corporation), 2727 East Imperial Highway, Brea, CA 92821; telephone (714) 984–1461; fax 714–984–1675, or at *www.goodrich.com*.

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Fort Worth, Texas, on September 27, 2013.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–30466 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30934; Amdt. No. 3569]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 27, 2013. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 27, 2013.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Availability—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit *http://www.nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPS, Takeoff Minimums and/or ODPS. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their depiction on charts printed

by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the, associated Takeoff Minimums and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as contained in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPS and Takeoff Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPS and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPS, Takeoff Minimums and ODPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on December 6, 2013.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 9 January 2014

Needles, CA, Needles, Takeoff Minimums and Obstacle DP, Amdt 1
Camilla, GA, Camilla-Mitchell County, Takeoff Minimums and Obstacle DP, Amdt 2
Bonners Ferry, ID, Boundary County, RNAV (GPS) RWY 2, Orig-B

Effective 6 February 2014

Deering, AK, Deering, RNAV (GPS) RWY 11, Orig-B
Deering, AK, Deering, RNAV (GPS) RWY 29, Orig-B
Elim, AK, Elim, RNAV (GPS) RWY 19, Orig-A
Rota Island, CQ, Benjamin Taisacan Mangiona Intl, NDB RWY 9, Amdt 4
Rota Island, CQ, Benjamin Taisacan Mangiona Intl, NDB RWY 27, Amdt 4
Rota Island, CQ, Benjamin Taisacan Mangiona Intl, RNAV (GPS) RWY 9, Amdt 1
Rota Island, CQ, Benjamin Taisacan Mangiona Intl, RNAV (GPS) RWY 27, Amdt 1
Rota Island, CQ, Benjamin Taisacan Mangiona Intl, Takeoff Minimums and Obstacle DP, Amdt 2
Terre Haute, IN, Terre Haute Intl-Hulman Field, RADAR–1, Amdt 5
Louisville, MS, Louisville Winston County, RNAV (GPS) RWY 17, Amdt 1
Louisville, MS, Louisville Winston County, RNAV (GPS) RWY 35, Amdt 1
Nashua, NH, Boire Field, VOR RWY 32, Orig

[FR Doc. 2013–30486 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30935; Amdt. No. 3570]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 27, 2013. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of December 27, 2013.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability—All SIAPs are available online free of charge. Visit *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420)Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore— (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97:

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC on December 6, 2013.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

§§97.23, 97.25, 97.27, 97.29. 97.31, 97.33, 97.35 [Amended]

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

Effective Upon Publication

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
1/9/14	NC	Chapel Hill	Horace Williams	3/0359	11/26/13	VOR/DME Rwy 27, Amdt 1A.
1/9/14	CA	Bakersfield	Meadows Field	3/1534	11/25/13	VOR A, Orig.
1/9/14	PR	Aguadilla	Rafael Hernandez	3/2328	11/26/13	VOR/DME or TACAN Rwy 26, Orig.
1/9/14	CA	Oakland	Metropolitan Oakland Intl	3/7464	12/2/13	VOR Rwy 10R, Amdt 9.
1/9/14	CA	Los Angeles	Los Angeles Intl	3/8760	11/22/13	ILS or LOC Rwy 25L, ILS Rwy 25L (CAT II), ILS Rwy 25L (CAT III), Amdt 12A.
1/9/14	CA	Los Angeles	Los Angeles Intl	3/8771	11/15/13	ILS or LOC Rwy 25L, ILS Rwy 25L (CAT II), ILS Rwy 25L (CAT III), Amdt 12A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
1/9/14	CA	Los Angeles	Los Angeles Intl	3/9143	11/15/13	ILS or LOC Rwy 24R, ILS Rwy 24R (CAT II), ILS Rwy 24R (CAT III), Amdt 24A.
1/9/14	CA	Los Angeles	Los Angeles Intl	3/9144	11/22/13	ILS or LOC Rwy 24R, ILS Rwy 24R (CAT II), ILS Rwy 24R (CAT III), Amdt 24A.

[FR Doc. 2013–30482 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2013–N–0002]

Withdrawal of Approval of New Animal Drug Applications; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal approval of five new animal drug applications (NADAs) for roxarsone oral dosage form products at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective January 6, 2014.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, *john.bartkowiak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following five NADAs for roxarsone oral dosage form products, used to make medicated drinking water for chickens, turkeys, and swine, because the products are no longer manufactured or marketed:

NADA	Proprietary name
005–414	REN–O–SAL (roxarsone) Tablets.
006–019	Zuco Poultry Tablets.
006–081	Korum Improved Formula.
008–274	Pig Scour Tablets.
093–025	3–NITRO (roxarsone) Soluble.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 005–414, 006–019, 006–081, 008–274, and 093–025, and all supplements and amendments thereto, is withdrawn, effective January 6, 2014. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§§ 520.2087, 520.2088, and 520.2089 [Removed]

■ 2. Remove §§ 520.2087, 520.2088, and 520.2089.

Dated: December 20, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–30838 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2013–N–0002]

Withdrawal of Approval of New Animal Drug Applications; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five new animal drug applications (NADAs) for roxarsone oral dosage form products at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective January 6, 2014.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, *john.bartkowiak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following five NADAs for roxarsone oral dosage form products, used to make medicated drinking water for chickens, turkeys, and swine, because the products are no longer manufactured or marketed:

NADA	Proprietary name
005–414	REN–O–SAL Tablets.
006–019	Zuco Poultry Tablets.
006–081	Korum Improved Formula.
008–274	Pig Scour Tablets.
093–025	3–NITRO Soluble.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 005–414, 006–019, 006–081, 008–274, and 093–025, and all supplements and amendments thereto, is hereby withdrawn, effective January 6, 2014.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: December 20, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–30837 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 207

Reservoirs at Headwaters of the Mississippi River; Use and Administration.

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers is amending the rules regarding use and administration of the reservoirs at the headwaters of the Mississippi River by deleting from the Code of Federal Regulations all references to minimum discharges and to operating limits for the reservoirs. Following extensive public input and environmental review, the St. Paul District of the Corps of Engineers recently adopted an updated operating plan for the Mississippi River Headwaters reservoirs containing minimum flow values that differ from those currently codified in the *Code of Federal Regulations*. Deleting all references to minimum flows in the regulations will eliminate the current discrepancy between the regulations and the approved operating plan for the reservoirs. The operating limits are also contained in the operating plan for the reservoirs, and eliminating both the minimum flow values and the operating limits from the rule will make it unnecessary to amend the regulations each time the values are modified in the operating plan in the future.

DATES: *Effective Date:* January 27, 2014.

FOR FURTHER INFORMATION CONTACT: Headquarters, Engineering and Construction Community of Practice, Washington, DC at 202–761–4922, or Mr. Kenton Spading, U.S. Army Corps of Engineers, St. Paul District, at 651–290–5623.

SUPPLEMENTARY INFORMATION:

Executive Summary

The purpose of this action is to amend the current rule regarding minimum discharges and minimum operating limits of the reservoirs at the headwaters of the Mississippi River to ensure that the regulations do not conflict with the current operating plan for those reservoirs.

The Corps' authority to amend the minimum flow values and minimum operating limits for the reservoirs of the headwaters of the Mississippi River is Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Section 216 of the Flood Control Act of 1970 (84 Stat. 1830; 33 U.S.C. 549a).

Background

The Rivers and Harbors Acts of June 14, 1880, and August 2, 1882, authorized the construction of dams at each of the six Mississippi River Headwaters lakes for the purpose of augmenting Mississippi River flow for navigation. The lakes affected by these acts are Winnibigoshish, Leech, Pokegama, Sandy, Cross (Pine River), and Gull. Following authorization of the reservoirs, the Secretary of War prescribed regulations governing operation of the reservoirs on February 11, 1931, which were codified at 33 CFR 207.340. The current regulations list minimum discharges for each reservoir at 33 CFR 207.340(d)(2). The current regulations also list minimum operating limits, or the lowest level at which the Corps may operate each reservoir, at 33 CFR 207.340(d)(7).

The Corps' procedure adopting and publishing regulations related to reservoirs has changed since the aforementioned regulations were originally codified in 1931. The present-day practice is to include minimum flow values, operating limits and other related information in Water Control Manuals that are adopted following an extensive public and environmental review process, as outlined in Engineer Regulation (ER) 1110–2–240. Moreover, the operating limits in the Water Control Manuals prescribe not only the minimum level at which a reservoir may operate but also the absolute upper limit on reservoir operations, effectively providing a band within which the Corps may operate a reservoir.

As a precursor to updating the Water Control Manuals for the Mississippi River Headwaters reservoirs in 2009, we completed a study known as the Mississippi River Headwaters Reservoir Operating Plan Evaluation (ROPE). The primary purpose of the ROPE was to evaluate alternative operating plans for the Headwaters reservoirs in an attempt to improve the operation of the system while balancing tribal trust obligations, flood risk reduction, environmental concerns, water quality, water supply, recreation, navigation, hydropower, and other public interests.

On January 19, 2010, after thoroughly assessing potential environmental impacts and involving the public in the process, the District Engineer for the St. Paul District signed a Record of Decision approving the ROPE's recommended operating plan for the Headwaters reservoirs. The ROPE's recommended plan adopts minimum discharges that were scientifically developed using a habitat in-stream flow analysis (Tenant 1976), as described in the ROPE. The minimum discharges in the ROPE's recommended plan differ from the minimum discharges listed in 33 CFR 207.340 as it is currently written. We are in the process of updating the Water Control Manuals for the Headwaters reservoirs to implement the recommendations from the 2009 ROPE. Once the Water Control Manuals are revised, the minimum discharge values in the revised Water Control Manuals will also be in conflict with 33 CFR 207.340 if the regulation is not amended. Table No. 1 illustrates the differences between the current regulations and the 2009 ROPE study minimum flows.

TABLE 1—MISSISSIPPI RIVER HEADWATER RESERVOIR SYSTEM OPERATING LIMITS AND CFR VERSUS ROPE MINIMUM DISCHARGES

	Winnibigoshish	Leech	Pokegama	Sandy	Cross L. Pine R.	Gull
Total Operating Limit	1294.94–1303.14	1292.70–1297.94	1270.42–1278.42	1214.31–1221.31	1225.32–1235.30	1192.75–1194.75.
Minimum Flow: 33 CFR § 207.340.	150 cfs	70 cfs	200 cfs	80 cfs	90 cfs	30 cfs.
Minimum Flow: 2009 ROPE.	≥ 1294.94 100 cfs < 1294.94 50 cfs.	≥ 1292.70 120 cfs < 1292.70 60 cfs.	≥ 1273.17 200 cfs < 1273.17 Sum of Flow From Winnibigoshish plus Leech.	≥ 1214.31 20 cfs < 1214.31 10 cfs.	≥ 1225.32 30 cfs < 1225.32 15 cfs.	≥ 1192.75 20 cfs < 1192.75 10 cfs

The Mississippi River Headwaters proposed rule change was published for review and comment in the **Federal Register** on July 15, 2013 (78 FR 42030). The regulations.gov docket number was COE–2013–0008. No comments were

received by the end of the review and comment period on September 13, 2013.

We are amending the regulations to delete all references to minimum flows to eliminate any conflict between the regulations and the Water Control Manuals that guide operations at the Mississippi River Headwaters reservoirs. We are removing the minimum operating limits from the regulations. Any future changes to the minimum flows or the operating limits of the Headwaters reservoirs will be handled through revisions to the Water Control Manuals, which will be accomplished in accordance with the guidance provided in ER 1110–2–240 after public input and any necessary environmental reviews. The change to the rule will eliminate the necessity of amending the Code of Federal Regulations each time a Water Control Manual is updated.

Administrative Requirements

Plain Language

In compliance with the principles in the President's Memorandum of June 1, 1998, (63 FR 31855) regarding plain language, this preamble is written using plain language. The use of "we" in this notice refers to the Corps. We have also used the active voice, short sentences, and common everyday terms except for necessary technical terms.

Paperwork Reduction Act

This action will not impose any new information collection burden under the provisions of the Paperwork Production Act (44 U.S.C. 3501 et seq.). The modification would eliminate minimum flow values and operating limits from the rule. Since the rule does not involve any additional collection of information from the public, this action is not subject to the Paperwork Reduction Act.

Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Corps must determine whether the regulatory action is "significant" and therefore subject to review by OMB and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, we have determined that the rule is not a "significant regulatory action" because it does not meet any of these four criteria. The rule modifies the regulations to be consistent with an approved, updated operating plan for the Mississippi River Headwaters reservoirs.

Executive Order 13132

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires the Corps to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications." The phrase "policies that have Federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

The rule does not have Federalism implications. We do not believe that amending the regulation to eliminate references to minimum flow values and operating limits for the Mississippi River Headwaters reservoirs will have substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. The rule does not impose new substantive requirements. In addition, the changes will not impose any additional substantive obligations on State or local governments. Therefore, Executive Order 13132 does not apply to this rule.

Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 et seq.

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, a small entity is defined as: (1) A small business based on Small Business Administration size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of the rule on small entities, we believe that this action will not have a significant economic impact on a substantial number of small entities. The rule is consistent with current agency practice, does not impose new substantive requirements, and therefore would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under Section 202 of the UMRA, the agencies generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating a rule for which a written statement is needed, Section 205 of the UMRA generally requires the agencies to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows an agency to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the agency publishes with the final rule an explanation why that alternative was not adopted. Before an agency establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed, under Section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially

affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

We have determined that the rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The rule is consistent with current agency practice, does not impose new substantive requirements and therefore does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Therefore, the rule is not subject to the requirements of Sections 202 and 205 of the UMRA. For the same reasons, we have determined that the rule contains no regulatory requirements that might significantly or uniquely affect small governments. Therefore, the rule is not subject to the requirements of Section 203 of UMRA.

Executive Order 13045

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, we must evaluate the environmental health or safety effects of the rule on children, and explain why the regulation is preferable to other potentially effective and reasonably feasible alternatives.

The rule is not subject to this Executive Order because it is not economically significant as defined in Executive Order 12866. In addition, it does not concern an environmental or safety risk that we have reason to believe may have a disproportionate effect on children.

Executive Order 13175

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires agencies to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." The phrase "policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

The rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. It is generally consistent with current agency practice and does not impose new substantive requirements. Therefore, Executive Order 13175 does not apply to this rule.

Environmental Documentation

The purpose of this rule is to make the Code of Federal Regulations consistent with the current operating plan for the Mississippi River Headwaters Reservoirs. This action is solely administrative in nature. There is no intended change in the use or operation of the reservoirs as a result of this action. The substantive change in reservoir operations has already occurred as a consequence of the adoption of an updated operating plan, as approved in the Record of Decision for Mississippi River Headwaters Reservoir Operating Plan Evaluation dated January 19, 2010. The potential environmental impacts of the updated operating plan were thoroughly assessed in the Final Integrated Reservoir Operating Plan Evaluation and Environmental Impact Statement dated September 2009. Because the present action is merely administrative and an environmental analysis was completed at the time the substantive changes to the operating plan were adopted, no additional environmental documentation will be required at this time.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. We will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The rule is not a "major rule" as defined by 5 U.S.C. 804(2).

Executive Order 12898

Executive Order 12898 requires that, to the greatest extent practicable and permitted by law, each Federal agency must make achieving environmental justice part of its mission. Executive Order 12898 provides that each Federal agency conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that such programs, policies, and activities do not have the effect of excluding persons (including populations) from participation in, denying persons (including populations) the benefits of, or subjecting persons (including populations) to discrimination under such programs, policies, and activities because of their race, color, or national origin.

The rule is not expected to negatively impact any community, and therefore is not expected to cause any disproportionately high and adverse impacts to minority or low-income communities.

Executive Order 13211

The rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The proposed rule is consistent with current agency practice, does not impose new substantive requirements and therefore will not have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects in 33 CFR Part 207

Navigation (water), Penalties, Reporting and recordkeeping requirements, Waterways.

Dated: December 20, 2013.

James R. Hannon,

Chief, Operations and Regulatory.

For the reasons stated in the preamble, the Corps amends 33 CFR part 207 as follows:

PART 207—NAVIGATION REGULATIONS

■ 1. The authority citation for part 207 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1).

■ 2. Revise § 207.340 to read as follows:

§ 207.340 Reservoirs at headwaters of the Mississippi River; use and administration.

(a) *Description.* These reservoirs include Winnibigoshish, Leech Lake, Pokegama, Sandy Lake, Pine River and Gull Lake.

(b) *Penalties.* The River and Harbor Act approved August 11, 1888 (25 Stat. 419, 33 U.S.C. 601) includes the following provisions as to the administration of the headwater reservoirs:

And it shall be the duty of the Secretary of War to prescribe such rules and regulations in respect to the use and administration of said reservoirs as, in his judgment, the public interest and necessity may require; which rules and regulations shall be posted in some conspicuous place or places for the information of the public. And any person knowingly and willfully violating such rules and regulations shall be liable to a fine not exceeding five hundred dollars, or imprisonment not exceeding six months, the same to be enforced by prosecution in any district court of the United States within whose territorial jurisdiction such offense may have been committed.

(c) *Previous regulations now revoked.* In accordance with the above act, the Secretary of War prescribed regulations for the use and administration of the reservoirs at the headwaters of the Mississippi River under date of February 11, 1931, which together with all subsequent amendments are hereby revoked and the following substituted therefor.

(d) *Authority of officer in charge of the reservoirs.* The accumulation of water in, and discharge of water from the reservoirs, including that from one reservoir to another, shall be under the direction of the U.S. District Engineer, St. Paul, Minnesota, and of his authorized agents subject to the following restrictions and considerations:

(1) Notwithstanding any other provision of this section, the discharge from any reservoir may be varied at any time as required to permit inspection of, or repairs to, the dams, dikes or their appurtenances, or to prevent damage to lands or structures above or below the dams.

(2) During the season of navigation on the upper Mississippi River, the volume of water discharged from the reservoirs shall be so regulated by the officer in charge as to maintain as nearly as practicable, until navigation closes, a sufficient stage of water in the navigable reaches of the upper Mississippi and in those of any tributary thereto that may be navigated and on which a reservoir is located.

(e) *Passage of logs and other floating bodies.* Logs and other floating bodies may be sluiced or locked through the dams, but prior authority for the sluicing of logs must be obtained from the District Engineer when this operation necessitates a material change in discharge.

(f) *Obstructions to flow of water.* No person shall place floating bodies in a stream or pond above or below a reservoir dam when, in the opinion of the officer in charge, such act would prevent the necessary flow of water to or from such dam, or in any way injure the dam and its appurtenances, its dikes and embankments; and should floating bodies lying above or below a dam constitute at any time an obstruction or menace as beforesaid, the owners of said floating bodies will be required to remove them immediately.

(g) *Trespass.* No one shall trespass on any reservoir dam, dike, embankment or upon any property pertaining thereto.

[FR Doc. 2013–31078 Filed 12–26–13; 8:45 am]

BILLING CODE 3720–58–P

POSTAL SERVICE

39 CFR Part 111

Deferral of Compliance Date: Full-Service Intelligent Mail Barcode Requirement To Qualify for Automation Prices

AGENCY: Postal Service™.

ACTION: Final rule; partial deferral of compliance date.

SUMMARY: The Postal Service gives notice that it is deferring the previously-announced compliance date of January 26, 2014, for mailers to use full-service Intelligent Mail® to qualify for automation prices when mailing First-Class Mail®, Standard Mail®, Periodicals®, and Bound Printed Matter® mailpieces.

DATES: The compliance date of the relevant portions of the final rule published April 18, 2013 (78 FR 23137) is delayed indefinitely.

FOR FURTHER INFORMATION CONTACT: Lizbeth J. Dobbins at 202–268–3781.

SUPPLEMENTARY INFORMATION: In Order No. 1890 (November 21, 2013), the Postal Regulatory Commission (PRC) determined that the price changes proposed in Docket No. R2013–10 could take effect as scheduled only if the Postal Service elected to defer the requirement for mailers to use full-service Intelligent Mail to qualify for automation prices.

Consistent with this Order, the United States Postal Service® hereby gives notice that the January 26, 2014, deadline to comply with the full-service Intelligent Mail requirements to qualify for automation prices, previously published on April 18, 2013, in a final rule in the **Federal Register** (78 FR 23137–23149), is deferred until further notice. Specifically, this deferral applies to the requirements specified in DMM 233.5.1 (First-Class commercial letters and cards); DMM 243.6.1.2, 243.6.4.1, 243.6.5.1, and 243.7.1 (Standard Mail letters); DMM 333.5.1 (First-Class automation flats); DMM 343.7.1 (Standard Mail automation flats); DMM 363.4.1 and 363.6.1 (Bound Printed Matter flats); DMM 705.24.1 (advanced preparation and special postage payment systems); and DMM 707.13.4, 707.14.1, and 707.14.2 (Periodicals). *See*, 78 FR 23146–23148.

All other requirements that were published in the **Federal Register** (78 FR 23137–23149) will be implemented on January 26, 2014.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–30705 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2009–0965; FRL–9904–71–Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Disapproval of State Implementation Plan Revision for ArcelorMittal Burns Harbor

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On December 10, 2009, Indiana submitted a request for a revision to its sulfur dioxide (SO_2) state implementation plan (SIP) for the ArcelorMittal Burns Harbor LLC (ArcelorMittal) facility in Porter County, Indiana. This revision would remove the SO_2 emission limit for the blast furnace gas flare at the facility. The Environmental Protection Agency (EPA) proposed to disapprove this requested revision on March 20, 2013. The EPA is addressing comments and finalizing the disapproval action.

DATES: This final rule is effective on January 27, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2009–0965. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Mary Portanova, Environmental Engineer, at (312) 353–5954 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Mary Portanova, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–5954, *Portanova.mary@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is the background for this action?

On December 10, 2009, the Indiana Department of Environmental Management (IDEM) submitted a request for revision of its SO_2 SIP. This revision would amend 326 Indiana Administrative Code (IAC) 7–4–14, Porter County SO_2 Emission Limitations, by removing the SO_2 limit for the blast furnace flare at the ArcelorMittal steel mill. To be approved, this SIP revision request must comply with section 110(l) of the Clean Air Act (CAA), which states that the Administrator shall not approve a SIP revision if it would interfere with attainment and maintenance of the national ambient air quality standards (NAAQS), reasonable further progress, and any other applicable requirements. 42 U.S.C. 7410(l).

After reviewing the state's submittal, EPA determined that the proposed SIP revision does not meet the requirements of CAA section 110(l). Removal of the flare limit eliminates the only requirement which directly addresses the sulfur content of the blast furnace gas which ArcelorMittal uses to fuel other combustion units in the facility. Although blast furnace gas is considered to be a low-sulfur fuel, the state's submittal indicates that the sulfur content of blast furnace gas can vary, and the proposed SIP revision would allow ArcelorMittal's blast furnace gas to increase in sulfur content without limit. This would be inconsistent with the state's prior attainment demonstration for the SO_2 NAAQS.

The state has not fully evaluated the ambient impact of new operating scenarios in which ArcelorMittal generates and uses higher-sulfur blast furnace gas. It did not provide sufficient information for EPA to confirm the assertion that the SIP emission limits would continue to be met, with or without the use of the flare, under maximum blast furnace capacity without limitations on blast furnace gas sulfur content. Since the state's SIP submittal did not meet the requirements of CAA section 110(l), EPA published a notice of proposed disapproval for this SIP revision request on March 20, 2013 (78 FR 17157). EPA received four letters commenting on the proposed disapproval.

II. What comments were received, and what is EPA's response?

EPA received two comments in support of the proposed disapproval, from an Indiana public interest group (March 22, 2013) and a private citizen (April 18, 2013). Both IDEM and ArcelorMittal disagreed with the proposal to disapprove the SIP revision request. IDEM submitted its comments on April 18, 2013. ArcelorMittal submitted its comments on April 19, 2013. Their comments are addressed below.

Comment: The flare limit represents an inequity in the state's treatment of blast furnace gas flares; a similar facility nearby does not have SO_2 limits on its functionally identical flares. The limits for Lake County, Indiana, were established after the limits for Porter County, where ArcelorMittal is located. Emission inventories and modeling parameters had improved, and through extensive consultation with EPA, it was determined to be unnecessary to establish SO_2 emission limits specific to the flares for similar facilities in Lake County (i.e. U.S. Steel Gary Works). IDEM was able to establish SIP limits for sources such as U.S. Steel Gary Works which did not include SO_2 limits on the flares. EPA approved those limits. There is no material reason for ArcelorMittal's blast furnace gas flares in Porter County to be treated different from the blast furnace gas flares operated by U.S. Steel in Lake County. It would be arbitrary for EPA to disapprove the Porter County SIP revision to remove blast furnace gas flare limits as unnecessary and redundant limits after approving the 2005 Lake County SO_2 SIP that did not include blast furnace gas flare limits because they were unnecessary and redundant. IDEM's attempt to remove this arbitrary difference between neighboring counties should be considered an appropriate correction to a historic error and approved. This SIP revision would harmonize the Lake and Porter County treatment of flares combusting excess blast furnace gas.

Response: Indiana's December 10, 2009, submission did not demonstrate that ArcelorMittal's revised SO_2 SIP would continue to protect the SO_2 NAAQS or meet the requirements of CAA section 110(l). Therefore, the SIP revision cannot be approved. Emission limits, or the lack thereof, at other facilities are not relevant to this demonstration. The fact that SO_2 SIPs have been approved without the need for SO_2 limits on certain flares is not in itself a justification for removing SO_2 limits on flares from other sources in the absence of a showing that the removal will not interfere with attainment and maintenance of the NAAQS.

Comment: This should not be considered a matter of backsliding or relaxation of the SIP, but a technical correction that is necessary to establish consistency. The limit should have been excluded from the start; therefore, this corrective action has no impact on the approved SIP or the modeling conducted to support it.

Response: The state established ArcelorMittal's flare limit in the SIP as part of its strategy to attain and maintain the SO_2 NAAQS in Porter County. The SIP was approved by EPA in 1989 and has remained in effect. CAA section 110(l) does not provide an exception for "technical corrections." Even if it did, it would not be appropriate to treat the state's December 10, 2009, SIP revision request as a technical correction because it can be expected to affect air quality and because the state has not provided a demonstration that in 1989 it did not intend to establish an SO_2 limit applicable to the blast furnace flare now operated by ArcelorMittal. Likewise, to the extent that the commenter is suggesting the SIP provision was approved in error and should be

corrected pursuant to CAA section 110(k)(6). EPA notes that the state has not provided a basis for concluding that the approval of this provision in 1989 was an error. In addition, EPA does not believe that emission limit relaxations can be justified on the basis of establishing consistency without also satisfying the requirements of CAA section 110(l). Therefore, the proposed SIP revision's effects on the existing SIP and on the state's maintenance of the NAAQS must be evaluated in accordance with CAA section 110(l).

Comment: IDEM and ArcelorMittal were led in 2007–2009 to believe that the flare limit removal would be approvable. IDEM and ArcelorMittal received no information to the contrary until 2012. EPA was unwilling to establish fruitful dialogue with the state prior to proposing disapproval. In its proposed disapproval, EPA did not cite or recognize the wealth of information provided to supplement the SIP revision.

Response: EPA's concerns with this SIP revision did not arise until EPA received and began review of Indiana's December 10, 2009, SIP submittal. Following a thorough review of the submittal and additional information subsequently provided by Indiana, EPA concluded that the submittal did not meet the requirements of CAA section 110(l). EPA regularly communicated the progress of EPA's review of the submittal during monthly conference calls with IDEM and offered opportunities for further dialogue, which is documented in call summaries prepared by IDEM.

As early as January 2010, EPA identified potential issues with this SIP revision request. EPA acknowledges that IDEM and ArcelorMittal provided EPA with additional information in response to its questions, which EPA carefully considered. However, the state's submittal, including supplemental information, did not demonstrate that the proposed SIP revision would satisfy CAA section 110(l). IDEM's monthly call summaries indicate that EPA had begun working on a disapproval in January 2012, after expressing continuing concerns in September 2011. EPA formally communicated the deficiencies of the revision in the March 20, 2013, notice of proposed rulemaking (78 FR 17157). EPA's proposal was based on an evaluation of the state's official submittal using the applicable requirements of the CAA, related regulations and guidance.

Comment: The flares should not have a limit, especially a mass limit (pounds per hour), because the flare needs to be available for full usage to maintain operational safety. Additionally, a flare limit presents a major hardship for compliance testing and enforcement.

Response: EPA agrees that the ArcelorMittal flare must be allowed to operate as necessary for operational safety and proper disposal of waste gases. EPA also agrees that direct compliance testing of flare emissions can be difficult. ArcelorMittal's existing flare emission limit would not limit the flare's actual usage while the blast furnace gas generated by the facility continued to meet the flare emission limit. Deleting the flare limit, however, has additional consequences for the SIP which Indiana did not adequately address in its SIP revision request.

Comment: The commenter states that the *Montana Sulphur* case which EPA cited does not apply to this SIP revision because Indiana's SIP includes limits on all the emissions from blast furnace gas combustion that were used in the modeling to demonstrate attainment. The flares were not attributed any mass emissions in the modeling demonstration or the SIP. The *Montana Sulphur* case involved a state's decision to include flares in the modeling demonstration but not include corresponding emission limits in the SIP rule.

Response: The *Montana Sulphur* case affirms that flares are not exempt from having SIP emission limits, particularly where flare emissions were quantified in an attainment demonstration that assumed flare emissions would occur at a certain level. Indiana has submitted information to EPA indicating that the blast furnace flare was included in the original modeled attainment demonstration for the Porter County SO_2 SIP, with its SO_2 emissions calculated from blast furnace gas with a sulfur content of 0.07 pounds SO_2 per million British Thermal Units (lb/mmBtu). Allowing higher-sulfur blast furnace gas would affect SO_2 emissions at several emission points, including the flare, which could affect the adequacy of the prior modeled attainment demonstration, which relied upon the use of blast furnace gas with a sulfur content of 0.07 lb/mmBtu. Therefore, it is reasonable for the SIP to require the flare and the other sources using blast furnace gas to meet that emission rate or demonstrate compliance with applicable emission limits based on that emission rate. Indiana has not provided a demonstration which fully addresses the effect on the attainment demonstration of relaxing the SIP requirements to allow the facility to generate, use, and flare higher-sulfur blast furnace gas. Likewise, in the SIP disapproval that was the subject of the *Montana Sulphur* case, the state's attainment demonstration had assumed SO_2 emissions from flares would occur at a certain rate, but had not shown in its enforceable SIP emissions limits how the assumed emissions would be achieved. It is true that EPA has not required all flares in all SO_2 SIPs to be subjected to emission limits. But where an attainment demonstration relies upon SO_2 emissions to occur at certain levels, including those from flares, the SIP must contain adequate emission limits to support the demonstration. The problem both in *Montana Sulphur* and here was that the attainment demonstration submitted by the state could not be so supported. (The blast furnace flare limit helped support Indiana's demonstration for the ArcelorMittal facility when the SO_2 SIP was approved in 1989.) Consequently, EPA's disapproval of the proposed SIP relaxation is fully consistent with the Court's reasoning in the *Montana Sulphur* case and with EPA's SIP disapproval action that was the subject of that case.

Comment: The flare SO_2 limit is in units of lb/mmBtu. This is not a mass limit, which would be given as pounds of SO_2 per hour (lb/hr). Therefore the form of the limit is not designed to be protective of the NAAQS. Only the mass based lb/hr limits are relevant to ensuring SO_2 NAAQS attainment in the SIP. The 0.07 lb/mmBtu SO_2 emission rate is a factor that is no longer necessary or relevant after the lb/hr limits were established and included in the SIP. Exclusion of this limit is no less protective than the current SIP limit.

Response: Emission limits given in units of lb/mmBtu are common in SO_2 SIPs. By directly limiting the sulfur content of the fuels combusted in a given unit or facility, this type of limit allows flexibility of unit operations. When the individual units are modeled at their maximum heat input rates (in units of million British Thermal Units per hour), assuming fuel at the lb/mmBtu limit, the SIP can be shown to protect the NAAQS for any actual heat input rate, including continual maximum operations, with compliant fuel. The removal of a lb/mmBtu emission limit would enable the burning of a higher-sulfur fuel, which could result in SO_2 concentrations in excess of the NAAQS and adversely affect public health.

Comment: Given the existing flare SIP limit of 0.07 lb/mmBtu, an emission rate of 8.9 lb/hr could be assumed for the flare, for modeling purposes. Over a year of continuous operation, this would total less than 39 tons per year, which is below the Significant Emission

Rate for SO_2 (40 tons per year). Actual emissions would be lower, because flares operate intermittently. Since the facility is in an attainment area, the flare would normally be excluded from modeling because it was considered de minimis. Recent EPA guidance suggests that intermittent sources can be excluded from modeling.

Response: The commenter's statements regarding the relative importance of the flare's SO_2 emissions do not eliminate the need for a CAA section 110(l) demonstration addressing the full effects of the proposed SIP revision. The comment references the flare's total annual emissions while in compliance with the current SO_2 emission limit, but it does not consider the increase in annual SO_2 emissions which the proposed SIP revision would allow. In comparing the flare's total annual emissions to the Significant Emission Rate, the commenter appears to be referencing New Source Review/ Prevention of Significant Deterioration program requirements which are not relevant to this SIP action. The designation of an area as attainment of the NAAQS does not automatically exempt emission sources from inclusion in SIP attainment demonstrations. It is not clear that ArcelorMittal's blast furnace flare would qualify as an intermittent source under EPA's March 1, 2011, memorandum *Additional Clarification Regarding Application of Appendix W Modeling Guidance for the 1-hour NO_2 National Ambient Air Quality Standard* (which is what EPA assumes the commenter is referencing), or that it would be appropriate to disregard the flare's emissions in a SIP modeling analysis per this memorandum, and the state did not provide an analysis justifying such an approach within a modeled demonstration for the 1-hour SO_2 standard.

Comment: The pressure surge events that concern EPA are rare and unexpected events that cannot be quantified. The allowable SO_2 emission rates are sufficiently conservative to account for all such surges within the current allowable emissions inventory. Therefore, the commenter disagrees with EPA's assertion that the SIP revision would enable an increase in allowable SO_2 emissions.

Response: EPA referenced pressure surges in the March 20, 2013, notice of proposed rulemaking because the documentation provided by the state indicated that the blast furnace flare gas generation or distribution systems were known to experience pressure surge events. However, the state's declarations regarding flare usage and worst-case facility operations did not address these events. We acknowledge the commenter's additional assurances regarding the frequency and magnitude of pressure surges. As discussed above, EPA is not solely concerned with pressure surge events, but also with the effect on air quality of removing the blast furnace flare limit from the SIP.

Comment: The commenter declared a strong economic incentive to use this gas as fuel, flaring as little of it as possible.

Response: EPA understands that it is ArcelorMittal's intent to use its blast furnace gas as fuel rather than flaring it, thus minimizing flare emissions. However, the company has acknowledged the need to use the flare for the safe operation of the blast furnace gas operating system, regardless of the economic incentives to do otherwise. Whether the flare is used frequently or not, the full effect of removing the flare's emission limit must be addressed. The state did not provide a CAA section 110(l) demonstration which adequately addressed the effect of the proposed SIP revision on air quality, taking into consideration the facility's ability to continue using all of its generated gases as fuel and the lack of a sulfur limit on blast furnace gas.

Comment: The commenter stated that the amount of process gas generation is limited by enforceable restrictions. The facility's Part 70 operating permit places a limit on the amount of hot metal that can be produced in the blast furnace, which effectively limits the amount of blast furnace gas that can be produced by the facility. The coke oven batteries have enforceable SIP limits on the amount of coke oven gas that can be produced. The commenter said that the maximum amount of blast furnace gas and coke oven gas that can be generated within these restrictions can be consumed in the existing combustion units when operated at maximum capacity. When IDEM modeled the allowable emissions from the facility, combustion of all the blast furnace gas and coke oven gas is properly included and there is no additional blast furnace gas to attribute to the flare.

Response: The commenter referred to hot metal production limits within the facility's Part 70 permit which were originally derived from a construction permit and are therefore permanent. The commenter stated that these restrictions would affect blast furnace gas production, but did not provide calculations or documentation which identified the maximum amount of blast furnace gas that can be generated while in compliance with the hot metal limitation in the facility's Part 70 permit. The total coke oven gas production allowable under the cited coke battery limits was not given. The SIP includes SO_2 emission limits for various fuel combustion units at ArcelorMittal which can use blast furnace gas and coke oven gas, such as the blast furnace stoves, coke battery underfire, slab mill soaking pits, and power station boilers, which are referred to in this document as "the combustion units." No calculations were provided to show the amount of process gas by volume which can be burned in the combustion units at their maximum heat input capacities, for comparison with maximum gas production in support of the commenter's assertion. The state's submittal did not address the amounts of each fuel gas which corresponded to the emission rates used in the dispersion modeling analysis which the state cited in support of the SIP revision. Therefore, EPA does not have sufficient information to confirm that the maximum amount of blast furnace gas and coke oven gas which can be generated within the facility's enforceable production restrictions can be entirely consumed in the combustion units when operated in compliance with the SO_2 SIP emission limits.

Comment: The sum of allowable SO_2 lb/hr rates for all combustion units burning process gases at the ArcelorMittal facility is 8,692 lb/hr. This rate is more than double the maximum SO_2 emissions from combustion of all the process gases that can be produced at the facility within current enforceable restrictions on hot metal and coke oven gas. The commenter provided calculations to support this assertion.

Response: The calculations which the commenter provided appear to be based on actual annual facility gas production data, rather than a calculated maximum value which would be allowed by the enforceable limits, as suggested by the comment. The comment letter contains a table of calculated SO_2 emissions from blast furnace gas and coke oven gas. This table is identical to a table in ArcelorMittal's June 29, 2011, letter to IDEM. In that letter, the blast furnace gas production data was identified as the facility's highest recent annual production amount (2004), and the coke oven gas was identified as the highest recent annual production amount (2009). EPA has already considered this information. The June 29, 2011, letter did not indicate that the 2004 blast furnace gas production totals represented the maximum amount of process gas that could be generated while in compliance with the hot metal limit in the Part 70 permit. The

comment on EPA's March 20, 2013, proposed disapproval does not provide additional calculations or documentation to identify the true maximum blast furnace gas production which would be possible within the hot metal limitation in ArcelorMittal's Part 70 permit, or to demonstrate that the 2004 actual production value is equal to the maximum possible production rate. EPA therefore concludes that the comment continues to cite actual production data from 2004, which is not sufficient to prove that the existing SIP limits will continue to accommodate all of the gas ArcelorMittal can generate, when the blast furnace gas sulfur content is no longer restricted by the flare limit.

Comment: Since the worst-case scenario attributes no blast furnace gas to the flare, a change in the actual emissions at the flare is irrelevant for purposes of attainment and maintenance of the SO_2 NAAQS. Any increase in emissions at the flare reflects a corresponding reduction from another source already modeled and must be considered a departure from the worst-case scenario that must be modeled for the attainment demonstration. This is how EPA endorsed modeling similar sources in Lake County.

Response: A change in actual SO_2 emissions at the flare is only irrelevant if the SIP truly covers all possible blast furnace gas production and sulfur content increases which would be allowed under the revised SIP. The range of potential blast furnace gas sulfur content at this facility has not been established. When blast furnace gas is no longer assured of meeting 0.07 lb/mmBtu, the new worst-case operating scenario may differ from the scenario which was previously modeled to support the original SO_2 SIP for this facility. The state has not demonstrated that the SIP fully covers new potential operating scenarios which could occur.

Comment: One of the commenters disagreed with EPA's statement that the limitations on the sulfur content of the process gases need to be addressed in the SIP. The comment stated that the purpose of the SIP is to attain and maintain the NAAQS and ensure reasonable further progress, and for this purpose, IDEM established the SO_2 lb/hr emission limits for all fuel burning sources that use process gases when operating at their full utilization rates. These rates were modeled and attainment of the SO_2 NAAQS was demonstrated at the time of adoption of 326 IAC 7–4–14 as noted in 53 FR 34314 (September 6, 1988). The modeled rates were included as emission limits in the SIP. The conservative modeled scenario provides an adequate margin of safety to ensure than the attainment demonstration remains valid and protective of the NAAQS. The modeled emission rates for the combustion units remain unchanged and are not affected by the SIP revision. Therefore, the revision does not interfere with protection of the NAAQS. The other commenter added the statement that the limits established to support compliance of the NAAQS are applicable regardless of the sulfur content in the fuel used.

Response: The SIP revision request removes an emission limit which is directly linked to the sulfur content of the blast furnace gas generated and used at ArcelorMittal. The sulfur content of the blast furnace gas is directly linked to the facility's compliance with its remaining lb/hr SIP emission limits, because the emissions from many of those units correspond directly to the sulfur content of the blast furnace gas and coke oven gas which are allowed to be used together as fuel. The state has not demonstrated how ArcelorMittal will continue to meet and demonstrate continuous compliance with these limits if blast furnace gas is no longer assured of meeting a sulfur content of 0.07 lb/mmBtu. The state has not limited or quantified the expected increase in blast furnace gas sulfur content under the revised SIP. The existing SIP does not require the sulfur content of blast furnace gas to be analyzed for compliance purposes. The facility's sampling and analysis plan under 326 IAC 7–4–14(1)(F) would allow ArcelorMittal to calculate its combustion unit SO_2 emissions by assuming that its blast furnace gas sulfur content is 0.07 lb/mmBtu, even though the SIP would no longer require the gas to meet that limit at any combustion unit. The state has not shown that 0.07 lb/mmBtu will continue to be a representative SO_2 emission factor for ArcelorMittal's blast furnace gas. The compliance requirements for the combustion units have not been revised. The state has not provided a basis for EPA to conclude that the revised SIP will have no effect on the operation of the combustion sources or on the facility's need to flare excess fuel gases. Therefore, the state has not demonstrated that relaxing ArcelorMittal's SIP will satisfy the requirements of CAA section 110(l).

Comment: The commenter disagrees that actual flaring data is needed for the SIP revision. Actual flaring events reflect something other than the worst-case operating scenario for blast furnace gas combustion and are therefore irrelevant for establishing attainment and maintenance of the NAAQS.

Response: As the commenter states, actual flaring data is not in itself a requirement for SIP approval. The state's arguments for removing the flare limit hinge on the concept that the facility intends to and is able to use all of its process gas in its combustion units, minimizing flare usage, and that flare usage events correspond to overall facility emissions below the SIP allowable levels. EPA's proposed disapproval simply pointed out that no historical flaring data was provided.

III. What action is EPA taking?

EPA is disapproving Indiana's December 10, 2009, submittal requesting a SIP revision to remove the SO_2 emission limit on the blast furnace gas flare at ArcelorMittal Burns Harbor in Porter County. The commenters on the proposed disapproval contend primarily that the facility's blast furnace gas flare does not need an emission limit in order to maintain the NAAQS. The comments did not demonstrate that the revised SIP satisfactorily addresses the results of removing an emission limit that had had the effect of requiring the facility to maintain a specific sulfur content in its blast furnace gas. Nor did other information in the record provide a basis to conclude that this SIP revision satisfies the requirements of CAA section 110(l). Accordingly, EPA is disapproving the submittal.

IV. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

This site-specific action is exempt from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

This action merely disapproves state law as not meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, I certify that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

Because this rule disapproves pre-existing requirements under state law

and does not impose any additional enforceable duty beyond that required by state law, it does not contain an unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely disapproves a state rule, and does not alter the relationship or the distribution of power and responsibilities established in the CAA.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (59 FR 22951, November 9, 2000).

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This SIP disapproval under section 110 will not in-and-of itself create any new rules but simply disapproves a state rule proposed for inclusion into the SIP.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a "significant regulatory action" under Executive Order 12866 or a "significant energy action," this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

In reviewing state submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a state submission, to use VCS in place of a state submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this action. In reviewing SIP submissions, EPA's role is to approve or disapprove state choices, based on the criteria of the CAA. Accordingly, this action merely disapproves certain state requirements for inclusion into the SIP under section 110 and will not in-and-of itself create any new requirements. Accordingly, it does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. section 804(2).

Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 25, 2014. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: December 12, 2013.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52–APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 52.781 is amended by adding paragraph (h) to read as follows:

§ 52.781 Rules and regulations.

* * * * *

(h) *Disapproval.* EPA is disapproving the December 10, 2009 submittal of 326 IAC 7–4–14 as a revision to the Indiana SIP.

[FR Doc. 2013–30885 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2012–0453; FRL–9904–35–Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Volatile Organic Compound Emission Control Measures for Industrial Solvent Cleaning for Northwest Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a request from the Indiana Department of Environmental Management to revise its volatile organic compound state implementation plan (SIP) for industrial solvent cleaning rule for manufacturers of coatings, inks, adhesives, and resins. These revisions are approvable because they are consistent with EPA's Industrial Solvent Cleaning Control Technique Guidelines document and therefore satisfy the reasonable available control technology requirements of the Clean Air Act. EPA proposed to approve these revisions on September 10, 2013, and did not receive any comments.

DATES: This final rule is effective on January 27, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2012–0453. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Anthony Maietta, Environmental Protection Specialist, at (312) 353–8777 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Environmental Protection Specialist, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 252–8777, *maietta.anthony@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is the background for the action?

On September 10, 2013, EPA proposed to approve rule revisions contained in a May 29, 2012, submittal from IDEM into the **Federal Register** (78 FR 55234). The submittal requested that EPA approve a revision to the Indiana SIP regarding the industrial solvent cleaning rule for manufacturers of coatings, inks, adhesives, and resins. EPA received no comments on the proposed action.

II. What action is EPA taking?

EPA is approving revisions to Title 326, Article 8, Rule 17 of the Indiana Administrative Code (IAC) as submitted to EPA on May 29, 2012. Specifically, EPA is approving revisions to 326 IAC 8–17–2, 326 IAC 8–17–4, and 326 IAC 8–17–7.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 25, 2014. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule

or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 6, 2013.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.770 the table in paragraph (c) is amended by adding a new entry in "Article 8. Volatile Organic Compound Rules" for "Rule 17. Industrial Solvent Cleaning Operations" in numerical order to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED INDIANA REGULATIONS

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
*	*	*	*	*
Article 8. Volatile Organic Compound Rules				
*	*	*	*	*
Rule 17. Industrial Solvent Cleaning Operations				
8–17–1	Applicability	1/2/2010	2/24/2010, 75 FR 8246	
8–17–2	Exemptions	5/3/2012	12/27/2013, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
8–17–3	"Composite partial vapor pressure" defined.	1/2/2010	2/24/2010, 75 FR 8246	
8–17–4	VOC emissions control requirements.	5/3/2012	12/27/2013, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
8–17–5	Compliance dates	1/2/2010	2/24/2010, 75 FR 8246	
8–17–6	Compliance test methods	1/2/2010	2/24/2010, 75 FR 8246	
8–17–7	Monitoring and recordkeeping	5/3/2012	12/27/2013, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
8–17–8	Reporting requirements for monitoring and recordkeeping information.	1/2/2010	2/24/2010, 75 FR 8246	
8–17–9	Requirements on compliance certification.	1/2/2010	2/24/2010, 75 FR 8246	
8–17–10	Recordkeeping requirements for exempt sources.	1/2/2010	2/24/2010, 75 FR 8246	
*	*	*	*	*

[FR Doc. 2013–30543 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0286; FRL–9904–30]

Copper Sulfate Pentahydrate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of copper sulfate pentahydrate when applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment at a maximum level in the end use concentration of 80 parts per million (ppm). Toxcel on behalf of OhSo Clean, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of copper sulfate pentahydrate.

DATES: This regulation is effective December 27, 2013. Objections and requests for hearings must be received on or before February 25, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0286, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review

the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0286 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 25, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0286, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of July 19, 2013 (78 FR 43115) (FRL–9392–9), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8116) by Toxcel, P.O. Box 363, 7140 Heritage Village Plaza, Gainesville, VA 20156, on behalf of OhSo Clean, Inc., 315 Pacific Ave., San Francisco, CA 94111. The petition requested that 40 CFR 180.940 be amended by establishing an exemption from the requirement of a tolerance for residues of copper sulfate pentahydrate (Chemical Abstracts Service Registry Number (CAS Reg. No.) 7758–99–8) when used as an inert ingredient (emulsion stabilizer) in antimicrobial pesticide formulations (food contact surface sanitizing solutions) not to exceed 80 ppm. That document referenced a summary of the petition prepared by Toxcel LLC., 7140 Heritage Village Plaza, Gainesville, VA 20155, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply non-toxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. To determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the

requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for copper sulfate pentahydrate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with copper sulfate pentahydrate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by copper sulfate pentahydrate, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies, are discussed in the final rule published in the **Federal Register** of August 11, 2006 (71 FR 46106) (FRL–8085–3).

Copper is ubiquitous in nature and is a necessary nutritional element for both animals (including humans) and plants. Copper is found naturally in the food we eat including fruits, vegetables, meats, and seafood. It is found in the water we drink, the air we breathe and in our bodies themselves. Some of the environmental copper is due to direct modification of the environment by humans such as mining and smelting of the natural ore. It is one of the elements found essential to life. The National Academy of Science establishes recommended daily allowances (RDAs) of vitamins and minerals for the diet. The RDA for copper ranges from approximately 400 micrograms per day (µg/d) in young children to 900 µg/d in adults. Additionally, over the counter dietary supplements containing copper at level ranging from 0.33 milligram (mg) to 3 mg are available for individuals with low levels of copper. The copper ion is present in the adult human body with nearly two-thirds of the body copper content located in the skeleton and muscle. The liver is the primary organ for the maintenance of plasma copper concentrations.

The 2006 Reregistration Eligibility Decision for copper compounds reviewed and summarized all toxicity studies submitted for copper and has determined that the toxicological database is sufficient to assess the hazard from pesticides containing copper. Copper generally has moderate to low acute toxicity based on acute oral, dermal, and inhalation studies in animals. However, copper sulfate pentahydrate specifically has a been classified as moderate for acute oral toxicity, low for acute dermal toxicity and dermal irritation, and high for primary eye irritation. All effects resulting from acute exposure to copper-containing pesticides are due to acute body responses to minimize excessive absorption or exposure to copper. Current available data in animals do not show any evidence of upper limit toxicity level that warrant determining acute toxicity endpoints.

Based on available data summarized in the 2006 Reregistration Eligibility Decision for Coppers, there is no evidence of any dietary, oral, and dermal or inhalation adverse effects warranting quantitative assessment of sub-chronic or chronic risk. Available short-term feeding studies with rats and mice indicate decreased food and water intake with increasing oral concentrations of copper. Irritation of the stomach was seen at higher copper concentrations. Longer-term feeding studies indicate decreased feed intake with reductions in body weight gains, and increased copper concentration of the liver. Available reproductive and developmental studies by the oral route of exposure generally indicate that the main concern in animals for reproductive and teratogenic effects of copper has usually been associated with the deficiency rather than the excess of copper.

Oral ingestion of excessive amounts of the copper ion from pesticidal uses including the proposed use is unlikely. Copper compounds are irritating to the gastric mucosa. Ingestion of large amounts of copper results in prompt emesis. This protective reflex reduces the amount of copper ion available for absorption into the human body. Additionally, at high levels humans are also sensitive to the taste of copper. Because of this organoleptic property, oral ingestion would also serve to limit high doses.

Only a small percentage of ingested copper is absorbed, and most of the absorbed copper is excreted. The human body appears to have efficient mechanisms in place to regulate total body copper. The copper ion occurs naturally in food and the metabolism of copper is well understood.

Finally, sulfate has little toxic effect and is routinely used in medicine as a cathartic when combined with magnesium or sodium; the only adverse manifestations from this use being dehydration if water intake is concurrently limited.

B. Toxicological Points of Departure/ Levels of Concern

No endpoints of toxicological concern were identified for risk assessment purposes for copper sulfate pentahydrate. Copper sulfate pentahydrate readily hydrolyzes into the copper cation and the sulfate anion. Copper is a required essential nutritional element for both plants and animals. Indeed, current available data and literature studies indicate that there is a greater risk from the deficiency of copper intake than from excess intake. Copper also occurs naturally in a number of food items including fruits, meats, seafood, and vegetables. In humans, as part of the utilization of copper as an essential nutrient, there is an effective homeostatic mechanism that is involved in the dietary intake of copper and that protects humans from excess body copper. Given that copper is ubiquitous, is an essential nutrient, and is routinely consumed as part of the daily diet, exposure to copper as a result of the use of copper sulfate pentahydrate as a pesticide chemical would not be of toxicological concern. Further, the sulfate anion is also ubiquitous; it is the substrate in a number of normal human biosynthetic reactions. Following ingestion, sulfate is poorly absorbed via the gastrointestinal tract and is excreted in the urine. Other than a slight laxative effect at extremely high doses, sulfate has no known adverse toxic effects.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to copper sulfate pentahydrate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from copper sulfate pentahydrate in food as follows:

The main source of copper for infants, children, and adults, regardless of age, is the diet. Copper is typically present in mineral rich foods like chocolate, fruits (peaches and raisins), grains (wheat and rye), nuts (peanuts and pecans), and vegetables (potatoes and legumes (beans and peas)) in levels that range from 0.3 to 3.9 ppm. It is not likely that the approval of this petition

would significantly increase exposure over that of the existing levels of copper.

2. *Dietary exposure from drinking water.* Copper is a natural element found in the earth's crust. As a result, most of the world's surface water and ground water that is used for drinking purposes contains copper. The actual amount varies from region to region, depending on how much is present in the earth, but in almost all cases the amount of copper in water is extremely low. Naturally occurring copper in drinking water is safe for human consumption, even in rare instances where it is at levels high enough to impart a metallic taste to the water. Residues of copper in drinking water are regulated under the Safe Drinking Water Act. A Maximum Contaminant Level Goal of 1.3 ppm has been set by the Agency for copper. According to the National Research Council's Committee on Copper in Drinking Water, this level is "set at a concentration at which no known or expected adverse health effects occur and for which there is an adequate margin of safety." The Agency believes that this level of protection would not cause any potential health problems, i.e., stomach and intestinal distress, liver and kidney damage, and anemia. It is not likely that the approval of this petition would significantly increase exposure over that of the existing levels of copper.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., carpets; hard surface disinfection on walls, floors, and tables; swimming pools; and textiles (clothing and diapers)).

Residential (oral, dermal, and inhalation) exposure to copper sulfate pentahydrate from its use as an inert ingredient in food-contact surface sanitizing solutions for public eating places, dairy processing equipment, and food-processing equipment and utensils is possible. However, since there are no toxicological effects of concern identified in the available database, it is not necessary to conduct a quantitative assessment of residential (non-occupational) exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found copper sulfate pentahydrate to share a common mechanism of toxicity with any other substances, and copper sulfate pentahydrate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that copper sulfate pentahydrate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

FFDCA, as amended by the Food Quality Protection Act (FQPA), directs the Agency to use an additional 10X safety factor (SF), to account for potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes the Agency to modify the 10X FQPA SF only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children. Since copper is an essential trace element, with copper deficiency more common in humans than toxicity from the excess, a quantitative assessment using safety factors was not conducted for potential human health exposure to copper sulfate pentahydrate. For the same reason the 10X FQPA SF was not retained.

E. Aggregate Risks and Determination of Safety

Taking into consideration the information discussed on copper sulfate pentahydrate, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to copper sulfate pentahydrate under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.940(a) for residues of copper sulfate pentahydrate when used as an inert ingredient in pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a limit of 80 ppm is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of copper sulfate pentahydrate in or on any food commodities. EPA is establishing a limitation on the amount of copper sulfate pentahydrate that may be used in pesticide formulations.

The limitation is enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). EPA will not register any pesticide for sale or distribution that contains greater than 80 ppm of copper sulfate pentahydrate in the pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for copper sulfate pentahydrate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for copper sulfate pentahydrate (CAS Reg. No. 7758–99–8) when used in antimicrobial pesticide formulations applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end use concentration of 80 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is

not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 20, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.940, alphabetically add the following inert ingredient to the table in paragraph (a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide chemical	CAS reg. no.	Limits
* * * * * * *		
Copper sulfate pentahydrate	7758–99–8	When ready for use, the end-use concentration is not to exceed 80 ppm
* * * * * * *		

* * * * *

[FR Doc. 2013–31101 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0420; FRL–9903–92]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indoxacarb in or on multiple commodities and removes previously established commodities that will be superseded by tolerances established in this action, which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 27, 2013. Objections and requests for hearings must be received on or before February 25, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0420, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0420 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 25, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0420, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL–9353–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8029) by IR–4, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.564 be amended by establishing tolerances for residues of the insecticide indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3*H*)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3*H*)-carboxylate, in or on bean, dry, seed at 0.07 parts per million (ppm); bean, forage at 37 ppm; bean, succulent at 0.64 ppm; berry, low growing, except strawberry, subgroup 13–07H at 0.9 ppm; small fruit, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.0 ppm. The petition additionally requested to remove established tolerances of indoxacarb in or on grape at 2.0 ppm and cranberry at 0.90 ppm, upon approval of the updated crop groups or subgroups. That document referenced a summary of the petition prepared on behalf of IR–4 by DuPont Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised several proposed tolerances, has corrected the commodity terminology for bean forage to cowpea forage, and has determined that a tolerance should be established on cowpea hay. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue* * *."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for indoxacarb including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with indoxacarb follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Indoxacarb products are frequently formulated as a mixture of the insecticidally active S-enantiomer (DPX–KN128) and the insecticidally inactive R-enantiomer (DPX–MP062). DPX–MP062 is an formula mixture containing the indoxacarb S-enantiomer and its R-enantiomer at approximately a 75:25 ratio. DPX–JW062 is the racemic mixture of the enantiomers at a 50:50 ratio. EPA has determined that it is appropriate to use data from DPX–

JW062 (50:50) to satisfy the requirements for dietary subchronic, chronic, oncogenicity and reproductive studies and that toxicology data using DPX–JW062 and DPX–MP062 may be bridged to DPX–KN128 formulations.

The toxicity profile for KN128, MP062, and JW062 in rats, mice, and dogs with both subchronic and chronic oral exposures were qualitatively similar. Dermal subchronic exposure in the rat also resulted in a similar profile. Signs of toxicity occurred at similar doses and with a similar magnitude of response (females generally being more sensitive than males), and included decreases in body weight, weight gain, food consumption, and food efficiency. These compounds also affected the hematopoietic system by decreasing the red blood cell count, hemoglobin, and hematocrit in rats, dogs, and mice. Exposure to indoxacarb was frequently accompanied by an increase in reticulocytes in all three species and an increase in Heinz bodies in dogs and mice only. These signs of toxicity did not appear to increase in severity over time.

Neurotoxicity was observed in rats and mice, and was characterized by one or more of the following symptoms in both male and female rats and mice: Weakness, head tilting, and abnormal gait or mobility with inability to stand or ataxia. There was possible evidence of lung damage in the acute inhalation studies with both MP062 and JW062.

The immunotoxicity study in mice did not indicate toxicity to the immune system at the highest dose tested. In the 28-day inhalation study in rats, increased spleen weights, pigmentation, and hematopoiesis in the spleen, and hematological changes were observed at the highest dose tested. Increased spleen weights were also observed in the 28-day dermal rat study. The increase in spleen weights are not considered immunological in origin but can be considered a result of the hemolytic effects, which is the mode of action of indoxacarb.

There was no evidence of carcinogenicity in either the rat or mouse in acceptable studies (JW062). JW062 was not mutagenic in a complete battery of mutagenicity studies. There was also no evidence of mutagenicity with either KN128 or MP062. Therefore, all formulations (KN128, MP062, and JW062) were classified as not likely to be carcinogenic in humans by all relevant routes of exposure.

Specific information on the studies received and the nature of the adverse effects caused by indoxacarb as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document: "Indoxacarb. Human Health Risk Assessment for the Proposed New Use on Dry Beans, Succulent Beans, Small Fruit Vine Climbing Subgroup (except kiwifruit) 13–07F and Low Growing Berry Subgroup (except strawberry) 13–07H" at pp. 50–55 in docket ID number EPA–HQ–OPP–2012–0420.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for indoxacarb used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR INDOXACARB FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children and females 13–49 years old).	NOAEL = 12 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Acute RfD = 0.12 mg/kg/day. aPAD = 0.12 mg/kg/day	Acute oral rat neurotoxicity study. LOAEL = 50 mg/kg based on decreased body weight and body-weight gain in females (MP062).*
Chronic dietary (All populations)	NOAEL= 2.0 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.02 mg/kg/day. cPAD = 0.02 mg/kg/day	Weight of evidence approach was used from four studies: 1. Subchronic toxicity study—rat (MP062). 2. Subchronic neurotoxicity study—rat (MP062). 3. Chronic/carcinogenicity study—rat (JW062). 4. 2-generation rat reproduction study (JW062). LOAEL = 3.3 mg/kg/day based on decreased body weight, body-weight gain, food consumption, and food efficiency; decreased hematocrit, hemoglobin, and red blood cells only at 6 months.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR INDOXACARB FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days), intermediate-term (1 to 6 months), and long-term (> 6 months).	NOAEL= 2.0 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Weight of evidence approach was used from four studies: 1. Subchronic toxicity study—rat (MP062). 2. Subchronic neurotoxicity study—rat (MP062). 3. Chronic/carcinogenicity study—rat (JW062). 4. Two generation rat reproduction study (JW062). LOAEL = 3.3 mg/kg/day based on decreased body weight, body-weight gain, food consumption, and food efficiency; decreased hematocrit, hemoglobin and red blood cells only at 6 months.
Inhalation short-term (1 to 30 days).	Inhalation study NOAEL= 6 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-day rat inhalation toxicity study (MP062). The LOAEL of 75.69 mg/kg/day is based on increased spleen weights, pigmentation, and hematopoiesis in the spleen, hematological changes and mortality (females).
Cancer (Oral, dermal, inhalation).	"Not likely" to be carcinogenic to humans since no evidence of carcinogenicity in either the rat or mouse studies, and no evidence of mutagenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

*The LOAEL of 50 mg/kg was based on a 7% body weight decrease in females only on day 8. No significant differences were noted for days 1, 2, or 15. Currently, a 10% decrease in adult body weight is the threshold for an adverse effect, thus this study NOAEL is considered to be conservative.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to indoxacarb, EPA considered exposure under the petitioned-for tolerances as well as all existing indoxacarb tolerances in 40 CFR 180.564. EPA assessed dietary exposures from indoxacarb in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for indoxacarb. In estimating acute dietary exposure, EPA utilized Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) from 2003 to 2008. Anticipated residues (ARs) for most registered and proposed food commodities were based on field trial data, and in some crops tolerance-level residues were used. Residue estimates for some current uses were further refined using percent crop treated (PCT) data, and 100 PCT estimates were assumed for the remaining uses.

Available processing data for indoxacarb were used to refine ARs for apples/pears (juice), cotton (oil), grapes (raisin and juice), peanut (oil), potato (dry, chips), prunes (dried), mint (oil), soybean (oil), and tomato (paste and puree), and other commodities where translation was applicable. DEEM-FCID™ (ver. 7.81) default processing factors were assumed for all other processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the same assumptions as described in Unit III.C.1.i.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that indoxacarb does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.*

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows for the acute dietary assessment: Apples, 10%; broccoli, 70%; cabbage, 35%; cauliflower, 60%; cherries, 2.5%;

lettuce, 40%; peaches, 2.5%; peanuts, 10%; pears, 2.5%; potatoes, 2.5%; soybeans, 2.5%; spinach, 5%; sweet corn, 10%; and tomatoes, 40%.

The Agency estimated the PCT for existing uses as follows for the chronic dietary risk assessment: Apples, 5%; broccoli, 50%; cabbage, 25%; cauliflower, 40%; celery, 5%; cherries, 1%; grapes, 1%; lettuce, 10%; peaches, 2.5%; peanuts, 2.5%; pears, 1%; potatoes, 1%; soybeans, 1%; spinach, 2.5%; sweet corn, 2.5%; and tomatoes, 20%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. In cases where the average PCT is less than 2.5, 2.5% is used as the average PCT. Similarly, in cases where the maximum PCT is less than 2.5, 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which indoxacarb may be applied in a particular area.

2. *Dietary exposure from drinking water.* A Total Toxic Residue (TTR) approach was used for the parent indoxacarb and the degradation products with toxicological concern (IN–JT333, IN–KG4333, IN–KT413, IN–ML437–0H) for the drinking water assessment. Therefore, the Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for indoxacarb and its metabolites in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of indoxacarb. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Provisional Cranberry Model and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of indoxacarb and its metabolites for surface water are expected to be 59.26 parts per billion (ppb) for acute exposures and 18.48 for chronic exposures. For ground water, the EDWC is estimated to be 0.33 ppb for acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration values of 59.26 ppb and 18.48 ppb were used to assess the contribution to drinking water for the acute and chronic dietary risk assessments, respectively.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Indoxacarb is currently registered for several uses that could result in residential exposures:

- Ready-to-use (RTU) bait stations.
- Spot-on applications of gels (crack and crevices and indoor spot directed treatments) for household insect control (indoor treatments).
- Spot-on treatments for the control of fleas and ticks on dogs and cats.
- Broadcast, perimeter and ant mound treatment on ornamentals, trees, and lawns/turf, utilizing granular and liquid formulations (outdoor treatments).
- Indoor spray applications with granular and liquid formulations for insect control on households/domestic dwellings (crack and crevice and spot directed treatments).

Adult handlers were assessed for potential short-term inhalation toxicity from mixing/loading/applying the following:

- Granular formulation for insect control on lawns/turf.
- Liquid flowable formulation for insect control on lawns/turf.
- Water-soluble packaging formulation for indoor spray applications with manually pressurized hand wand (crack and crevice and spot directed treatments) for insect control in households/domestic dwellings.
- Liquid flowable formulation for indoor spray applications with manually pressurized hand wand (crack and crevice and spot directed treatments) for insect control on households/domestic dwellings.

Residential handler exposure is expected to be short-term in duration only, as intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.

Potential postapplication exposures to indoxacarb were considered for adults and children (1–<2 years old), based on the following scenarios:

- Treated pets (dogs and cats) to children from short-, intermediate-, and long-term incidental oral exposures.
- Physical activities on turf to children from short-term incidental oral exposures.
- Crack and crevice and indoor spot-directed spray applications, including short-term inhalation exposures to adults and both short-term inhalation and short-term incidental oral exposures to children.

Since there is no expectation of non-dietary oral exposures to adults from contact with treated pets, that aggregate risk is not quantified.

Since inhalation and incidental oral exposure routes share a common toxicological endpoint (i.e., hematological changes), risk estimates have been combined for those routes. Therefore, the postapplication exposure scenarios that were combined for children 1 < 2 years old are the inhalation and hand-to-mouth (the highest incidental oral exposure assessment) for the indoor surfaces directed spray applications. This combination is considered protective of children's exposure to indoxacarb from residential uses.

Because of the preventative nature of pet products and the potential for extended use in more temperate parts of the country, the residential

postapplication exposures to treated pets may be short-, intermediate-, or long-term in duration. Postapplication incidental oral exposures from treated golf courses were not quantified since youth old enough to play golf are not expected to exhibit significant hand-to-mouth behavior. Furthermore, the residential lawn assessment provides the highest estimate of potential exposure from turf applications and is protective of any exposures to children from indoxacarb turf treatment scenarios. Finally, the residential handler and postapplication assessments consider inhalation and/or oral exposures only, since a dermal toxicity endpoint has not been identified for indoxacarb.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found indoxacarb, an oxadiazine class insecticide, to share a common mechanism of toxicity with any other substances, and indoxacarb does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that indoxacarb does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no quantitative or qualitative evidence of increased prenatal or postnatal sensitivity in the two developmental toxicity studies in rats with DPX–JW062, one developmental toxicity study in rats with DPX–MP062 and DPX–KN128, one developmental toxicity study in rabbits with DPX–JW062, one 2-generation reproduction studies in rats with DPX–JW062, and the developmental neurotoxicity (DNT) study in rats with DPX–KN128. In these studies, developmental toxicity was observed only in the presence of maternal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for indoxacarb is complete.

ii. EPA has determined that an additional uncertainty factor is not needed to account for neurotoxicity. Neurotoxicity was seen in animal studies in rats and mice, but at higher doses than the hematologic effects on which EPA's risk assessments are based. To evaluate the potential for increased sensitivity of infants and children to neurotoxic effects, EPA required a rat developmental neurotoxicity (DNT) study. There was no evidence of increased sensitivity of offspring in the submitted study. Clinical observations, motor activity, acoustic startle habituation, and learning and memory testing were all comparable between the control and treated groups. Mean brain weight, gross and microscopic examinations, and morphometric measurements of the brain were also comparable between the controls and treated groups.

iii. There is no evidence that indoxacarb results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessments utilized anticipated residues that are based on reliable field trial, as well as PCT data. For the new uses, a conservative estimate of 100 PCT is assumed. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to indoxacarb in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by indoxacarb.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to indoxacarb will occupy 49% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to indoxacarb from food and water will utilize 12% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Long-term (chronic) aggregate risk for indoxacarb also includes the contribution from dietary (food and drinking water) exposure plus the long-term postapplication exposure to treated pets. EPA has concluded the combined long-term food, water, and residential exposures result in an aggregate MOE of 420 for children 1-<2 years old. Because EPA's level of concern for indoxacarb is a MOE of 100 or below, this MOE is not of concern.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Indoxacarb is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to indoxacarb.

Using the exposure assumptions described in this unit for short-term

exposures, EPA has concluded the aggregate short-term exposure (food, water, and residential exposures) result in the lowest aggregate MOEs of 110 for children 1-<2 years old (resulting from the postapplication crack and crevice and spot directed treatment indoor spray) and 1,600 for adults (resulting from the handler turf use). Because EPA's level of concern for indoxacarb is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Indoxacarb is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to indoxacarb.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures (from pet treatments) result in an aggregate MOE of 420 for children 1-<2 years old Because EPA's level of concern for indoxacarb is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, indoxacarb is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to indoxacarb residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)/column switching/ultraviolet (UV) method AMR 2712–93 with confirmation/specificity provided by gas chromatography (GC)/mass-selective detector method AMR 3493–95, Supplement No. 4) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for indoxacarb in or on cranberries at 1 ppm, dry chickpea at 0.2 ppm, dry cowpea at 0.1 ppm, dry mung bean at 0.2 ppm, and grapes at 2 ppm, based on measurement of indoxacarb and its R-enantiomer. U.S. tolerances for subgroup 13–07F (represented by grape) at 2 ppm and subgroup 13–07H (represented by cranberry) at 1 ppm are harmonized with the corresponding Codex MRLs. Additionally, the U.S. tolerance level for dry bean is being established at 0.2 ppm, in order to harmonize with the Codex MRLs for dry chickpea and dry mung bean. The Codex has not established MRLs for the other commodities associated with this action.

C. Revisions to Petitioned-For Tolerances

Based on the data submitted with the petition, EPA revised the proposed tolerances for several commodities, as follows: Succulent bean from 0.64 ppm to 0.9 ppm; and low growing berry, except strawberry, subgroup 13–07H from 0.9 ppm to 1 ppm. EPA also determined that the proposed tolerance in or on bean forage at 37 ppm should be revised to 50 ppm, and the Agency determined that the commodity should be listed as cowpea forage because the cowpea forage and hay are the only significant feedstuffs associated with dry beans. Because of that reason, EPA also determined that a tolerance is necessary for cowpea hay at 100 ppm. Finally, EPA revised the tolerance on bean, dry, seed from 0.07 ppm to 0.2 ppm in order to harmonize with Codex MRLs. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization of Economic Cooperation and Development (OECD) tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3*H*)-carboxylate, in or on bean, dry seed at 0.2 ppm; bean, succulent at 0.9 ppm; cowpea, forage at 50 ppm; cowpea, hay at 100 ppm; berry, low growing, except strawberry, subgroup 13–07H at 1 ppm; and fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2 ppm. This regulation additionally removes the established tolerances in or on cranberry at 0.90 ppm and grape at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule,

the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 16, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.564:

■ a. Remove the commodities "Cranberry" and "Grape" in the table in paragraph (a)(1).

■ b. Add alphabetically the following commodities to the table in paragraph (a)(1). The amendments read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Bean, dry, seed	0.2
Bean, succulent	0.9
* * * * *	
Berry, low growing, except strawberry, subgroup 13–07H	1
* * * * *	
Cowpea, forage	50
Cowpea, hay	100
* * * * *	
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	2
* * * * *	

* * * * *

[FR Doc. 2013–30585 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0071; FRL–9904–04]

Pendimethalin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the current tolerance for combined residues of pendimethalin and its metabolite, expressed as pendimethalin equivalents in or on almond, hulls. BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709 requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 27, 2013. Objections and requests for hearings must be received on or before February 25, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0071, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0071 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 25, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0071, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL–9380–2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8133) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.361 be amended by establishing a tolerance for the combined residues of the herbicide pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6- dinitrobenzenamine, and its 3,5-dinitrobenzyl alcohol metabolite (CL202347), in or on almond, hulls at 6.0 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pendimethalin - including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pendimethalin follows.

The toxicity database for pendimethalin is complete. On August 29, 2012, the Agency published a final rule (77 FR 52240) (FRL–9360–5) establishing tolerances for combined residues of pendimethalin and its metabolite in or on various commodities. In the risk assessment supporting that action, EPA assessed the toxicity of pendimethalin. Since that assessment, EPA's hazard characterization of pendimethalin has not changed, and no additional data were needed to assess an increase in the tolerance of pendimethalin on almond hulls (see "Pendimethalin: Human Health Risk Assessment to Support an Amended Use on Almonds"; in docket ID number EPA–HQ–OPP–2013–0071).

In the 2012 assessment, EPA assessed the dietary risk from residues of pendimethalin on almond hulls, which are an animal feed item. Based on that assessment, EPA concluded that there is no reasonable expectation of finite residues in meat, milk, poultry, and eggs. Because EPA expects residues of pendimethalin on almond hulls to be higher under this revised tolerance, EPA recalculated the ruminant reasonable dietary burden with the new tolerance levels for almond hulls and concluded that there would be no increase in the ruminant dietary burden. Furthermore, the increase in tolerance on almond hulls will not impact the residential exposure and risk assessments that the Agency conducted in 2012. As there is no change to the residential and dietary risk assessments, a new aggregated risk assessment was not needed.

Therefore, based on the findings of the 2013 risk assessment and the 2012 final rule and risk assessment, the Agency concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to pendimethalin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

PAM Volume II lists four Gas Chromatography/Electron Capture Detector (GC/ECD), methods for the determination of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite in plant commodities. Methods I and III determine residues of the parent, whereas Methods II and IV determine residues of the 3,5-dinitrobenzyl alcohol metabolite.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for almond hulls for pendimethalin.

C. Revisions to Petitioned-For Tolerances

Although the petitioner requested that EPA establish a new tolerance for residues of pendimethalin on almond hulls, there is already a tolerance for almond hulls at 0.4 ppm. Therefore, EPA is simply revising that existing tolerance, rather than establishing a new tolerance.

V. Conclusion

Therefore, 40 CFR 180.361 is amended by revising the established tolerance for the combined residues of the herbicide pendimethalin and its metabolite, in or on almond, hulls from 0.4 ppm to 6.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule modifies a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 16, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.361, in the table in paragraph (a), revise the tolerance level for "Almond, hulls" to read as follows:

§ 180.361 Pendimethalin; tolerances for residues.(a) * * *

Commodity	Parts per million
* * * * *	
Almond, hulls	6.0
* * * * *	

* * * * *

[FR Doc. 2013–30575 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0509; FRL–9903–53]

Isopyrazam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isopyrazam in or on apple and peanut for which there are no accompanying United States registrations. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 27, 2013. Objections and requests for hearings must be received on or before February 25, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0509, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0509 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 25, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0509, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 28, 2012 (77 FR 59578) (FRL–9364–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8039) by Syngenta Crop Protection, Inc., 410 Swing Rd., P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.654 be amended by establishing tolerances for residues of the fungicide isopyrazam, in or on apple at 0.6 parts per million (ppm) and peanut at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition EPA has proposed a higher tolerance level for apple. The reason for this change is explained in Unit IV.D.

There are no registered food uses for isopyrazam in the United States. These tolerances were requested in connection with use of isopyrazam on apples and peanuts grown outside the United States. These tolerances will allow apples and peanuts containing isopyrazam residues to be imported into the United States.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for isopyrazam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isopyrazam follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Subchronic and chronic oral toxicity studies in the rat, mouse, and dog demonstrate that the primary target organ for isopyrazam is the liver (increased organ weight and centrilobular hepatocyte hypertrophy). Liver toxicity is usually accompanied by reductions in bodyweight and food consumption.

Isopyrazam did not cause reproductive toxicity. Effects seen in the offspring (bodyweight gain during lactation and increase liver weight at weaning) in the rat reproduction study

occurred at the same doses that cause general toxicity in the parents. Developmental effects described as small eyes and/or microphthalmia were observed in both the Himalayan and New Zealand rabbit strains. However, in the Himalayan strain, the intraocular abnormalities occur in the absence of maternal toxicity while in the New Zealand the ocular abnormalities occurred at doses that were maternally toxic. Developmental effects observed in the rat (increased post-implantation loss, reduced fetal weight and a slight retardation of ossification) occurred at doses that also produced maternal toxicity (mortality, decreased body weights, body weight gains, and food consumption).

No evidence of specific neurotoxicity was seen in acute and subchronic oral neurotoxicity studies in rats. Clinical signs seen in two subchronic dog studies (side-to-side head wobble, ataxia, reduced stability) are consistent with neurotoxic effects. However detailed and specific neuropathological analyses were not conducted for the dog studies (i.e., functional observational battery, motor activity, detailed histopathology with special stains). Consequently, there is uncertainty regarding whether the effects seen in the dog studies are in fact signs of neurotoxicity. However, clear no observed adverse effect levels (NOAELs)/lowest adverse effect levels (LOAELs) were established for both subchronic dog studies. The point of departure selected for the acute dietary assessment is based on clinical signs seen on day 2 in one of four males in the subchronic dog study. This study provides the lowest NOAEL in the database (most sensitive endpoint) for a single dose effect. The dose used for the chronic dietary risk assessment is eight times lower than the dose at which clinical effects were seen at four weeks in the second subchronic dog study.

There is no evidence of immunotoxicity based on a 28-day dietary immunotoxicity study in rats. The LOAEL for immunotoxicity was not identified and the NOAEL for immunotoxicity was 1,356 milligrams/kilograms (mg/kg).

Isopyrazam is classified as "Likely to be Carcinogenic to Humans" based on increased incidence of uterine endometrial adenocarcinomas and liver hepatocellular adenomas in female rats and increased incidence of thyroid follicular cell adenomas and/or carcinomas in male rats. Isopyrazam is not carcinogenic in the mouse. There is no evidence of genotoxicity, mutagenicity, or clastogenicity in the *in vivo* and *in vitro* studies. There are no structural relationships with other known carcinogens. A linear low-dose approach (Q_1*) was used to extrapolate experimental animal tumor data for the quantification of human cancer risk.

Isopyrazam is of low acute toxicity by the oral, dermal, and inhalation routes and is not a skin or eye irritant.

Specific information on the studies received and the nature of the adverse effects caused by isopyrazam as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document "Human Health Risk Assessment for the Establishment of Tolerances with No U.S. Registrations for Isopyrazam in/on Imported Apple and Peanut" at pp. 14–18 in docket ID number EPA–HQ–OPP–2012–0509.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*. A summary of the toxicological endpoints for used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ISOPYRAZAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure (mg/kg/day)	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment (mg/kg/day)	Study and toxicological effects
Acute Dietary (All populations)	NOAEL= 30	UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.30 aPAD = 0.30	Subchronic Toxicity—Dog. LOAEL = 100 mg/kg/day based on clinical signs (side-to-side head wobble) in male dogs.
Chronic Dietary (All populations).	NOAEL = 5.5	UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.055. cPAD = 0.055	Chronic Toxicity/Carcinogenicity—Rats. LOAEL = 27.6 mg/kg/day based on decreased body weight and body weight gain in females; increased incidences of hepatocellular hypertrophy, pigment in centrilobular hepatocytes, eosinophilic foci of altered hepatocytes, vacuolation of centrilobular hepatocytes, bile duct hyperplasia, and bile duct fibrosis in both sexes; and brown pigment in the kidney in females.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ISOPYRAZAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure (mg/kg/day)	Uncertainty/ FQPA safety factors	RfD, PAD, level of concern for risk assessment (mg/kg/day)	Study and toxicological effects
Cancer (All routes)	Classification: CARC classified isopyrazam as "Likely to be Carcinogenic to Humans" based on increased liver and uterine endometrial epithelial tumors in female rats and increased thyroid follicular cell tumors in male rats. A cancer slope factor (Q_1^*) of 0.00629 (mg/kg/day)$^{-1}$ was calculated based on an increase in increase in liver tumors in female rats.			

CARC = Cancer Assessment Review Committee. Food Quality Protection Act Safety Factor = FQPA SF. LOAEL = lowest observed adverse effect level. mg/kg/day = milligram/kilogram/day. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). Point of Departure = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. Q_1^* = Linear low-dose approach. RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isopyrazam, EPA considered exposure under the petitioned-for tolerances as well as all existing isopyrazam tolerances in 40 CFR 180.654. EPA assessed dietary exposures from isopyrazam in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, maximum residues of isopyrazam (as the sum of its *syn*-isomer and *anti*-isomer) plus its tertiary alcohol metabolite (CSCD460260; as the sum of its *syn*-isomer (CSCD459488; free and conjugated) and *anti*-isomer (CSCD459489; free and conjugated)) from field trials reflecting maximum use rates and 100 percent crop treated (PCT) assumptions were used. Dietary Exposure Evaluation Model (DEEM) default processing factors were used for all processed commodities including dried apple (8.0), apple juice/cider (1.3), dried banana/plantain (3.9), and peanut butter (1.89). In the absence of peanut processing data, the maximum theoretical concentration factor was used for peanut oil (2.8).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA used the same residue levels, processing factors and PCT assumptions as in the acute dietary exposure analysis.

iii. *Cancer.* Isopyrazam is classified as "Likely to be Carcinogenic to Humans" based on increased liver and uterine endometrial epithelial tumors in female rats and increased thyroid follicular cell tumors in male rats. In the absence of mode of action data, a linear low dose extrapolation for cancer risk assessment was used. A cancer slope factor (Q_1^*) of 0.00629 (mg/kg/day)$^{-1}$ was used for the quantification of human cancer risk. In evaluating cancer risk, EPA used the same residue levels, processing factors, and PCT assumptions as the acute and chronic dietary exposure analyses.

iv. *Anticipated residue and PCT information.* While EPA did not use PCT information in the dietary assessment for isopyrazam; anticipated residues were used. Maximum residues from field trials conducted at the maximum use rates were used to estimate residues of isopyrazam (as the sum of its *syn*-isomer and *anti*-isomer) plus its tertiary alcohol metabolite (CSCD460260; as the sum of its *syn*-isomer (CSCD459488; free and conjugated) and *anti*-isomer (CSCD459489; free and conjugated)). Analyses assumed 100 PCT and used DEEM default processing factors. In the absence of peanut processing data, the maximum theoretical concentration factor was used as a processing factor for peanut oil (2.8).

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* An assessment of residues in drinking water is not needed for isopyrazam because there is no drinking water exposure associated with the existing (banana) and proposed uses (apple and peanut) which are all non-domestic.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Isopyrazam is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found isopyrazam to share a common mechanism of toxicity with any other substances, and isopyrazam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isopyrazam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate

the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no residual uncertainties for pre- and/or post natal susceptibility even though qualitative susceptibility was observed in the range-finding developmental studies in rabbits. Developmental effects (eye abnormalities) were observed in the absence of maternal toxicity in two range finding developmental toxicity studies in the Himalayan rabbit. However, the eye effects were only observed at relatively high doses (200–400 mg/kg/day) with clear NOAELs/LOAELs established for the developmental effects. Developmental effects observed in the rat (reduced fetal weight and a slight retardation of ossification) occurred only at doses that also produced maternal toxicity (mortality, decreased body weights, body weight gains, and food consumption). There was no evidence of increased susceptibility in a 2-generation reproduction study following pre- or postnatal exposure to isopyrazam. There was also no evidence of neuropathology or abnormalities in the development of the fetal nervous system from the available toxicity studies conducted with isopyrazam. Clear NOAELs/LOAELs were established for the developmental effects observed in rats and rabbits as well as for the offspring effects (increased liver weights) seen in the 2-generation reproduction study and a dose-response relationship for the effects of concern is well characterized. The dose used for the acute dietary risk assessment (30 mg/kg/day), based on effects seen in the subchronic dog study, is protective of the developmental effects seen in rats (44.5 mg/kg/day) and rabbits (200 mg/kg/day). Based on these considerations, there are no residual uncertainties for pre- and/or postnatal susceptibility

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for isopyrazam is complete.

ii. As discussed in Unit III.D.2, there are no residual uncertainties for pre- and/or postnatal susceptibility and thus, it is unnecessary to retain the 10X FQPA SF to adequately protect infants and children.

iii. The dietary risk assessment is based on parent plus metabolite residues and will not underestimate dietary exposure to isopyrazam. For the acute, chronic and cancer dietary analyses, maximum residues of parent plus metabolite and 100 PCT assumptions were used for all treated commodities. There are no residual uncertainties identified in the exposure databases.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to isopyrazam will occupy 4.2% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isopyrazam from food will utilize 6.1% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Isopyrazam is not registered in the United States. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD, no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for isopyrazam.

4. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions discussed in this unit for cancer exposure, the cancer dietary risk estimate for the U.S. population is 2×10^{-6}.

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible. The precision that can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. For isopyrazam, EPA's exposure assessment assumes maximum residues of concern from field trials reflecting the maximum use rates, default processing factors, the maximum theoretical concentration for residues in peanut oil and 100 PCT, which is highly conservative. Accordingly, EPA has concluded the cancer risk from exposure to isopyrazam falls within the range of 1×10^{-6} and is thus negligible.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to isopyrazam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology.

Adequate enforcement methodology (Method GRM006.01B) is available to enforce the tolerance expression. The

method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs). MRLs established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

No Codex or MRLs have been established for residues of isopyrazam in or on apple or peanut commodities.

C. Response to Comments

EPA received a comment to the notice of filing which said that no residues of isopyrazam should be permitted on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by FFDCA section 408 states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

For the purposes of harmonization with a pending European Union MRL for residues of isopyrazam in or on pome fruit (0.7 mg/kg), EPA is establishing a tolerance of 0.70 ppm in or on apple in lieu of the 0.6 ppm as requested by the petitioner. This increase to the proposed tolerance is supported by the data reviewed for the petition. No changes were made to the proposed tolerance for peanut.

V. Conclusion

Therefore, tolerances are established for residues of isopyrazam in or on apple at 0.70 ppm and peanut at 0.01 ppm. The Agency is also revising the tolerance expression to clarify that determining compliance with the tolerance requires measuring both the *syn*-isomer and the *anti*-isomers of isopyrazam. This change is supported by the available enforcement method which sums the two isomers for the tolerance detection. The tolerance expression revision will not impact the current banana tolerance.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 19, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.654:

■ a. Revise the introductory text in paragraph (a).

■ b. Add alphabetically the commodities "Apple" and "Peanut" to the table in paragraph (a).

■ c. Revise footnote one to the table in paragraph (a).

The additions and revisions read as follows:

§ 180.654 Isopyrazam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide isopyrazam, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only isopyrazam (3-(difluoromethyl)-1-methyl-*N*-[1,2,3,4-tetrahydro-9-(1-methylethyl)-1;4-methano-naphthalen-5-yl]-1*H*-pyrazole-4-carboxamide), as the sum of its *syn*-isomer (3-(difluoromethyl)-1-methyl-*N*-[(1RS, 4SR, 9RS)-1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methanonaphthalen-5-yl]-1*H*-pyrazole-4-carboxamide) and *anti*-isomer (3-(difluoromethyl)-1-methyl-*N*-[(1RS, 4SR, 9SR)-1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methano-naphthalen-5-yl]-1*H*-pyrazole-4-carboxamide) in or on the commodity.

Commodity	Parts per million
Apple [1]	0.70
* * * * *	
Peanut [1]	0.01

[1] There are no U.S. registrations for use of isopyrazam on apple, banana, or peanut.

* * * * *

[FR Doc. 2013–30874 Filed 12–26–13; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0777; FRL–9904–15]

Extension of Tolerances for Emergency Exemptions (Multiple Chemicals)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in this document. These actions are in response to EPA's granting of emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. In addition, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

DATES: This regulation is effective December 27, 2013. Objections and requests for hearings must be received on or before February 25, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0777 is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0777 in the subject line on the first page of your submission. All requests must be in writing, and must be received by the Hearing Clerk on or before February 25, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0777 by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

EPA published final rules in the **Federal Register** for each chemical listed. The initial issuance of these final rules announced that EPA, on its own initiative, under FFDCA section 408, 21 U.S.C. 346a, was establishing time-limited tolerances.

EPA established the tolerances because FFDCA section 408(l)(6) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18 . Such tolerances can be established without providing notice or time for public comment.

EPA received requests to extend the use of these chemicals for this year's growing season. After having reviewed these submissions, EPA concurs that emergency conditions exist. EPA assessed the potential risks presented by residues for each chemical. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIRA section 18.

The data and other relevant material have been evaluated and discussed in the final rule originally published to support these uses. Based on that data and information considered, the Agency reaffirms that extension of these time-limited tolerances will continue to meet the requirements of FFDCA section 408(l)(6). Therefore, the time-limited tolerances are extended until the date listed. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on the date listed, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on the commodity after that date will not be unlawful, provided the residue is present as a result of an application or use of a pesticide at a time and in a manner that was lawful under FIFRA, the tolerance was in place at the time of the application, and the residue does not exceed the level that was authorized by the tolerance. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Tolerances for the use of the following pesticide chemicals on specific commodities are being extended:

Fenoxaprop-ethyl. EPA has authorized under FIFRA section 18 the use of fenoxaprop-ethyl on grasses grown for seed for control of grassy weeds in Oregon. This regulation extends the time-limited tolerances for residues of the herbicide fenoxaprop-ethyl, (±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate, and its metabolites, 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, calculated as the stoichiometric equivalent of fenoxaprop-ethyl, in or on grass forage and grass hay at 0.05 ppm for an additional 3-year period. These tolerances will expire and are revoked on December 31, 2016. The time-limited tolerances originally published in the **Federal Register** of June 13, 2008 (73 FR 33714) (FRL–8366–6).

Propiconazole. EPA has authorized under FIFRA section 18 the use of propiconazole on avocado for control of Laurel wilt in Florida. This regulation extends the time-limited tolerance for residues of the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole) and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on avocado at 10 ppm for an additional 3-year period. This tolerance will expire and is revoked on December 31, 2016. The time-limited tolerance originally published in the **Federal Register** of May 11, 2011 (76 FR 27261) (FRL–8873–2).

Fipronil. EPA has authorized under FIFRA section 18 the use of fipronil on rutabaga and turnip for control of the cabbage maggot in Oregon. This regulation extends the time-limited tolerances for residues of the insecticide fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile) and its metabolites 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1H-pyrazole-3-carbonitrile and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1H-pyrazole-3-carbonitrile and its photodegradate 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)]-1H-pyrazole-3-carbonitrile in or on turnip and rutabaga at 1.0 ppm for an additional 3-year period. These tolerances will expire and are revoked on December 31, 2016. The time-limited tolerances originally published in the **Federal Register** of August 22, 2007 (72 FR 46906) (FRL–8142–6).

Bifenazate. EPA has authorized under FIFRA section 18 the use of bifenazate on timothy grass for control of spider mites in Nevada. This regulation extends the time-limited tolerances for residues of the miticide bifenazate, (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) and its metabolite diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on timothy forage at 50 ppm and timothy hay at 150 ppmfor an additional 3-year period. These tolerances will expire and are revoked on December 31, 2016. The time-limited tolerances originally published in the **Federal Register** of January 28, 2005 (70 FR 4032) (FRL–7696–2).

III. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for propiconazole in or on avocado; fenoxaprop-ethyl in or on grass forage or hay; fipronil in or on rutabaga or turnip; nor for bifenazate in or on timothy forage or hay.

IV. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require

any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 19, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.430 [Amended]

■ 2. In § 180.430, in the table to paragraph (b), amend the entries for grass, forage and grass, hay by revising the expiration dates "12/31/13" to read "12/31/16."

§ 180.434 [Amended]

■ 3. In § 180.434, in the table to paragraph (b), amend the entry for avocado by revising the expiration date "12/31/13" to read "12/31/16."

§ 180.517 [Amended]

■ 4. In § 180.517, in the table to paragraph (b), amend the entries for rutabaga and turnip by revising the expiration dates "12/31/13" to read "12/31/16."

§ 180.572 [Amended]

■ 5. In § 180.572, in the table to paragraph (b), amend the entries for timothy, forage and timothy, hay by revising the expiration dates "12/31/13" to read "12/31/16."

[FR Doc. 2013–30877 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0540; FRL–9902–90]

2,5-Furandione, polymer With ethenylbenzene, Reaction Products With polyethylene-polypropylene glycol 2-aminopropyl Me ether; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether; minimum number average molecular weight (in amu), 14,000 (CASRN 162568–32–3); when used as an inert ingredient in a pesticide chemical formulation. Huntsman Corp. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether on food or feed commodities.

DATES: This regulation is effective December 27, 2013. Objections and requests for hearings must be received on or before February 25, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0540, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0540 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 25, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0540, by one of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of September 12, 2013 (78 FR 56187) (FRL–9399–7), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (IN–10607) filed by Huntsman Corp., 8600 Gosling Rd., The Woodlands, TX 77381. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether. That notice included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any comments.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and use in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . ." and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.
2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.
3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).
4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.
6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.
7. The polymer does not contain certain perfluoroalkyl moieties

consisting of a CF3- or longer chain length as specified in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

8. The polymer's number average MW is greater than or equal to 10,000 daltons. The polymer contains less than 2% oligomeric material below MW 500 and less than 5% oligomeric material below MW 1,000.

Thus, 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether is 14,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether to share a common mechanism of toxicity with any other substances, and 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative*.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether.

VIII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether.

IX. Conclusion

Accordingly, EPA finds that exempting residues of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these rules from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant

to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes, or otherwise have any unique impacts on local governments. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

Although this action does not require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 17, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.960, in the table, alphabetically add the following polymer before the entry for "Hexadecyl acrylate-acrylic acid copolymer * * *" to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

Polymer	CAS No.
* * * * *	
2,5-Furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether; minimum number average molecular weight (in amu), 14,000	162568–32–3
* * * * *	

[FR Doc. 2013–31108 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS–1454–F]

RIN 0938–AR70

Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the exception to the physician self-referral law that permits certain arrangements involving the donation of electronic health records items and services. Specifically, this final rule extends the expiration date of the exception to December 31, 2021, excludes laboratory companies from the types of entities that may donate electronic health records items and services, updates the provision under which electronic health records software is deemed interoperable, removes the electronic prescribing capability requirement, and clarifies the requirement prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services.

DATES: With the exception of the amendment to § 411.357(w)(13), this regulation is effective on March 27, 2014. The amendment to § 411.357(w)(13) is effective on December 31, 2013.

FOR FURTHER INFORMATION CONTACT: Lisa Ohrin, (410) 786–8852.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Regulatory Action

Section 1877 of the Social Security Act (the Act), codified at 42 U.S.C. 1395nn, also known as the physician self-referral statute: (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless the requirements of an exception are satisfied; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless the requirements of an

exception are satisfied. The statute establishes a number of exceptions and grants the Secretary the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Since the original enactment of the statute in 1989, we have published a series of final rules interpreting the statute and promulgating numerous exceptions.

In accordance with our statutory authority, we published an exception to the physician self-referral law to protect certain arrangements involving the provision of interoperable electronic health records software or information technology and training services. The final rule for this exception was published on August 8, 2006 (71 FR 45140) (hereinafter referred to as the August 2006 final rule) and is scheduled to expire on December 31, 2013 (see 42 CFR 411.357(w)(13)). In the April 10, 2013 **Federal Register** (78 FR 21308), we published a proposed rule that would update certain aspects of the electronic health records exception and extend the expiration date of the exception. The purpose of this final rule is to address the public comments received on the proposed rule and to finalize certain aspects of the proposed rule.

B. Summary of the Final Rule

This final rule amends the current exception in several ways. First, this final rule extends the expiration date of the exception to December 31, 2021. Second, it excludes laboratory companies from the types of entities that may donate electronic health records items and services. Third, this rule updates the provision under which electronic health records software is deemed interoperable. Fourth, this rule clarifies the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services. Finally, it removes from the exception the requirement related to electronic prescribing capability.

C. Costs and Benefits

This final rule modifies an existing exception to the physician self-referral law. The exception permits certain entities to provide to physicians certain software and information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. The modifications to the exception do not impose new requirements on any party. This is not a major rule, as defined at 5 U.S.C. 804(2). It is also not economically significant, because it will not have a significant effect on program expenditures and there are no additional substantive costs to implement the resulting provisions. We expect the exception, as modified by this final rule, to continue to facilitate the adoption of electronic health records technology.

II. Background

A. Physician Self-Referral Statute and Exceptions

Section 1877 of the Act, codified at 42 U.S.C. 1395nn, also known as the physician self-referral statute: (1) prohibits a physician from making referrals for certain DHS payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless the requirements of an exception are satisfied; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless the requirements of an exception are satisfied. The statute at 42 U.S.C. 1395nn(b)(4) establishes a number of exceptions and grants the Secretary the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Since the original enactment of the statute in 1989, we have published a series of final rules interpreting the statute and promulgating numerous exceptions.

B. The Electronic Health Records Items and Services Exception

On August 8, 2006 (71 FR 45140), we published a final rule that, among other things, finalized at § 411.357(w) an exception to the physician self-referral law for protecting certain arrangements involving interoperable electronic health records software or information technology and training services (the "electronic health records exception"). Also in the August 8, 2006 **Federal Register** (71 FR 45110), the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) published similar final regulations at § 1001.952 that, among other things, adopted a safe harbor under the Federal anti-kickback statute (section 1128B(b) of the Act, codified at 42 U.S.C. 1320a–7b(b)) for certain arrangements involving interoperable electronic health records software or information technology and training services. As set forth at § 411.357(w)(13) and § 1001.952(y)(13), the physician self-referral law electronic health records exception and the Federal anti-kickback electronic health records safe harbor, respectively, are scheduled to expire on December 31, 2013.

On April 10, 2013 (78 FR 21308), we published a proposed rule that would set forth certain proposed changes to the electronic health records exception. First, we proposed to update the provision under which electronic health records software is deemed interoperable. Second, we proposed to remove from the exception the requirement related to electronic prescribing capability. Third, we proposed to extend the expiration date of the exception. In addition to these proposals, we solicited public comment on other possible amendments to the exception, including our proposal to limit the types of entities that may donate electronic health records items and services under the exception and to add or modify conditions to limit the risk of data and referral lock-in. Elsewhere in the same issue of the **Federal Register** (78 FR 21314), OIG proposed almost identical changes to the Federal anti-kickback statute safe harbor. Within the limitations imposed by the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between our proposed modifications to the exception at § 411.357(w) and OIG's proposed modifications to the safe harbor. We noted in the proposed rule that, due to the close nexus between our proposed rule and the OIG's proposed rule, we might consider comments submitted in response to OIG's proposal in finalizing this rule.

This final rule adopts some of the proposed changes to the electronic health records exception to the physician self-referral law. First, this final rule extends the expiration date of the exception to December 31, 2021. Second, it excludes laboratory companies from the types of entities that may donate electronic health records items and services under the exception. Third, this rule updates the provision under which electronic health records software is deemed interoperable. Fourth, this rule clarifies the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services. Finally, it removes from the exception the requirement related to electronic prescribing capability.

Elsewhere in this issue of the **Federal Register**, the OIG is finalizing almost identical changes to the electronic health records safe harbor [1] under the Federal anti-kickback statute. We attempted to ensure as much

[1] 42 CFR 1001.952(y).

consistency as possible between our changes to the physician self-referral law exception and OIG's safe harbor changes. We have considered and responded to the timely comments we received as well as those received by OIG. Similarly, OIG considered comments submitted in response to our proposed rule in crafting its final rule. For purposes of this final rule, we treat comments that were made with respect to the Federal anti-kickback statute as if they had been made with respect to the physician self-referral law, except where they relate to differences in the underlying statutes.

III. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

We received approximately 110 timely items of correspondence for the proposed rule. We summarize and respond to comments later in this section of the final rule. For ease of reference, we divided the comments and responses into the following categories: the deeming provision; the electronic prescribing provision; the "sunset" provision; and additional proposals and considerations.

A. The Deeming Provision

Our current electronic health records exception requires at § 411.357(w)(2) that the donated software must be "interoperable" (as defined at § 411.351) at the time it is provided to the physician. This provision further provides that software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician. We proposed two modifications to § 411.357(w)(2), which is known as the "deeming provision." Both modifications to the deeming provision were proposed to reflect recent developments in the Office of the National Coordinator for Health Information Technology's (ONC) certification program.

The first proposed modification would reflect ONC's responsibility for authorizing certifying bodies. The second would modify the timeframe during which donated software must be certified. Currently, to comply with the deeming provision, the exception requires donated software to be certified no more than 12 months prior to the date of donation.

After the issuance of the August 2006 final rule, ONC developed a regulatory process for adopting certification criteria and standards which is anticipated to result in a cyclical rulemaking process. (For more information, see ONC's September 4, 2012 final rule entitled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" (77 FR 54163).) Our proposal would have modified the deeming provision to track ONC's anticipated regulatory cycle. As a result, software would be eligible for deeming if, on the date it is provided to the physician, it has been certified to any edition of the electronic health record certification criteria that is identified in the then-applicable definition of Certified EHR Technology in 45 CFR part 170. By way of example, for 2013, the applicable definition of Certified EHR Technology includes both the 2011 and the 2014 editions of the electronic health record certification criteria. Therefore, in 2013, software certified to meet either the 2011 edition or the 2014 edition would have satisfied the requirement of the exception as we proposed to modify it. Additionally, we solicited comments on whether removing the current 12-month certification requirement would impact donations and whether we should retain the 12-month certification period as an additional means of determining eligibility under the deeming provision.

After consideration of the public comments received, we are finalizing the proposed revisions to § 411.357(w)(2) with one clarification to our proposed regulatory text to ensure that the deeming provision closely tracks ONC's certification program. We are revising § 411.357(w)(2) to state that software is deemed to be interoperable if, on the date that it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable 45 CFR part 170. As we stated in the August 2006 final rule (71 FR 45156), we understand "that the ability of software to be interoperable is evolving as technology develops. In assessing whether software is interoperable, we believe the appropriate inquiry is whether the software is as interoperable as feasible given the prevailing state of technology at the time the items or services are provided to the physician recipient." We believe that our final rule with respect to this requirement is consistent with that understanding and our objective of ensuring that software is certified to the current required standard of interoperability when it is donated.

Comment: All of the commenters that addressed this issue in their comments supported the proposed modification that would amend the exception to recognize ONC as the agency responsible for authorizing certifying bodies on behalf of the Secretary, with one commenter requesting that we clarify that software need not be certified to ONC's standards to be eligible for donation.

Response: We appreciate the commenters' support for this modification. With respect to the request for clarification, the commenter is correct that § 411.357(w)(2) does not require software to be certified to ONC's standards in order to be eligible for donation. As we discussed in the August 2006 final rule (71 FR 45156), the deeming provision offers one way for parties to be certain that the interoperability requirement of § 411.357(w)(2) is met at the time of donation. Even if donated software is not deemed to be interoperable, the arrangement would satisfy the interoperability requirement of the exception if the software meets the definition of "interoperable" at § 411.351.

Comment: One commenter expressed concerns about linking the interoperability requirement of the exception to ONC's certification criteria and standards because they do not, in the commenter's assessment, reflect contemporary views of interoperability. The commenter suggested that we instead implement a broad definition of interoperability adopted by the International Organization for Standardization or, alternatively, that we adopt interoperability functional definitions developed by the American National Standards Institute.

Response: Although we are mindful that other non-governmental organizations may be developing their own standards to encourage the adoption of interoperable electronic health records technology, ONC's certification criteria and standards are the core policies the Department is utilizing to accelerate and advance interoperability and health information exchange. On March 7, 2013, ONC and CMS jointly published a Request for Information (78 FR 14793) to solicit public feedback on a set of possible policies "that would encourage providers to routinely exchange health information through interoperable systems in support of care coordination across health care settings." The process by which ONC considers the implementation of new certification

criteria and standards is a public, transparent effort that allows the Department's electronic health records technology experts to consider appropriately the comments submitted in light of the goal "to accelerate the existing progress and enhance a market environment that will accelerate [health information exchange] across providers. . . ." (78 FR 14795).

We believe that it is reasonable and appropriate to link the deeming provision to ONC's certification criteria and standards because of ONC's expertise and its public process for considering and implementing its criteria and standards. ONC is the agency within the Department with expertise in determining the relevant criteria and standards to ensure that software is as interoperable as feasible given the prevailing state of technology. ONC expects to revise and expand such criteria and standards incrementally over time to support greater interoperability of electronic health records technology. (See the September 4, 2012 final rule (77 FR 54269).) Additionally, we believe that utilizing ONC's certification criteria and standards, which are implemented through a public process, affords the best opportunity for interested parties to comment on, understand, and ultimately implement those criteria and standards. Therefore, we are not adopting the commenter's suggestion.

Comment: One commenter stated that many electronic health records systems lack the capabilities to function within a patient-centered medical home. The commenter suggested that we finalize policies that further strengthen the use of core electronic health records features.

Response: We are not adopting the commenter's suggestion. As discussed, ONC is the agency within the Department with expertise in determining the relevant criteria and standards for electronic health records technology, including those related to the use of core features. The public process through which ONC's certification criteria and standards are implemented affords the best opportunity for interested parties to comment on, understand, and ultimately implement those criteria and standards.

Comment: Of the commenters that addressed the deeming provision, most supported our proposal to modify the timeframe within which donated software must have been certified to track more closely the current ONC certification program. Commenters asserted that aligning the exception's certification timeframe with ONC's certification program will provide donors and physician recipients more certainty about the deemed status of donated software because the software must be certified to meet only one set of standards on the same certification cycle to comply with both ONC's certification criteria and the deeming provision of the exception. One commenter supported the modification, but suggested that the 12-month certification timeframe also be retained or, alternatively, that we allow software to be deemed to be interoperable if it has been certified to *any* edition of ONC's electronic health record certification criteria.

Response: We agree that aligning the exception's certification timeframe with ONC's certification program provides more certainty to donors and physician recipients. We believe that the modification we are making to the requirement at § 411.357(w)(2) will support the dual goals of the deeming provision: (1) to ensure that donated software is as interoperable as feasible given the prevailing state of technology at the time it is provided to the physician recipient; and (2) to provide donors and physician recipients a means to have certainty that donated software satisfies the interoperability requirement of the exception.

We are not persuaded to adopt the commenter's suggestion to retain the 12-month certification timeframe, as this would not ensure that software is certified to the current required standard of interoperability. In the course of evaluating the commenter's suggestion, however, we realized that our proposed regulatory text may be too narrow to satisfy the dual goals of the deeming provision. Under our proposed regulatory text, software would be deemed interoperable if it was certified to an edition [2] of certification criteria referenced in the then-applicable definition of "Certified EHR Technology" at 45 CFR 170.102. That definition applies only to the Medicare and Medicaid Electronic Health Record Incentive Programs (the EHR Incentive Programs). See generally, 42 CFR part 495. However, ONC also has the authority to adopt into its regulations in 45 CFR part 170 certification criteria for health information technology, including electronic health records, that may not be referenced in the definition of "Certified EHR Technology" because they are not related to the EHR Incentive Programs. If we finalize the proposed regulatory text, software certified to criteria in editions not included in the definition "Certified EHR Technology" would not be eligible for deeming under the exception. Further, we have recently learned that ONC intends to retire outdated editions of certification criteria by removing them from the regulatory text in 45 CFR part 170. Accordingly, software certified to an edition identified in the regulations in effect on the date of the donation would be certified to a then-applicable edition, regardless of whether the particular edition was also referenced in the then-applicable definition of Certified EHR Technology. Thus, we are finalizing revisions to § 411.357(w)(2) to track more closely ONC's certification program in the deeming provision: We are finalizing a modification to our regulatory text to provide that software is deemed to be interoperable if, on the date it is provided to the physician recipient, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We believe that this is consistent with our intent, as articulated in the proposed rule, to modify the deeming provision by removing the 12-month timeframe and substituting a provision that more closely tracks ONC's certification program. Further, we believe that the regulatory text, as modified, will support the goals of the deeming provision described previously.

Comment: One commenter suggested that, for deeming purposes, we should require that software be certified to the *latest* edition of electronic health record certification criteria rather than any edition then applicable. This commenter also suggested that the electronic directory of service (e-DOS) standard should be a certification requirement for donated software, and asserted that both recommendations would help ensure electronic health records software is interoperable.

Response: We decline to adopt the commenter's suggested requirements for the exception at § 411.357(w). We believe that requiring donated software to be certified to editions that are adopted and not yet retired by ONC through its certification program ensures that the software is certified to interoperability standards updated regularly by the agency of the Department with the relevant expertise. Further, adding requirements to the ONC certification criteria and standards is outside the scope of this rulemaking. Therefore, we are not implementing the commenter's suggestions.

[2] ONC has recently begun characterizing sets of adopted certification criteria as "editions."

B. The Electronic Prescribing Provision

At § 411.357(w)(11), our current electronic health records exception specifies that the donated software must "contain [] electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided." In the preamble to the August 2006 final rule (71 FR 45153), we stated that we included "this requirement, in part, because of the critical importance of electronic prescribing in producing the overall benefits of health information technology, as evidenced by section 101 of the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173]." We also noted that it was "our understanding that most electronic health records systems already include an electronic prescribing component" (71 FR 45153).

We continue to believe in the critical importance of electronic prescribing. However, in light of developments since the August 2006 final rule, we proposed to delete from the exception the requirement at § 411.357(w)(11). Based on our review of the public comments and for the reasons stated in the proposed rule, we are finalizing our proposal to eliminate the requirement that electronic health records software contain electronic prescribing capability in order to qualify for protection under the exception at § 411.357(w).

Comment: Two commenters disagreed that it is no longer necessary to require the inclusion of electronic prescribing capability in donated electronic health records software. One of the commenters stated that it was encouraged by the growth in the number of physicians using electronic prescribing between 2008 and 2012, but believed that the requirement should remain for patient safety reasons because electronic prescribing is critical to lowering the incidences of preventable medication errors.

Response: Like the commenters, and as we stated in the proposed rule (78 FR 21311), we believe in the importance of electronic prescribing. However, we are persuaded that other existing policy drivers, many of which did not exist in August 2006 when the exception was promulgated, sufficiently support the adoption of electronic prescribing capabilities. We do not want to undermine important public policy goals by requiring redundant and sometimes expensive software capabilities that may not contribute to the interoperability of a given system. As we discussed in the proposed rule, electronic prescribing technology will remain eligible for donation under the electronic health records exception or under the electronic prescribing exception at § 411.357(v). We do not believe that removing this requirement would increase the risk of fraud or abuse posed by donations made pursuant to the exception.

Comment: Many commenters supported our proposal to eliminate the requirement that donated software must include electronic prescribing capability at the time it is provided to the physician recipient, agreeing that developments since the promulgation of the exception make it unnecessary to retain this requirement. One of the commenters asserted that the goal of the requirement for the inclusion of electronic prescribing technology in donated electronic health records software—that is, increasing the use of electronic prescribing—had been achieved through the electronic prescribing incentive program authorized by the Medicare Improvements for Patients and Providers Act of 2008.

Response: We appreciate the commenters' support and, for the reasons explained in more detail previously in this final rule, we are eliminating the requirement at § 411.357(w)(11) that donated electronic health records software must contain electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.

C. The "Sunset" Provision

Protected donations under the current electronic health records exception must be made on or prior to December 31, 2013. In adopting this requirement of the electronic health records exception, we acknowledged in the August 2006 final rule (71 FR 45162), "that the need for donations of electronic health records technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice."

As we discussed in the proposed rule, although the industry has made great progress in the adoption and meaningful use of electronic health records technology, the use of such technology has not yet been adopted nationwide. Continued use and further adoption of electronic health records technology remains an important goal of the Department. We continue to believe that, as progress on this goal is achieved, the need for an exception for donations of electronic health records items and services should continue to diminish over time. Accordingly, we proposed to extend the expiration date of the exception to December 31, 2016, selecting this date for the reasons described in the proposed rule (78 FR 21311). We also specifically sought comment on whether we should, as an alternative, select a later expiration date and what that date should be. For example, we stated that we were considering an expiration date of December 31, 2021 (78 FR 21311). In response to comments, we are extending the expiration date of the exception to December 31, 2021.

Comment: Numerous commenters urged us to make permanent the exception at § 411.357(w). According to these commenters, a permanent exception could: (1) provide certainty with respect to the cost of electronic health records technology for physicians; (2) encourage adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an electronic health records system; (3) encourage adoption by providers and suppliers that are not eligible for incentive payments through the Medicare and Medicaid programs; and (4) preserve the gains already made in the adoption of interoperable electronic health records technology, especially where hospitals have invested in health information technology infrastructure through protected donations of such technology. According to some commenters, although the exception was implemented to encourage the adoption of health information technology, it is now a necessity for the creation of new health care delivery and payment models. Some commenters also stated their support for a permanent exception because the adoption of electronic health records technology has been slower than expected, and allowing the exception to expire in 2016 would adversely affect the rate of adoption. Some of these commenters requested that, if CMS is not inclined to make the exception permanent, we extend the availability of the exception through the latest date noted in the proposed rule—December 31, 2021.

Response: We agree with the commenters that the continued availability of the exception at § 411.357(w) plays a part in achieving

the Department's goal of promoting electronic health records technology adoption. However, we do not believe that making the exception permanent is required or appropriate at this time. The permanent availability of the exception could serve as a disincentive to adopting interoperable electronic health records technology in the near-term. Moreover, as described in the proposed rule (78 FR 21312) and elsewhere in this final rule, we are concerned about inappropriate donations of electronic health records items and services that lock in data and referrals between a donor and physician recipient, among other risks. A permanent exception might exacerbate these risks over the longer term without significantly improving adoption rates. However, in light of other modifications we are making in this final rule to mitigate such ongoing risks, including removing laboratory companies as protected donors of electronic health records items and services, we are persuaded to permit use of the exception for more than the additional 3-year period that we proposed.

The adoption of interoperable electronic health records technology still remains a challenge for some providers and suppliers despite progress in its implementation and meaningful use since the August 2006 promulgation of the exception at § 411.357(w). (*See* ONC's Report to Congress on Health IT Adoption (June 2013) at *http://www.healthit.gov/sites/default/files/rtc_adoption_of_healthit_and_relatedefforts.pdf* and the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation's EHR Payment Incentives for Providers Ineligible for Payment Incentives and Other Funding Study (June 2013) at *http://aspe.hhs.gov/daltcp/reports/2013/ehrpi.shtml*.) Although we believe that the protection afforded by the exception encourages the adoption of such technology, its permanence is not essential to the achievement of widespread adoption. It is only one of a number of ways that physicians are incented to adopt electronic health records technology, including the incentives offered by the EHR Incentive Programs and the movement in the health care industry toward the electronic exchange of patient health information as a means to improve patient care quality and outcomes.

Balancing our desire to encourage further adoption of interoperable electronic health records technology against our concerns about potential disincentives to adoption and the misuse of the exception to lock in referral streams, we are establishing a December 31, 2021 expiration date for the exception. We believe that this expiration date will support earlier adoption of electronic health records technology, provide a timeframe that aligns with the financial incentives for electronic health records adoption currently offered by the Federal government, and safeguard against foreseeable future fraud risks, while still providing adequate time for donors and physician recipients to maximize the financial incentives currently offered by the Federal government.

Comment: Two commenters agreed that the availability of the exception at § 411.357(w) should be extended, but not beyond December 31, 2016. One of these commenters asserted that a relatively short extension of the sunset date for the exception would allow a wider range of people to obtain access to health information technology services while not diminishing the incentive for providers to acquire, implement and standardize the necessary electronic health records systems. Another commenter supported our proposal to extend the availability of the exception through December 31, 2016, and encouraged us to consider an additional extension as that date approaches. One commenter suggested that we extend the availability of the exception for at least 6 years, although a shorter or longer time period could be established after review of adoption rates across the range of providers that may or may not be eligible for meaningful use incentives under the EHR Incentive Programs. Other commenters supported our alternative proposal to extend the availability of the exception through December 31, 2021, which corresponds to the statutory end of the Medicaid incentive program. These commenters noted that more remains to be done to promote electronic health records technology adoption, and suggested that maintaining the exception through this date will help maximize the incentives for eligible physicians to adopt electronic health records technology and thereby increase use of electronic health records. Two other commenters suggested tying the expiration of the exception to the corresponding date for assessing "penalties" under the Medicare EHR Incentive Program in order to align appropriately Federal regulation of electronic health records technology adoption and use.

Response: We share the commenter's concerns regarding diminishing incentives for providers to acquire, implement and standardize the necessary electronic health records systems. However, after consideration of all of the comments on this issue, we believe that an extension of the exception would advance the Department's goals regarding the adoption of interoperable electronic health records technology and improvements in patient care, while providing an incentive for providers to adopt electronic health records technology in the near-term. Therefore, we are extending the availability of the exception at § 411.357(w) through December 31, 2021, which corresponds to the end of incentive payments under the Medicaid EHR Incentive Program.

We note that the two commenters that suggested tying the expiration of the exception to the corresponding date for assessing penalties under the Medicare EHR Incentive Program appear to misunderstand the duration of the downward payment adjustments under this program, which will continue until an eligible participant adopts and meaningfully uses appropriate electronic health records technology. (For additional information, see the July 28, 2010 (75 FR 44448) final rule entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program.") The practical effect of the commenters' suggestion would be to extend permanently the exception at § 411.357(w). For the reasons stated elsewhere in this final rule, we do not believe that making the exception permanent is required or appropriate at this time, and we are not adopting the commenters' suggestion.

Comment: A few commenters expressed general support for extending the availability of the exception, but did not specify whether the extension should be for 3 years, 8 years, or some other length of time. Commenters noted that failure to extend the availability of the exception would negatively impact the adoption of electronic health records technology, as well as its continued use.

Response: As described previously, we are finalizing our alternative proposal to extend the exception through December 31, 2021.

Comment: A number of commenters urged us to let the exception at § 411.357(w) expire on December 31, 2013. Some of the commenters asserted that the exception permits the exact behavior the law was intended to stop, namely, referrals tied to financial relationships between physicians and entities furnishing DHS, in this case, entities that donate electronic health records items and services. Other commenters asserted that the exception permits "legalized extortion" or provides "legal sanction to trample the competition." Another commenter

asserted that the inclusion of "non-market factors" (that is, the influence of donors, rather than end users) in the decision to adopt electronic health records technology may result in lower quality products or services and/or higher costs, often with an adverse impact on technology adoption and innovation. Still others asserted that, given the financial incentives that the government itself has provided, it is no longer necessary to spur the adoption of electronic health records technology through the underwriting of the cost of electronic health records technology by outside entities.

Response: Although we appreciate the commenters' concerns, we continue to believe that the exception serves to advance the adoption and use of interoperable electronic health records. However, we caution that a compensation arrangement involving the donation of electronic health records technology runs afoul of the physician self-referral law unless it satisfies each requirement of the exception at § 411.357(w). Arrangements that disguise the "purchase" or lock-in of referrals and donations that are solicited by the physician recipient in exchange for referrals would fail to satisfy the requirements of the exception. We disagree with the commenters that asserted that encouragement for the "underwriting" of electronic health records technology by organizations other than the government is no longer necessary, particularly in light of the developments in integrated patient care delivery and payment models.

Comment: Numerous commenters suggested that the exception at § 411.357(w) should sunset as scheduled on December 31, 2013, but only with respect to laboratories and pathology practices, "ancillary service providers," entities not listed in section 101 of the MMA (authorizing an exception for certain donations of electronic prescribing items and services), or entities that are not part of an accountable care organization or not integrated in a meaningful manner.

Response: We consider these comments to be related to "protected donors" and address them in section III.D.1. of this final rule.

D. Additional Proposals and Considerations

1. Protected Donors

As we discussed in the proposed rule, despite our goal of expediting the adoption of electronic health records technology, we have concerns about the potential for abuse of the exception by certain types of providers and suppliers (including suppliers of ancillary services that do not have a direct and primary patient care relationship and a central role in the health care delivery infrastructure). The OIG indicated that it has concerns related to the potential for laboratories and other ancillary service providers to abuse its safe harbor, as it has received comments suggesting that abusive donations are being made under the electronic health records safe harbor. In order to address these concerns, we proposed to limit the scope of protected donors under the electronic health records exception.

In the proposed rule, we stated that we were considering revising the exception to cover only the MMA-mandated donors we originally proposed when the exception was first established: hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage (MA) organizations. We stated that we were also considering whether other individuals or entities with front-line patient care responsibilities across health care settings, such as safety net providers, should be included, and, if so, which ones. Alternatively, we stated that we were considering retaining the current broad scope of protected donors, but excluding specific types of donors—suppliers of ancillary services associated with a high risk of fraud and abuse—because donations by such suppliers may be more likely to be motivated by a purpose of securing future business than by a purpose of better coordinating care for beneficiaries across health care settings. In particular, we discussed excluding laboratory companies from the scope of permissible donors, as their donations have been the subject of complaints. We also discussed excluding other high-risk categories of potential donors, such as durable medical equipment (DME) suppliers and independent home health agencies. We sought comment on the alternatives under consideration, including comments (with supporting reasons) regarding particular types of providers or suppliers that should or should not be permitted to utilize the exception given its goals.

Many commenters raised concerns about donations of electronic health records items and services by laboratory companies and strongly urged us to adopt our proposal to eliminate protection for such donations, either by excluding laboratory companies from the scope of protected donors (if we extend the availability of the exception), or by letting the exception sunset altogether. (For more detailed discussion of comments concerning the sunset provision, see section III.C. of this final rule.) Other commenters raised similar concerns, but did not suggest a particular approach to address them.

We carefully considered the comments that we received on this proposal and, based on the concerns articulated by commenters and the wide-ranging support from the entire spectrum of the laboratory industry (from small, pathologist-owned laboratory companies to a national laboratory trade association that represents the industry's largest laboratory companies), we are finalizing our proposal to exclude laboratory companies from the types of entities that may donate electronic health records items and services under the exception. We believe this decision is consistent with and furthers our continued goal of promoting the adoption of interoperable electronic health records technology that benefits patient care while reducing the likelihood that the exception will be misused by donors to secure referrals. We also believe that our decision will address situations identified by some of the commenters involving physician recipients conditioning referrals for laboratory services on the receipt of, or redirecting referrals for laboratory services following, donations from laboratory companies.

Comment: Many commenters raised concerns that, notwithstanding a clear prohibition in the exception, laboratory companies are, explicitly or implicitly, conditioning donations of electronic health records items and services on the receipt of referrals from the physician recipients of those donations or establishing referral quotas and threatening to require the physician recipient to repay the cost of the donated items or services if the quotas are not reached. Some commenters suggested that such *quid pro quo* donations, and donations by laboratory companies generally, are having a negative effect on competition within the laboratory services industry (including increased prices for laboratory services) and impacting patient care, as referral decisions are being made based on whether a laboratory company donated electronic health records items or services, not whether that company offers the best quality services or turnaround time. A few commenters also raised concerns that laboratory companies are targeting potential physician recipients based on the volume or value of their anticipated referrals.

Response: The current requirement at § 411.357(w)(6) prohibits determining the eligibility of a physician recipient or the amount or nature of the items or

services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Accordingly, the *quid pro quo* arrangements and targeted donations described by the commenters would not satisfy this requirement of the exception. Such arrangements are not consistent with the purpose of the exception and can result in the precise types of harm the physician self-referral law is designed to prevent, such as financial self-interest that may affect a physician's medical decision making. We urge those with information about such arrangements to contact the OIG's fraud hotline at 1–800–HHS–TIPS or visit *https://forms.oig.hhs.gov/hotlineoperations/* to learn of other ways to report fraud.

We appreciate the commenters' support for our proposal to remove donations by laboratory companies from the protection of the exception. We believe that our decision to exclude laboratory companies from the scope of protected donors is the best way to encourage and facilitate the adoption of interoperable electronic health records technology without risk of program or patient abuse.

Comment: Several commenters raised concerns about laboratory company arrangements with electronic health records technology vendors. The commenters described agreements involving laboratory companies and vendors that result in the vendors charging other laboratory companies high fees to interface with the donated technology or prohibiting other laboratory companies from purchasing the technology for donation to their own clients. One of the commenters also raised a concern that volume discount arrangements between laboratory companies and vendors of electronic health records technology are resulting in donations of electronic health records items and services that may not best suit the needs of the physician recipient. The commenter asserted that donor laboratory companies are pushing a particular vendor's specific electronic health records system onto physician recipients because of the donor's close relationship with the vendor.

Response: Excluding potential competitors of the donor from interfacing with donated items or services, as described by the commenters, can result in data and referral lock-in. We discuss the issue of lock-in elsewhere in this final rule in more detail. We believe that our determination to exclude laboratory companies from the scope of protected donors will help address the data and referral lock-in risks posed by arrangements such as those described by the commenters. We also believe that the changes to § 411.357(w)(1) that we are finalizing regarding the types of entities that may donate electronic health records items and services will help address the commenter's concern about the negative impact of relationships between laboratory companies and vendors on the selection of electronic health records technology by physicians. We stated in the August 2006 final rule that, although physician recipients remain free to choose any electronic health records technology that suits their needs, we do not require donors to facilitate that choice for purposes of the exception. However, as we also stated in the August 2006 final rule (71 FR 45157), our regulations require donors to offer interoperable products and donors must not impede the interoperability of any electronic health records software they decide to offer. Any agreement between a donor and a vendor that precludes or limits the ability of competitors to interface with the donated electronic health records software would raise significant questions regarding whether the donation meets the requirement at § 411.357(w)(3).

Comment: Many commenters noted that several states—including Missouri, New Jersey, New York, Pennsylvania, Tennessee, Washington, and West Virginia—have prohibited or restricted donations of electronic health records technology by laboratory companies to address fraud and abuse concerns. Some of the commenters urged us to effectuate a similar prohibition or restriction by removing laboratory companies as potential donors under the exception. One of these commenters asserted that laboratory companies licensed in states that strictly prohibit them from donating to referring physicians all or part of the costs of electronic health records technology are put at a considerable disadvantage in the marketplace because of "the need for [electronic health records technology] subsidies to compete for business."

Response: We believe that our determination to exclude laboratory companies from the types of entities that may donate electronic health records items and services under the exception will address the fraud and abuse concerns referenced by the commenters. With respect to the commenter's concern about being disadvantaged, we note that our decision to prohibit laboratory companies from utilizing the exception applies equally to all laboratory companies, regardless of their location.

Comment: Several commenters, including a national laboratory trade association that represents the industry's largest laboratory companies, took exception to what they perceived as an allegation that laboratory companies are solely responsible for problematic donations of electronic health records items and services. Some of these commenters asserted that electronic health records technology vendors are encouraging physicians to seek or demand donations from laboratory companies, and that physicians are threatening to withhold referrals or send laboratory business elsewhere if donations are not made. According to one commenter, because physicians are not paying for a significant portion of the cost of these items and services, electronic health records technology vendors are able to charge high prices and the size of donations (in dollars) has increased exponentially in recent years. The commenter also suggested that vendors may be manipulating pricing to maximize the amount a laboratory company pays for donated items and services while minimizing or eliminating any physician responsibility. Another commenter raised a related concern that electronic health records technology vendors have increased the costs of their products because they know that laboratories are paying for them. Generally, commenters raising concerns about the conduct of electronic health records technology vendors and physicians recommended that we remove laboratory companies from the universe of permissible donors under the exception.

One commenter asserted that physicians are no longer choosing electronic health records technology based on which system is most appropriate, but rather based on which will produce the largest donation of items and services. Another commenter asserted that many physicians will change laboratory companies and seek a new donation once an existing donor laboratory company ceases to subsidize the physicians' electronic health records technology costs. This commenter stated that such conversions to different electronic health records technology are not only inefficient, but undermine the spirit of the regulatory requirement that physicians do not possess the same or equivalent items or services as those being donated.

Response: Our proposed modification related to the universe of donors potentially covered under the exception; thus, the focus of our discussion in the proposed rule was on donor conduct. Some of the comments we describe in

this final rule also raise concerns about the conduct of physician recipients. In response, we are clarifying that we do not believe that problematic donations involving laboratory companies are solely the result of questionable conduct by laboratory companies. We believe that our decision to exclude laboratory companies from the universe of protected donors is the best way to reduce the risk of misuse of the exception at this time and addresses the concerns identified by the commenters.

We note that § 411.357(w)(5) prohibits the physician recipient and the physician recipient's practice from making the receipt, amount or nature of the donated items or services a condition of doing business with the donor. This provision recognizes the program integrity risk posed by a potential physician recipient who demands a donation in exchange for referrals. This type of *quid pro quo* arrangement is no less troubling than *quid pro quo* arrangements that originate with the donor and would not satisfy the requirements of the exception. Whether a *quid pro quo* donation is for an initial installation of a donated item or service or a conversion to a different donated item or service would not change our analysis. Additionally, we caution those engaging in conversion arrangements to be mindful of the limitations in the exception at § 411.357(w)(8) concerning the donation of equivalent items or services.

Comment: Several commenters suggested that laboratory companies should be prohibited from donating electronic health records items and services to physicians or that physicians should pay for their own electronic health records technology. Other commenters asserted that laboratory companies do not share an essential interest in their referring clients having electronic health records technology. Still other commenters stated simply that laboratory companies represent a high risk of fraud and abuse.

Response: Based on the complaints previously received by OIG, which are described in more detail in the proposed rule, and the information provided by the commenters regarding some of the arrangements between laboratory companies and physician recipients of donated electronic health records items and services, we agree that donations of electronic health records items and services by laboratory companies present a high risk of fraud and abuse. Exceptions promulgated using our authority under section 1877(b)(4) of the Act may provide protection from the physician self-referral law's prohibitions only for those financial relationships that pose no risk of program or patient abuse. We do not believe that continuing to permit laboratory companies to make protected donations under the exception at § 411.357(w) would meet this standard. Therefore, we are modifying the requirements of the exception to eliminate laboratory companies from the types of entities that may provide donations under the exception. We do not agree with the commenters that laboratory companies necessarily do not have an essential interest in their referring clients having electronic health records technology. It is the behavior of laboratory companies and physician recipients of donations from laboratory companies of which we are aware that drives our determination to finalize our proposal to eliminate laboratory companies from the types of entities that may provide donations under the exception.

Comment: A few commenters noted that, rather than electronic health records, laboratory companies typically use a laboratory information system (LIS), anatomic pathologist information system, and/or blood banking system to store and share patients' laboratory results, and that these systems should not be confused with an electronic health record that includes a patient's full medical record comprised of information from many medical specialties, including pathology. One of these commenters asserted that laboratories already bear the cost of establishing LIS interfaces that they provide to physicians in order to exchange laboratory services data electronically, and that clinical and anatomic laboratories could continue to do so legally even if they were no longer protected donors under the exception. One commenter lamented the costs associated with interfaces, other commenters requested that CMS clarify its position on the donation of interfaces by laboratory companies, and one commenter asserted that interfaces were not analogous to facsimile machines, which we have stated in the past may be provided to physicians under certain circumstances.

Response: We appreciate the general information provided by the commenters regarding the various types of technology that laboratory companies generally use or do not use. The more relevant technology in the laboratory setting is the interface that exchanges data electronically between the laboratory and its referral sources. These comments provide us an opportunity to discuss more fully our position on the donation of interfaces by laboratory companies.

Our decision to exclude laboratory companies from the universe of protected donors under the exception does not affect our interpretation of the physician self-referral law as it relates to whether the provision of an item or service qualifies as "remuneration" that establishes a compensation arrangement that implicates the law's referral and billing prohibitions. In section 1877(h)(1)(A) of the Act, "compensation arrangement" is defined as "any arrangement involving any remuneration" between a physician (or an immediate family member of such physician) and an entity furnishing DHS. Section 1877(h)(1)(B) of the Act defines "remuneration" to include "any remuneration, directly or indirectly, in cash or in kind." However, under section 1877(h)(1)(C) of the Act, "remuneration" does not include "the provision of items, devices, or supplies that are used solely to: (i) collect, transport, process, or store specimens for the entity providing the item, device, or supply; or (ii) order or communicate the results of tests or procedures for such entity." Therefore, the provision of such items, devices or supplies does not result in a compensation arrangement that implicates the physician self-referral law's referral and billing prohibitions. We discussed this further in CMS Advisory Opinion 2008–01, which can be found at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2008-01.pdf*. Accordingly, the provision of certain interfaces, such as those described by the commenters, need not satisfy the requirements of § 411.357(w).

We disagree with the commenter that asserted that interfaces are not sufficiently analogous to facsimile machines. We believe that a limited-use interface (as described previously) is the contemporary analog to the limited-use computer or facsimile described in the example from the 1998 proposed rule preamble (63 FR 1693 and 1694 (January 9, 1998)). Moreover, the mode of technology is not restricted by the language of section 1877(h)(1)(c) of the Act nor is its cost, which is, in any event, outside the scope of this rulemaking.

Comment: Several commenters inquired whether our proposal to prohibit use of the exception for donations of electronic health records items and services by laboratory companies would apply to suppliers of both anatomic and clinical pathology services, and suggested that our proposal should apply to both. Commenters also inquired about the application of this proposal to hospitals

that operate laboratory companies for non-hospital affiliated customers. Raising concerns about an uneven playing field, some of these commenters urged us to exclude such hospitals from the universe of protected donors if we determined to exclude laboratory companies. One commenter suggested that we effectuate this limitation by restricting protected hospital donations to those made to the hospital's employed physicians and the hospital's wholly-owned physician practices.

Response: Our proposal applied to "laboratory companies" and did not distinguish between those that provide anatomic pathology services and those that provide clinical pathology services. We intend that references to "laboratory company" or "laboratory companies" include entities that furnish both types of DHS.

With respect to the commenters' suggestion to limit or prohibit hospital donations of electronic health records items and services, we appreciate the concerns articulated by the commenters, but are not adopting their suggestion at this time. We continue to believe that hospitals have a substantial and central stake in patients' electronic health records. Further, the types and prevalence of the concerns that have been brought to the OIG's attention and discussed elsewhere in this final rule about donations by laboratory companies have not arisen, to our knowledge, in the hospital-donation context.

We are also clarifying that, if a hospital furnishes clinical laboratory services through a laboratory that is a department of the hospital for Medicare purposes (including cost reporting), and the hospital bills for the services through the hospital's provider number, then the hospital would not be a "laboratory company" and would continue to qualify as a protected donor under the modified exception. However, if a hospital-affiliated or hospital-owned company with its own supplier number furnishes clinical laboratory services that are billed using a billing number assigned to the company and not to the hospital, the company would be a "laboratory company" and would no longer qualify as a protected donor. The ability of the affiliated hospital to avail itself of the exception would be unaffected. We remind readers that it is the substance, not the form, of an arrangement that governs under the physician self-referral law.

Comment: One commenter requested that, if we finalize our proposal to exclude laboratory companies from the universe of protected donors, we specifically clarify that "[laboratory companies] are prohibited from providing [ ] software to physicians unless they comply with another one of the existing exceptions." The commenter went on to cite examples of software leases and sales at fair market value that could potentially qualify for protection under an exception other than the one at § 411.357(w).

Response: We decline the commenter's invitation to make this clarification. Exceptions set forth specific requirements that, if satisfied, assure the parties involved that physician referrals to the entity for DHS are not prohibited and that the entity may bill Medicare for the services furnished pursuant to those physician referrals. As we have stated in prior rulemakings, an arrangement need not satisfy the requirements of a particular exception. Rather, the parties to an arrangement may avail themselves of any applicable exception to protect the physician's referrals to the DHS entity with which he or she (or an immediate family member) has a financial relationship.

Comment: One commenter shared its concerns about a practice that it described as "post-donation in-sourcing." The commenter stated that it is aware of situations in which laboratory companies are donating electronic health records technology to referring physicians only to have those physicians in-source their laboratory services shortly after the donation. The commenter suggested that the donations enable referring physicians to avoid bearing the full cost of electronic health records technology without continued referrals to the donating laboratory company.

Response: We are not modifying the exception to address the commenter's concern. We remind stakeholders that the exception does not require the physician recipient to make referrals to the donor. To the contrary, § 411.357(w)(5) prohibits the physician recipient and his or her practice from making the receipt, amount, or nature of the donated items or services a condition of doing business with the donor. Moreover, § 411.357(w)(6) prohibits determining the eligibility of a physician recipient or the amount or nature of the items or services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Whether protection is afforded under the exception to the types of arrangements described by the commenter will depend on whether all of the requirements of the exception are satisfied.

Comment: Two commenters raised issues regarding the type of remuneration permissible under the exception at § 411.357(w). One commenter characterized the exception as allowing laboratory companies to donate funds to physician recipients to help them implement electronic health records technology. Another commenter noted that some donations from laboratory companies have included hardware.

Response: We remind stakeholders that the exception at § 411.357(w) applies only to the donation of *nonmonetary* remuneration (in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records. As stated in the preamble to the August 2006 final rule (71 FR 45161), reimbursement for previously incurred expenses is not protected, as it poses a substantial risk of program and patient abuse. We also remind stakeholders that the exception does not protect the donation of hardware.

Comment: Although the majority of commenters supported excluding laboratory companies from the types of entities that may donate electronic health records items and services under the exception, some commenters made other recommendations related to protected donors. A number of commenters recommended that we maintain our current scope of protected donors; that is, allow any entity (as defined at § 411.351) to provide electronic health records items and services to a physician. Some of these commenters stated that limiting the scope of protected donors could have an impact on specialists, who, according to the commenters, still have relatively low rates of electronic health records adoption. Along the same lines, one commenter stated that limiting the categories of donors that may seek protection under the exception will negatively impact physician recipients by preventing certain entities from helping to move the entire healthcare system toward more interoperable electronic health record systems. Others cautioned that restricting the universe of permissible donors will stymie innovation and restrict learning from the technology. Finally, some commenters contended that laboratory companies and other ancillary service providers have a legitimate clinical interest in donating electronic health records technology and that many physician practices depend on it.

Some commenters, while acknowledging our concerns regarding abusive donation practices, suggested

alternative means to address the concerns we articulated in the proposed rule. These commenters variously recommended that we strengthen interoperation requirements, provide physician education materials, or adopt enforcement policies to prevent abuses rather than limiting the universe of potential donors of electronic health records items and services.

Response: We agree with many of the reasons articulated by the commenters supporting a fully expansive universe of protected donors under the exception. We recognize that limiting the universe of potential donors could constrain the ability of many physicians to adopt electronic health records technology. However, we are persuaded by the commenters that cited examples or patterns of program abuse by laboratory companies and are amending the exception to limit permissible donors under § 411.357(w) by excluding laboratory companies. Other than with respect to laboratory companies, the universe of protected donors will remain the same. We will continue to monitor and may, prior to the end of 2021, reconsider in a future rulemaking the risk of program or patient abuse relating to the use of the exception by other donors or categories of donors.

We appreciate the suggestions from commenters regarding alternative means of addressing abusive donation practices. However, our authority under section 1877(b)(4) of the Act permits us to establish exceptions to the physician self-referral law only where protected financial relationships would pose no risk of program or patient abuse. We do not believe that adopting the commenters' alternative suggestions for addressing our concerns would meet this standard.

Comment: We received a number of comments requesting that we retain certain categories of providers and suppliers within the universe of permissible donors of electronic health records items and services under the exception at § 411.357(w). For example, commenters that provide dialysis services specifically requested that they remain protected donors. One of the dialysis-provider commenters noted that excluding this specialty would have a chilling effect on the development and availability of the specialized electronic health records systems used by nephrologists. A few commenters requested that we continue to include hospitals and health systems as protected donors in order for them to retain the ability to assist physicians in adopting electronic health records technology. Other commenters requested that we explicitly retain home health agencies as permissible donors. In support of retaining home health agencies, one commenter stated that the depth, breadth, and frequency of communications between home health agencies and other direct care providers makes the use of interoperable electronic health records technology essential to improving clinical outcomes and financial efficiencies. We also received comments in support of retaining safety net providers and pharmacies as protected donors.

Response: We agree generally with the thrust of these comments. We recognize the value of permitting entities that participate directly in the provision of health care to patients and that have a need to coordinate with care providers to donate electronic health records items and services to facilitate those interactions. We take no action in this final rule to prohibit entities other than laboratory companies from utilizing the exception.

Comment: Some commenters agreed with the option we presented in the proposed rule to retain the ability of any DHS entity to donate electronic health records items and services, except suppliers of ancillary services associated with a high risk of fraud and abuse. A few of these commenters suggested that a targeted approach would minimize the risk of unintended consequences. One of these commenters asserted that we should exclude the particular individuals or entities that have been the subject of complaints. Another of these commenters specifically recommended that we target categories of suppliers with a history or pattern of abusive behavior.

Other commenters variously recommended excluding laboratories, DME suppliers, home health agencies, or safety net providers from the types of entities that may donate electronic health records items and services under the exception. One commenter asserted that entities like laboratory companies and DME suppliers do not have an overarching and essential interest in having physicians use electronic health records, nor do they coordinate the patient's care. In contrast, one commenter objected to singling out a provider or supplier type to exclude from the scope of protected donors. This commenter stated that such an action unjustly: (1) penalizes a whole category of providers or suppliers when most, in the commenter's assessment, are law-abiding; and (2) supports other providers or suppliers that may have similar motivations.

Response: We respond elsewhere in this final rule to the commenters who expressly recommended removing only laboratory companies from the universe of permissible donors. With respect to the other commenters, we note that, in the proposed rule (78 FR 21312), we specifically requested comments, "with supporting reasons," regarding whether particular provider or supplier types should be prohibited from utilizing the exception at § 411.357(w). Some commenters suggested that we prohibit other types of entities from donating electronic health records items and services under the exception, but the comments did not provide specific examples of abusive practices with respect to donations of electronic health records items and services by such donors, nor did the comments indicate problems with other types of entities comparable to those that are arising in the context of laboratory companies. Finally, we do not agree with the commenters that laboratory companies, DME suppliers, home health agencies, safety net providers, or, for that matter, any other "ancillary" service providers necessarily do not have an overarching and essential interest in having physicians use electronic health records, or that they do not coordinate the patient's care. It is the behavior of laboratory companies and physician recipients of donations from laboratory companies of which we are aware that drives our determination to finalize our proposal to exclude laboratory companies from the types of entities that may provide donations under the exception. We have not heard the same concerns about other categories of donors or types of donation arrangements and, therefore, believe it is premature to exclude potential donors (other than laboratory companies). We also decline to identify particular individuals or organizations in the regulation.

Comment: A few commenters recommended restricting the entities that may donate electronic health records items and services under the exception to those types listed in the MMA. These commenters also suggested imposing additional restrictions on donations from this limited universe of donors. For example, one commenter recommended limiting the application of the exception to hospitals and providers operating in an integrated setting and to MA plans and providers under contract with them. Another commenter suggested limiting the application of the exception to a similar integration model, and to hospitals that donate electronic health records items and services to their employed physicians and the physician groups that they own. In contrast, one

commenter suggested that limiting the protected donor types to the original MMA list would be too restrictive. The commenter believed that some provider types not listed in the MMA should have the opportunity to make donations (for example, ambulatory surgical centers that now perform many procedures previously only performed in hospitals).

Response: We agree that providers and suppliers operating in an integrated environment need interoperable electronic health records. However, we do not believe that the need for this technology is limited to those individuals and entities in an integrated care setting. Patients may receive care from providers and suppliers that are not in the same integrated system, and the patient's medical records need to be shared with those providers and suppliers that also care for the patient. The Department's goal continues to be fostering broad adoption of interoperable electronic health records technology. In furtherance of that goal, we seek to limit the applicability of the exception vis-à-vis permissible donors only to the extent necessary to prevent program and patient abuse. At this time, we believe that excluding laboratory companies from the types of entities that may utilize the electronic health records exception, rather than limiting the universe of permissible donors to the MMA list of donors (or some other subset of permissible donors) strikes the right balance between furthering the Department's goal and preventing program and patient abuse.

2. Data Lock-In and Exchange

We solicited comments on what new requirements could be added to, or how we could modify existing requirements of, the exception at § 411.357(w) in order to achieve our goals of: (1) preventing misuse of the exception that results in data and referral lock-in; and (2) encouraging the free exchange of data (in accordance with protections for privacy). Additionally, we requested comments on whether such requirements, if any, should be in addition to, or in lieu of, our proposal to limit the entities whose donations of electronic health records items and services may qualify for protection under the exceptions. Finally, we solicited comments on possible modifications to § 411.357(w)(3), which requires that, in order to qualify for the protection of the exception, "[t]he donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems." We solicited these comments to explore whether this requirement could be modified to reduce the possibility of data and referral lock-in.

Comment: Many commenters asserted that the current requirements of the exception provide adequate safeguards to prevent donations of electronic health records items and services that result in data or referral lock-in between the donor and physician recipient. These commenters expressed general support for the investigation of arrangements that may not satisfy the requirements of the exception. Several of these commenters were also concerned that adding or modifying requirements may increase the burden of compliance and, therefore, lead to fewer entities willing to make appropriate donations of electronic health records items and services.

Response: In general, we agree with these commenters. We are not persuaded to adopt significant new requirements or modifications to the exception to address the issue of data or referral lock-in. In addition, we do not wish to take any action that inadvertently discourages donors and physician recipients from entering into appropriate donation arrangements. However, we are making limited clarifications to § 411.357(w)(3) to reflect our intended meaning of this requirement and our interpretation of existing requirements for interoperability as it pertains to potential data or referral lock-in. We also remain committed to assisting our law enforcement partners in the investigation of potentially abusive arrangements that purport to satisfy the requirements of the exception but, in fact, do not.

Comment: Several commenters expressed concerns about donations of electronic health records items and services that lead to data lock-in. As described elsewhere in this final rule, some commenters suggested that, although some donated electronic health records software has the ability to be interoperable, vendors may charge providers who do not use the same donated software high fees to interface with it. The commenters contended that these business practices result in electronic health records software that is not practically interoperable because non-donor providers cannot afford to connect to the donated electronic health records items and services. Other commenters expressed general concerns that donated electronic health records items or services are capable of interoperation, but that physician recipients implicitly agree to send referrals using the technology only to the donor. These commenters did not provide specific recommendations to modify the data lock-in requirements of the exception, but generally supported our efforts to prevent data lock-in.

Two commenters representing laboratory companies expressed specific concerns about a feature of donated software that may lead to data lock-in. These commenters explained that some software is designed to limit the accessibility of data that is received from an electronic health records system that is different than the donated software. Most often, data sent from the non-donated electronic health records system cannot populate automatically in a patient's electronic health record or other limits are placed on the portability of data sent from the non-donated electronic health records system. According to these commenters, the limited accessibility of the data makes it harder for the physician recipient to access and use it for clinical purposes. As a result, a physician recipient is more likely to utilize only the donor's services to make sure that necessary data is easily accessible. These commenters asserted that there are no technical solutions to reducing the possibility of data lock-in; rather, the only solution is to remove laboratory companies from the types of entities whose donations may be protected under § 411.357(w).

Several other commenters generally endorsed our efforts to prevent data and referral lock-in. These commenters evidenced strong support for the free exchange of health information across different provider types to better coordinate care for patients. However, apart from supporting our efforts to ensure that electronic health records systems are interoperable, the commenters made no specific recommendations regarding modifications to the exception.

Response: We share the commenters' concerns about the interoperability of donated electronic health records software. Arrangements involving the donation of electronic health records software that has limited or restricted interoperability due to action taken by the donor or by any person on the donor's behalf (which could include the physician recipient acting on the donor's behalf) would fail to satisfy the requirement at § 411.357(w)(3) and would be inconsistent with an important purpose of the exception, which is to promote the use of technology that is able to communicate with products from other vendors. For example, arrangements in which the donor takes an action to limit the use,

communication, or interoperability of the electronic health records items or services by entering into an agreement with the physician recipient to preclude or inhibit any competitor from interfacing with the donated items or services would not satisfy the requirement of § 411.357(w)(3). Other donation arrangements described by the commenters in which electronic health records technology vendors charge high interface fees to non-recipient providers or competitors may also fail to satisfy the requirements of § 411.357(w)(3). We believe that any action taken by a donor (or any person on behalf of the donor, including the electronic health records technology vendor or the physician recipient) to limit the use of the donated electronic health records items or services by charging fees to prevent non-recipient providers and the donor's competitors from interfacing with the donated items or services would pose legitimate concerns that parties were improperly locking in data and referrals, and that the arrangement in question would not satisfy the requirements of the exception. However, whether a donation actually satisfies the requirements of the exception depends on the specific facts of the donation arrangement.

Comment: One commenter expressed concern regarding data lock-in and supported ensuring that donations of electronic health records items and services are transparent and free of any attempts to steer future business. Although it denied knowledge of any specific abuse of the exception, the commenter requested that we allow individuals or entities to remedy noncompliance with the physician self-referral law due to a donation that may not be protected by the exception. The commenter suggested that the remedy for violation of the physician self-referral law due to an arrangement's failure to satisfy the requirements of the exception at § 411.357(w) should be to make physician recipients pay the fair market value of any costs for ongoing support of the donated electronic health records items or services. The commenter suggested allowing 3 years for the physician recipient to either pay full value for the donated electronic health records items and services or transition to a new system.

Response: We appreciate the commenter's concern and recommendation; however, we decline to make the suggested modification. Implementing the commenter's suggestions would be outside the scope of our statutory authority under section 1877(b)(4) of the Act to promulgate exceptions to the physician self-referral law that pose no risk of program or patient abuse.

Comment: A few commenters urged us to amend the exception to require the physician recipient or the donor to participate in health information exchange with an electronic health records system that is different from the one donated. One commenter specifically suggested that the physician recipient should have to demonstrate exchange with at least one other electronic health records system within a certain timeframe after receipt of the donation. Another commenter suggested that the donor should have to—upon request—enable the physician recipient of the donation to engage in bi-directional exchange of data with competitors not using the same electronic health records system.

Response: We appreciate the commenters' recommendations; however, we are not modifying the exception to require the parties to an arrangement for the donation of electronic health records items and services to demonstrate interoperation. We question whether adequate demonstration of interoperation could occur only after the donation has been made, which would create uncertainty about whether the donation satisfies the requirements of the exception. This uncertainty would undermine the Department's broad goal for the exception—that is, to support widespread adoption of interoperable electronic health records technology. However, it is our intent and expectation that interoperation of donated items and services will, in fact, occur, and we believe the requirements of the exception, in their entirety, promote such interoperation. Moreover, routine interoperation with systems other than those of the donor may be evidence that neither the donor nor any person on the donor's behalf has taken any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems, as required under § 411.357(w)(3).

Further, we note that the Department is considering a number of policies to accelerate and advance interoperability and health information exchange. As part of this process, ONC and CMS issued a notice requesting input from the public on possible policies and programmatic changes to accelerate electronic health information exchange among individuals and entities that furnish health care items and services, as well as new ideas that would be both effective and feasible to implement (78 FR 14793). We believe that the process through which ONC and CMS will jointly act is better-suited than this exception to consider and respond to evolving functionality related to the interoperability of electronic health records technology. The paper that addresses the public comments we received and outlines the Department's strategy for accelerating health information exchange is available at: *http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie.*

Comment: In response to our solicitation of comments, some commenters provided suggestions as to how we could broaden the current requirements related to data lock-in. Two commenters suggested amending § 411.357(w)(3), which prohibits the donor (or any person on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other "electronic prescribing or electronic health records systems." Specifically, the commenters suggested that we replace the reference to "electronic prescribing or electronic health records systems" with "health information technology platforms or other health care providers." The commenters asserted that this proposed change reflects the development of health information technology that may not be classified as an electronic health records system, but supports the free exchange of health information. These two commenters also suggested that we modify § 411.357(w)(3) to state that neither the donor *nor the physician recipient* may take any action to limit the interoperability of donated electronic health records items or services and that we require that the modified condition be included as part of the written agreement required under § 411.357(w)(7).

Another commenter suggested amending § 411.357(w)(3) by providing a non-exhaustive list of actions that would cause a donation not to satisfy this requirement and by establishing a process for entities to provide the Department with information about potential abuses of the exception. A representative of several health plans suggested modifying the exception to ensure that, in the context of health information exchange, the interoperability requirement of the exception requires that all key stakeholders, including health insurance plans, have access to the health information exchange. The commenter suggested that we modify the interoperability condition at 42 CFR 411.357(w)(2) to prohibit restrictions on the communication and exchange of

data with any covered entity as defined at 45 CFR 160.103.

Response: The language in the existing regulatory text prohibits donors (or persons on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of donated items or services with other "electronic prescribing or electronic health records systems." The term "electronic prescribing or electronic health records systems" was intended to be broad in order to account for developments in the health information technology industry. Based on the commenters' suggestions it appears, however, that stakeholders may have read this term more narrowly. This narrow reading is inconsistent with our intended meaning. We have always believed and continue to believe that an action taken by a donor (or on behalf of the donor) that limits the use, compatibility, or interoperability of donated items or services with *any other health information technology* may impede the free exchange of data and limit the ability of providers and suppliers to coordinate care, which is inconsistent with the goals of the exception. Therefore, we are clarifying 42 CFR 411.357(w)(3) by adding, by way of example and without limitation, a non-exhaustive list of some of the forms of technologies that we believe are included within the meaning of the existing regulatory language. We are not adopting the commenters' suggested edit, as we do not believe that it is necessary in light of our clarification. We also decline to modify 42 CFR 411.357(w)(2) to prohibit restrictions on the communication and exchange of data with any covered entity as defined at 45 CFR 160.103. We believe that existing 42 CFR 411.357(w)(3), which we have clarified in this final rule as including health information technology applications, products, or services, promotes interoperability with a variety of providers and suppliers, as well as other health care entities that may play a role in the coordination of care, including health plans that operate health information technology applications, products, or services.

We are also not adopting the commenters' suggestion to modify the exception to state that neither the donor nor the physician recipient may take any action to limit the interoperability of donated electronic health records items or services. The requirement at § 411.357(w)(3) prohibits the donor (or any person on behalf of the donor) from taking any action that limits or restricts the use, compatibility, or interoperability of the donated electronic health records items or services. To the extent that a physician recipient takes an action on the donor's behalf to limit the use, compatibility, or interoperability of donated items or services, that donation would fail to qualify for protection under the exception. Because we see no obvious reason, other than at the behest of the donor or as a condition of the donation, why a physician recipient would take action to limit the use, compatibility, or interoperability of donated items or services, we believe that any action of this type by a physician recipient would be suspect. We are not making the suggested modification because we believe the concern articulated by the commenters is already addressed by the existing regulatory language and the policies we are adopting in this final rule. Accordingly, we are not making any corresponding revisions to require that the recommended provision be incorporated into the written agreement required under § 411.357(w)(7).

Finally, we are not revising the exception to provide in regulation text examples of actions that may cause a donation not to satisfy the requirements of § 411.357(w)(3). Whether a donation satisfies the requirements of the exception requires a case-by-case analysis and depends on the specific facts of the donation.

Comment: One commenter objected to the use of the exception to address the issue of data lock-in. The commenter contended that data lock-in may arise in response to legitimate concerns, such as the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules, liability issues, licensing requirements, and antitrust issues. Further, according to the commenter, data lock-in conditions may cause uncertainty for donors because parties may not be able to determine whether a donation satisfies the requirements of the exception until after donation.

Response: Nothing in this final rule is intended to prohibit legitimate actions taken to ensure that electronic health records items and services appropriately protect data, including measures to ensure the privacy and security of health information data. We recognize that there may be appropriate security, privacy and other business reasons to protect data. This final rule addresses only actions that inappropriately lock in data, for example, locking in data to secure future referrals.

Comment: One commenter expressed support for preventing electronic health records data lock-in and the free exchange of data. However, the commenter did not agree that additional requirements designed to promote these goals would be effective. Instead, the commenter suggested that we adopt payment models that continue to foster care coordination activities.

Response: We appreciate the commenter's suggestion; however, changes to our payment models are outside the scope of the proposed rule. We note that, in our joint Request for Information, we and ONC solicited input on options for improving several different CMS payment models to support better the adoption of interoperable electronic health records technology (78 FR 14797). As noted earlier, the paper that addresses the public comments we received and outlines the Department's strategy for accelerating health information exchange is available at: *http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie.*

Comment: Two commenters suggested data lock-in could be limited by requiring electronic health records software to be open or "open source." Both commenters asserted that open source software would limit data lock-in due to the transparent nature of open source software. In addition, it would lead to greater interoperability of electronic health records systems. One commenter also suggested that we require mandatory advance disclosure of the operational and business policies and practices associated with the electronic health records technologies. One commenter suggested that we adopt the e-DOS standard as certification criteria for electronic health records.

Response: Although we share the commenters' support for the free exchange of health information where appropriate protections for privacy and security exist, we are not adopting their recommendations because software certification criteria and standards are determined by ONC and are, therefore, outside the scope of this rulemaking.

3. Covered Technology

In the proposed rule, we noted that we received questions concerning whether certain items or services fall within the scope of the technology potentially covered under the exception at § 411.357(w). There, we stated that the answer to such questions depends on the exact items or services being donated. We referenced our discussion in the August 2006 final rule regarding our interpretation of the term "software, information technology and training services necessary and used predominantly." We stated that we believe that the current regulatory text, when read in light of the preamble discussion, is sufficiently clear concerning the scope of covered

technology. Nonetheless, because we received suggestions from stakeholders to modify § 411.357(w) to reflect explicitly this interpretation, in the proposed rule (78 FR 21313), we sought comments from the public regarding this issue. After considering the public comments with respect to this issue, we determined not to make any changes to the regulation text to address the scope of covered technology.

Comment: Several commenters stated that the regulatory text describing the scope of technology covered by the exception, when read in light of the August 2006 final rule preamble, is sufficiently clear. One of these commenters urged us not to revise the regulation in any way that might limit the scope of covered technology, limit the ability of donors and physician recipients in the design and selection of items and services, or create barriers to achieving interoperability. Other commenters agreed that the current definition of covered technology is appropriate, with two of these commenters suggesting that we revisit the definition in the future as health information technology evolves. Still other commenters asserted that the existing regulatory language can be interpreted to include "services that enable the interoperable exchange of electronic health records data;" thus, no revisions to the regulatory text are required. In contrast, one commenter suggested that we incorporate into the regulatory text the preamble language from the August 2006 final rule where we discussed examples of items and services that would qualify for coverage under the exception. Another commenter suggested that we revise the regulatory text to include as many examples of covered "software, information technology and training services" as possible while emphasizing that the list is not exhaustive.

Response: We agree that maintaining flexibility is important, particularly as health information technology evolves. We endeavor to avoid revisions to the regulation text that could inadvertently narrow the exception, which is intended to promote the adoption of interoperable electronic health records technology. Moreover, our interpretation of what is covered by the exception has not changed. As we stated in the proposed rule (78 FR 21313), whether specific items or services fall within the scope of covered technology under the exception depends on the exact items or services that are being donated. If the "services that enable the interoperable exchange of electronic health records data" are of the type that do not meet the requirements for covered technology (for example, because they include hardware, storage devices, or have core functionality other than electronic health records), they would not be eligible for protection under the exception at § 411.357(w).

For these reasons, we are not revising the regulation text at § 411.357(w) to identify any specific types of items or services that may be donated if the other requirements of the exception are satisfied. We are also not modifying the examples identified in the preamble discussion in the August 2006 final rule (71 FR 45151). The exception continues to protect nonmonetary remuneration in the form of software, information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

Comment: A few commenters requested clarification regarding whether third-party fees related to the exchange of health information, such as health information exchange service charges for interconnectivity, are "covered technologies" under the exception.

Response: The exception protects only *nonmonetary* remuneration, in the form of software and information technology and training services, that is necessary and used predominantly to create, maintain, transmit, or receive electronic health records. Whether particular items or services, such as interconnectivity services, may be donated under the exception depends on the exact items or services being donated.

Comment: One commenter suggested that, in addition to maintaining as much flexibility as possible, we broaden the scope of the technology covered by the exception to include software and services used for care coordination, quality measurement, improving population health, or improving the quality or efficiency of health care delivery among parties. The commenter noted that some of these items may be covered by the waivers issued in connection with the Medicare Shared Savings Program (MSSP); however, because those waivers extend only to parties participating in that program, protection for the donation of items or services that advance the Department's goal of encouraging the adoption of health information technology that supports public policy objectives is not available to other health care industry stakeholders. To advance these goals in a broader way, the commenter suggested that the exception be expanded to include items potentially covered by the MSSP pre-participation waiver, such as electronic health information exchanges that allow for electronic data exchange across multiple platforms, data reporting systems (including all-payer claims data reporting systems), and data analytics (including staff and systems, such as software tools, to perform analytic functions). Another commenter suggested that we broaden the scope of technology covered by the exception to include software separate from the certified electronic health records software as long as it is interoperable with the electronic health records software. The commenter gave as examples of such electronic health records-associated components "patient portals that support patient engagement, direct and other standards-compliant means for secure patient information exchange between providers, solutions to support transition care, and tools that may assist in inter- and intra-patient matching." A third commenter urged us to consider a broader array of covered technologies, provided that they support policy goals such as reducing hospital readmissions and coordinated care across settings outside of traditional office settings, including telemonitoring and telemedicine. Another commenter suggested that we expand the protection of the exception to cover "any additional items or services that will be required or helpful in meeting Stage 2 or Stage 3 requirements for [the EHR Incentive Programs]."

Response: As stated previously, whether specific items or services fall within the scope of covered technology under the exception at § 411.357(w) depends on the exact items or services that are being donated. Some of the particular items and services that may be included within the broad categories identified by the commenters may be eligible for donation. For example, if a particular software product related to transitions of care was necessary and used predominantly to create, maintain, transmit, or receive electronic health records, then it would be eligible for donation, provided that the donation satisfied all of the other requirements of the exception. As noted previously in this final rule, software is not required to be certified to ONC certification criteria in order to be donated under the exception at § 411.357(w). Thus, software that is separate from certified software may still be eligible for donation if it satisfies the definition of "interoperable" at § 411.351.

To the extent that the commenters suggested that we expand the scope of the exception to protect items and services that are not already eligible for donation, we note that revision of the exception to include such items or services would be outside the scope of

this rulemaking. In the proposed rule (78 FR 21313), with respect to the scope of technology potentially covered by the exception, we sought input from the public regarding the singular issue of "whether the current regulatory text, when read in light of the preamble discussion, is sufficiently clear concerning the scope of covered technology." With regard to whether the scope of the technology covered under the exception should be broadened—as opposed to clarified—we are mindful of the important issues raised by the commenters and may consider them in the future. Further, we note that other exceptions to the physician self-referral law exist to protect financial relationships between physicians and entities furnishing DHS. Depending on the circumstances, some of the arrangements described by the commenters may satisfy the requirements of another exception or may not implicate the physician self-referral law.

Comment: One commenter suggested that we define "equivalent technology" for purposes of the requirement in the exception that the donor of electronic health records items or services may not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the physician recipient possesses or has obtained items or services equivalent to those being donated. This commenter also suggested that we prohibit a physician from seeking or accepting a donation of electronic health records technology before a certain period of time has elapsed since the receipt of a previous donation. Another commenter urged us to eliminate maintenance and service agreements from the scope of potentially protected donations under the exception. In the alternative, the commenter suggested that we impose a restriction on the time period that donations of such services would be permitted. The commenter noted concerns that donors may use ongoing donations of maintenance and service agreements to lock in referrals from physician recipients. A commenter that urged us not to extend the availability of the exception suggested that we prohibit the donation of all technology except interfaces for reporting of laboratory results.

Response: Although we appreciate the commenters' suggestions, we are not making the requested changes. We believe that the modifications to and clarifications of § 411.357(w) adopted in this final rule and the clarifications offered in this preamble address the concerns raised by these commenters.

Comment: One commenter asserted that the prohibition on donating equivalent items or services currently included in the exception locks physician practices into a vendor, even if they are dissatisfied with the technology, because the physician recipient must choose between paying the full amount for a new system and continuing to pay 15 percent of the cost of the substandard system. The commenter asserted that the cost differential between these two options is too high and effectively locks physician practices into electronic health records technology vendors.

Response: Although we appreciate the commenter's concern, we continue to believe that items and services are not "necessary" if the physician recipient already possesses equivalent items or services. As we stated in the August 2006 final rule (71 FR 45154), "the provision of equivalent items and services poses a heightened risk of abuse, [because] such arrangements potentially confer independent value on the physician recipient (that is, the value of the existing items and services that might be put to other uses) unrelated to the need for electronic health records technology." Therefore, we are retaining the regulatory preclusion of protection for donation arrangements where the donor has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the physician recipient possesses or has obtained equivalent items or services. We expect that physicians would not select or continue to use a substandard system if it posed a threat to patient safety.

Comment: One commenter referenced the proposed rule's statement that "software or information technology and training services necessary and used predominantly for electronic health records purposes" included "information services related to patient care (but not separate research or marketing support services)" (78 FR 21313). The commenter requested that we retract that statement and clarify that it is appropriate for health researchers to use data in electronic health records for research that is related to, for example, evidence-based medicine, population management, or other research, provided that the use complies with applicable Federal, state, and institutional requirements.

Response: We decline to retract our statement in the proposed rule. To promote adoption of electronic health records without risk of abuse, the scope of items and services permitted to be donated under the exception is limited to electronic health records items and services in the form of software and information technology and training services that are "necessary and used predominantly to create, maintain, transmit, or receive electronic health records." Donations of software used for research that is separate from clinical support and information services related to patient care are not consistent with the primary goals of the exception.

The exception at § 411.357(w) addresses only the donation of electronic health records items and services, and not the use of data. Thus, the portion of the comment related to data use is outside the scope of this rulemaking. We note, however, that nothing in the exception prohibits the use of data in electronic health records systems for research purposes (assuming the parties comply with all other applicable laws, including HIPAA privacy protections).

Comment: One commenter requested that CMS confirm that patient portals are within the scope of the technology potentially protected by the exception.

Response: We are not certain what the commenter precisely means by "patient portals." Patient portals come in a variety of forms; the key to the analysis is whether the specific item or service donated is: (1) In the form of software, information technology and training services and; (2) necessary and used predominantly to create, maintain, transmit or receive electronic health records. As we stated in the August 2006 final rule in response to a commenter's recommendation that the exception specifically protect the provision of patient portal software that enables patients to maintain on-line personal medical records, including scheduling functions (71 FR 45152), nothing in the exception precludes protection for patient portal software if it satisfies all of the requirements of the exception.

E. Comments Outside the Scope of This Rulemaking

In addition to the comments described and to which we responded previously, we received several comments from stakeholders, including suggestions on policy changes, that are outside the scope of this rulemaking. For example, one commenter raised concerns about a private insurer's proposed fee schedule for laboratory services. Another commenter expressed concern about "outrageous bills" the commenter received from a laboratory company. Although we appreciate the commenters taking the time to present these concerns, we do not address them here, as they are outside the scope of this rulemaking.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the proposed revisions stated in the proposed rule. Specifically, we are revising the exception to exclude laboratory companies from the types of entities that may donate electronic health records items and services under the exception, and are modifying the regulation text at § 411.357(w)(1) to effectuate this change. We are also amending § 411.357(w)(2) by deleting the phrase "recognized by the Secretary" and by replacing it with the phrase "authorized by the National Coordinator for Health Information Technology" and replacing the 12-month timeframe for certification of electronic health records software with a requirement that the software be certified to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170 (ONC's certification program). We are clarifying the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services. In addition, we are eliminating the requirement at § 411.357(w)(11) that donated electronic health records software include electronic prescribing capability. Finally, we are modifying § 411.357(w)(13) to extend the expiration of the exception from December 31, 2013 to December 31, 2021.

V. Waiver of the Delay in the Effective Date

Ordinarily, we provide a delay of at least 30 days in the effective date of a final rule after the date that the rule is issued. However, the 30-day delay in effective date can be waived if the rule grants or recognizes an exemption or relieves a restriction. We believe that it is appropriate to waive the 30-day delay in effective date for § 411.357(w)(13), which relieves a restriction on donations of electronic health records items and services. Specifically, this final rule amends § 411.357(w)(13) to extend the expiration of the existing exception from December 31, 2013 to December 31, 2021. Without a waiver of the requirement for a delayed effective date, the entire exception will expire on December 31, 2013 and will not be available to protect any ongoing donation arrangements or new donations of electronic health records items and services made to physicians after December 31, 2013. By waiving the 30-day delay in effective date, the exception will not expire, thereby allowing parties to continue utilizing the exception to protect donations of electronic health records items and services. We stress, however, that donations of electronic health records items and services that occur between January 1, 2014 and the effective date of the remaining provisions of this final rule (March 27, 2014) will need to satisfy all of the requirements of the existing exception. The waiver of the 30-day delay in effective date simply serves to maintain the status quo until the rest of this final rule becomes effective.

The 30-day delay in effective date can also be waived if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and reasons in the rule issued. We find that it is unnecessary to provide a 30-day delay in effective date for § 411.357(w)(13) because an earlier effective date simply allows parties to continue making donations under the existing electronic health records items and services exception; it does not impose any new requirements or restrictions on potentially affected parties. Moreover, we find that a 30-day delayed effective date for § 411.357(w)(13) is impracticable because it would cause the entire exception to expire, thereby nullifying this final rule.

VI. Collection of Information Requirements

The provisions in this final rule will not impose any new or revised information collection, recordkeeping, or disclosure requirements. Consequently, this rule does not need additional Office of Management and Budget review under the authority of the Paperwork Reduction Act of 1995.

VII. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We believe that this final rule does not reach the economic threshold for being considered economically significant and, thus, is not considered a major rule. It is not economically significant because it will not have a significant effect on program expenditures, and there are no additional substantive costs to implement the resulting provisions. The rule modifies an existing exception to the physician self-referral law, and the modifications would not impose additional substantive costs on those seeking to utilize the exception. Further, the donation of electronic health records items or services and the use of the exception to protect such donations is entirely voluntary. In section III. of this final rule, we provide a detailed discussion and analysis of the alternatives considered in this final rule, including those considered for extending the expiration date of the electronic health records exception, limiting the types of entities that may donate electronic health records items and services, and tying the timeframe for deeming electronic health records software to ONC's certification program. Finally, we received no public comments specific to the RIA set forth in the proposed rule.

This final rule extends the exception's expiration date to December 31, 2021; excludes laboratory companies from the types of entities that may donate electronic health records items and services; updates the provision under which electronic health records software is deemed interoperable; clarifies the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services; and removes the requirement related to electronic prescribing capability. Neither this final rule nor the regulations it amends requires any entity to donate electronic health records items and services to physicians, but we expect these changes to continue to facilitate the adoption of electronic health records technology by eliminating perceived barriers rather than creating the primary means by which physicians would adopt this technology.

The summation of the economic impact analysis regarding the effects of electronic health records in the ambulatory setting that is presented in

the August 2006 final rule (71 FR 45164) still pertains to this final rule. However, since the August 2006 final rule, several developments have occurred to make us conclude that it is no longer necessary to retain a requirement related to electronic prescribing capability in the electronic health records exception. These developments include the passage of two laws encouraging adoption of electronic prescribing and electronic health records: (1) the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Public Law 110–275; and (2) the Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111–5. In addition, there has been an increase over the past few years in the rate of electronic health records-based electronic prescribing capabilities.[3]

As discussed in more detail in the preamble to the proposed rule, section 132 of MIPPA authorized an electronic prescribing incentive program (starting in 2009) for certain types of eligible professionals. The HITECH Act authorized us to establish the EHR Incentive Programs for certain eligible professionals, eligible hospitals, and critical access hospitals. Also, the HITECH Act required that eligible professionals under the EHR Incentive Programs demonstrate meaningful use of certified electronic health records technology, including the use of electronic prescribing. Specifically, the final rule for Stage 2 EHR Incentive Programs (September 4, 2012; 77 FR 53968) includes more demanding requirements for electronic prescribing and identifies electronic prescribing as a required core measure. As a result, beginning in calendar year 2015, an eligible professional risks a reduction in the Medicare Physician Fee Schedule payment amount that will otherwise apply for covered professional services if he or she is not a meaningful electronic health records technology user for a reporting period during that year. Our intent remains to allow physicians not to receive products or services they already own, but rather to receive electronic health records items and services that advance the adoption and use of electronic health records. Lastly, according to ONC, electronic prescribing by physicians using electronic health records technology has increased from 7 percent in December 2008 to approximately 48 percent in June 2012.[4] Furthermore, the rules recently published to implement Stage 2 of the EHR Incentive Programs (77 FR 54198 and 77 FR 53989), continue to encourage physicians' use of electronic prescribing technology. However, due to data limitations, we are unable to estimate accurately how much the electronic health records exception has contributed to the increase in electronic prescribing. Nevertheless, we believe that, as a result of recent developments, physician adoption of electronic prescribing and electronic health records technology will continue to increase despite removal of the electronic prescribing capability requirement in the electronic health records exception.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million to less than $35.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. This final rule does not result in an economic effect on small entities of 3 to 5 percent or more of their total revenues or costs. As a result, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The Secretary has determined that this final rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals (that is, an effect of more than 3 to 5 percent of their total revenues or costs).

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This final rule imposes no mandates and, as a result, will have no consequential effect on State, local, or tribal governments, or on the private sector, of $141 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. For the reasons stated earlier, this final rule will not have a substantial effect on State or local governments, nor does it preempt State law or have Federalism implications.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects for 42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 411 as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 2. Section 411.357 is amended as follows:

■ A. Revising paragraphs (w)(1) through (3).

■ B. Removing and reserving paragraph (w)(11).

■ C. In paragraph (w)(13), removing the date "December 31, 2013" and adding the date "December 31, 2021" in its place.

The revision reads as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(w) * * *

(1) The items and services are provided to a physician by an entity (as defined at § 411.351) that is not a laboratory company.

[3] See, for example, State Variation in E-Prescribing Trends in the United States, available at *http://www.healthit.gov/sites/default/files/us_e-prescribingtrends_onc_brief_4_nov2012.pdf.*

[4] See, for example, State Variation in E-Prescribing Trends in the United States, available at *http://www.healthit.gov/sites/default/files/us_e-prescribingtrends_onc_brief_4_nov2012.pdf.*

(2) The software is interoperable (as defined in § 411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services).

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 5, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 12, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–30923 Filed 12–23–13; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 95

[ET Docket No. 08–59; FCC 12–54]

Medical Body Area Networks

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission ("Commission") announces that certain rules revised in the "Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks" adopted in a *First Report and Order,* ET Docket No. 08–59 (FCC 12–54), to the extent it contained information collection requirements that required approval by the Office of Management and Budget (OMB) was approved on October 26, 2013. This document is consistent with the *First Report and Order,* which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules.

DATES: The amendments to 47 CFR 95.1215(c), 95.1217(a)(3), 95.1223 and 95.1225 published at 78 FR 55715, September 11, 2012 are effective December 27, 2013. In addition the incorporation by reference listed in 47 CFR 95.1223 of the rules is approved by the Director of the Federal Register as of December 27, 2013.

FOR FURTHER INFORMATION CONTACT: Nancy Brooks, Policy and Rules Division, Office of Engineering and Technology, at (202) 418–7866, or email: *Nancy.Brooks@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that, on November 26, 2013 OMB approved, for a period of three years, the revised information collection requirements relating to Spectrum for the Operation of Medical Body Area Networks rules contained in the Commission's *First Report and Order,* FCC 12–54, published at 78 FR 55715, September 11, 2012. The OMB Control Number is 3060–0936. The Commission publishes this document as an announcement of the effective date of the rules.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received final OMB approval on November 26, 2013, for the information collection requirements contained in the modifications to the Commission's rules in 47 CFR part 95.

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0936.

The foregoing document is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control No.: 3060–0936.

OMB Approval Date: November 26, 2013.

OMB Expiration Date: November 30, 2016.

Title: Sections 95.1215, 95.1217, 95.1223 and 95.1225—Medical Device Radiocommunications Service (MedRadio).

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit and not-for-profit institutions.

Number of Respondents: 3,120 respondents; 3,120 responses.

Estimated Time per Response: 1–3 hours.

Frequency of Response: On occasion reporting requirement, third party disclosure requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151 and 303 of the Communications Act of 1934, as amended.

Total Annual Burden: 9,120 hours.

Total Annual Cost: $462,600.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: No information is requested that would require assurance of confidentiality.

Needs and Uses: The Commission received approval from the Office of Management and Budget (OMB) to revise OMB 3060–0936 to reflect new and/or modified information collections as a result of a *First Report and Order.*

On May 24, 2012, the Commission released a Report and Order, ET Docket No. 08–59, FCC 12–54, titled: "Amendment of the Commission's rules to Provide Spectrum for the Operation of Medical Body Area Networks", these rules revised the requirements for manufacturers of transmitters for the "Medical Device Radiocommunication Service" to include with each transmitting device a statement regarding harmful interference and to label the device in a conspicuous location on the device. The *First Report and Order* also adopted rules for "Medical Body Area Network" (MBAN), which requires the Commission to establish a process by which MBAN users will register and coordinate the use of certain medical devices. The frequency coordinator will make the database available to equipment manufacturers and the public. The coordinator will also notify users of potential frequency conflicts.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2013–30649 Filed 12–26–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130312236–3999–02]

RIN 0648–BD05

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery Off the Southern Atlantic States; Amendment 27

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 27 (Amendment 27) to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP), as prepared and submitted by the South Atlantic Fishery Management Council (South Atlantic Council). Amendment 27 and this final rule extend the South Atlantic Council's management responsibility for Nassau grouper into the Gulf of Mexico (Gulf) exclusive economic zone (EEZ); increase the number of allowable crew members to four on dual-permitted snapper-grouper vessels (*i.e.*, vessels holding a South Atlantic Charter Vessel/Headboat Permit for Snapper-Grouper and a commercial South Atlantic Unlimited or a 225-Pound Trip Limit Snapper-Grouper Permit) that are fishing commercially; remove the prohibition on retaining any fish under the aggregate bag limit for grouper and tilefish or the vermilion snapper bag limit by captains and crew of federally permitted for-hire vessels; modify the snapper-grouper framework procedures to allow acceptable biological catch levels (ABCs), annual catch limits (ACLs), and annual catch targets (ACTs) to be adjusted via an abbreviated framework process; and remove blue runner from the FMP. The purposes of this final rule are to streamline management of Nassau grouper, improve vessel safety for dual-permitted vessels, implement consistent regulations regarding captains and crew retention limits for snapper-grouper species, expedite adjustments to snapper-grouper catch limits when new scientific information becomes available, and minimize socio-economic impacts to fishermen who harvest and sell blue runner.

DATES: This rule is effective January 27, 2014.

ADDRESSES: Electronic copies of Amendment 27, which includes an environmental assessment, a regulatory flexibility act analysis and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Kate Michie, telephone: 727–824–5305, or email: *kate.michie@noaa.gov*.

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic is managed under the FMP. The FMP was prepared by the South Atlantic Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On September 18, 2013, NMFS published a notice of availability for Amendment 27 and requested public comment (78 FR 57337). On September 27, 2013, NMFS published a proposed rule for Amendment 27 and requested public comment (78 FR 59635). NMFS approved Amendment 27 on December 16, 2013. The proposed rule and Amendment 27 outline the rationale for the actions contained in this final rule. A summary of the actions implemented by Amendment 27 and this final rule is provided below.

Management Measures Contained in This Final Rule

Extension of Management Authority for Nassau Grouper in the Gulf of Mexico to the South Atlantic Council

Amendment 27 and this final rule extend the South Atlantic Council management responsibility for Nassau grouper into Federal waters of the Gulf. The current restrictions on the harvest or possession of Nassau grouper in the Gulf EEZ and South Atlantic EEZ continue through this final rule.

Increase in Crew Member Limit for Dual-Permitted Vessels

This final rule increases the crew size limit from three to four persons on dual-permitted vessels (vessels with both a South Atlantic Charter Vessel/Headboat Permit for Snapper-Grouper and a commercial South Atlantic Unlimited or 225-Pound Permit for Snapper-Grouper) when operating commercially.

Removal of Captains and Crew Bag Limit Retention Restrictions for Snapper-Grouper Species

This final rule removes the current restriction that prohibits the captains and crew on a vessel operating as a charter vessel or headboat from retaining the bag limits of gag, black grouper, red grouper, scamp, red hind, rock hind, coney, graysby, yellowfin grouper, yellowmouth grouper, yellowedge grouper, snowy grouper, misty grouper, vermilion snapper, sand tilefish, blueline tilefish, and golden tilefish.

Modify the Framework Procedures in the Snapper-Grouper FMP

This final rule allows an ABC, ACL, and ACT to be modified using an abbreviated framework procedure. After the South Atlantic Council has taken final action to change an ABC, ACL, and/or ACT, the Council submits a letter with supporting data and information to the NMFS Southeast Regional Administrator (RA) requesting the desired change to those applicable harvest parameters. Based on the information provided by the South Atlantic Council, the RA determines whether or not the requested modifications may be warranted. If the requested modifications may be warranted, NMFS develops the appropriate documentation to comply with the National Environmental Policy Act (NEPA) and other applicable law, and proposes the action through rulemaking.

Remove Blue Runner From the FMP

Finally, this final rule removes blue runner from the FMP.

Comments and Responses

NMFS received 12 unique comment submissions on Amendment 27 and the proposed rule. The comments were submitted by one fishing association, one state agency, one environmental organization, one Federal agency, and eight individuals. One individual and one fishing association expressed general support for all the actions in the amendment. One individual and one environmental organization expressed support for the Framework Procedure modifications. Two individuals opposed, and one favored, allowing captains and crew to retain all snapper-grouper species. One individual opposed increasing the number of crew members on dual-permitted vessels. One state agency and one individual supported removing blue runner from the FMP, and one individual opposed extending the jurisdiction for Nassau grouper management. One comment was beyond the scope of the actions contained within the amendment. A summary of the comments and NMFS' responses to those comments appears below.

Comment 1: One commenter opposed extending the South Atlantic Council's

jurisdictional management authority of Nassau grouper into the Gulf.

Response: The South Atlantic Council's assumption of management authority of Nassau grouper throughout its range in the Southeast Region is consistent with Magnuson-Stevens Act National Standard (NS) 3, which states that an individual stock of fish shall be managed as a unit throughout its range, and NS 7 because it removes a duplication of management effort. The Gulf Council took action to remove Nassau grouper from the Gulf reef fish fishery management unit, for the purpose of allowing the South Atlantic Council to extend its area of jurisdiction for management of Nassau grouper to include Federal waters of the Gulf. Without the South Atlantic Council extending its jurisdiction for management of Nassau grouper into the Gulf, Nassau grouper would not be managed throughout its range. The majority of Nassau grouper are found in the South Atlantic Region; therefore, NMFS and both Councils determined that giving the South Atlantic Council sole regulatory authority over Nassau grouper in the Southeast Region is the most efficient arrangement for monitoring and managing the species.

Comment 2: Two commenters opposed allowing captains and crew of for-hire vessels (charter vessels and headboats) to harvest bag limit quantities of all snapper-grouper species because the recreational ACLs could be caught faster and could result in additional fishing pressure on the resource. One commenter supported allowing captains and crew of for-hire vessels to harvest bag limit quantities of all snapper-grouper species.

Response: For species with very low recreational ACLs (such as snowy grouper), allowing the captain and crew to retain bag limits may cause the ACL to be met earlier and reduce the amount of time private recreational anglers have access to certain species. However, the biological impacts analysis in Amendment 27 indicates the average increase in harvest of the most commonly landed snapper-grouper species under this action will be only 0.02 percent for the headboat sector and 0.35 percent for the charter vessel sector. These minor increases in harvest are not likely to result in a significantly accelerated pace of harvest compared to current harvest rates for most snapper-grouper species. Additionally, these negligible increases are unlikely to result in negative biological impacts, particularly since ACLs and accountability measures (AMs) are in place to prevent overfishing from occurring. Allowing crew members of for-hire vessels to harvest and retain bag limit quantities of gag, black grouper, red grouper, scamp, red hind, rock hind, coney, graysby, yellowfin grouper, yellowmouth grouper, yellowedge grouper, snowy grouper, misty grouper, vermilion snapper, sand tilefish, blueline tilefish, and golden tilefish will create consistent regulations for retention of all snapper-grouper species by for-hire captain and crew members in the South Atlantic. Therefore, in the South Atlantic, this action will eliminate confusion about retention restrictions for snapper-grouper species, and could help streamline enforcement efforts within this fishery.

Comment 3: One commenter opposed allowing a fourth crew member to work onboard dual-permitted vessels, because allowing the captains and crew to keep their bag limit would shorten the fishing seasons.

Response: This commenter is confusing two actions in the amendment. There is an action to remove the prohibition for captains and crew on for-hire vessels to retain the snapper-grouper bag limits (discussed in response to Comment 2), and there is an action to extend the maximum crew size limit on dual-permitted vessels from three to four. Currently, there is no restriction on the number of crew members on for-hire vessels, but there is a restriction on the number of crew members on vessels that have both a commercial vessel permit and a for-hire vessel permit for South Atlantic snapper-grouper. Allowing one additional commercial crew member to work onboard dual-permitted vessels may lead to increased efficiency of commercial fishing operations; however, the rate of harvest is not expected to substantially increase. Therefore, the addition of one crew member is not likely to result in snapper-grouper ACLs from being met earlier in the fishing season compared to the status quo.

The action to increase the crew size from three people to four on these dual-permitted vessels will resolve a conflict between the South Atlantic Council's maximum crew size restrictions (no more than three crew members) and the United States Coast Guard's minimum crew size requirements (at least four crew members) for vessels required to have a Certificate of Inspection. This action will increase safety onboard dual-permitted vessels because it allows crew members to properly use the buddy system (*i.e.*, diving as a pair instead of individually) while engaging in diving operations.

Additionally, allowing four crew members onboard dual-permitted vessels in the South Atlantic would create consistent regulations with those that apply in the Gulf of Mexico, which will benefit fishermen and the administrative environment by simplifying enforcement of the maximum crew size restriction.

Comment 4: One commenter supported more flexibility in management and minimizing regulatory delay in response to new stock assessments. One environmental organization supported the abbreviated Framework Procedure included in Amendment 27, but stressed the need for continued compliance with NMFS' Operational Guidelines, which established the circumstances under which the abbreviated Framework Process may be applied, and ensures adequate public notice and comment during the abbreviated Framework Process.

Response: Amendment 27 and this final rule will modify the current Framework Procedure for the FMP to allow for an abbreviated process for changing ABCs, ACLs, and ACTs for species in the snapper-grouper fishery management unit in response to a stock assessment. The abbreviated Framework Procedure will be utilized for the routine adjustment of these harvest parameters in keeping with NMFS' Operational Guidelines. This action will give the South Atlantic Council and NMFS the ability to implement appropriate levels of harvest more quickly in response to the latest scientific information, while ensuring adequate notice and public comment. NMFS anticipates that this more streamlined approach will minimize administrative impacts for routine changes to harvest parameters. Any action implemented through the abbreviated Framework Process will comply with the Magnuson-Stevens Act and all other applicable law.

Comment 5: One individual and one state agency supported removing blue runner from the FMP. The Florida Fish and Wildlife Conservation Commission (FWC) specifically referenced a letter from the FWC Chairman to the South Atlantic Council Chairman dated May 20, 2013. The letter explained the intent of the FWC to extend state management measures for blue runner into adjacent Federal waters if Amendment 27 is approved for implementation.

Response: According to Amendment 27, from 2005 through 2011, most recreational (99 percent) and commercial (99 percent) blue runner harvest were from Federal and state waters off Florida, and of that harvest, 76 percent of blue runner landings came from state waters. Blue runner is not

commonly retained for human consumption, is primarily used as bait, and is currently subject to management in Florida state waters, including gear prohibitions, a recreational bag limit, bycatch restrictions, penalties for unlicensed sale of blue runner, a Saltwater Products License requirement, and trip ticket requirements. Additional restrictions (gear, area closures, etc.) apply to blue runner in waters off certain Florida counties. At its September 5–6, 2013, meeting the FWC considered a draft rule for blue runner that would:

(1) Define blue runner as any fish of the species *Caranx crysos* (as it is currently defined in the Federal FMP, but was recently inadvertently mislabeled in the NMFS regulations as *Caranx bartholomaei* (yellow jack));

(2) Establish a statewide recreational daily bag limit of 100 fish per person per day;

(3) Extend this bag limit into adjacent Federal waters if Federal rules are removed; and

(4) Clarify that a Saltwater Products License is required for commercial harvest of blue runner in both state and Federal waters.

At its November 21–22, 2013, meeting the FWC approved this draft rule and stated the final rule would become effective after blue runner is removed from the Federal FMP.

Because blue runner is predominantly harvested in Florida state waters and is infrequently harvested off states other than Florida, and because Florida currently manages blue runner and intends to extend its management for fishing vessels registered under Florida law into Federal waters off Florida, NMFS determined that it is appropriate to remove the species from the FMP without having a negative biological impact on the stock.

Classification

The Regional Administrator, Southeast Region, NMFS has determined that this final rule is necessary for the conservation and management of South Atlantic snapper-grouper and is consistent with Amendment 27, the FMP, the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

A final regulatory flexibility analysis (FRFA) was prepared for this action. The FRFA incorporates the IRFA, a summary of the significant economic issues raised by public comment, NMFS' responses to those comments, and a summary of the analyses completed to support the action. The FRFA follows.

No public comments specific to the IRFA were received and, therefore, no public comments are addressed in this FRFA. Certain comments with socioeconomic implications are addressed in the comments and responses section. No changes in the final rule were made in response to public comments.

NMFS agrees that the South Atlantic Council's choice of preferred alternatives would best achieve the South Atlantic Council's objectives for Amendment 27 to the FMP while minimizing, to the extent practicable, the adverse effects on fishers, support industries, and associated communities. The preamble to this final rule provides a statement of the need for and objectives of this rule.

The final rule extends the South Atlantic Council's jurisdictional authority for management of Nassau grouper to include Gulf Federal waters and continues the harvest prohibition of Nassau grouper in the Gulf and South Atlantic EEZ; increases, from three to four, the number of crew members on any dual-permitted vessel (a vessel with both a South Atlantic for-hire snapper-grouper and a South Atlantic commercial snapper-grouper permit) when operating commercially; removes the snapper-grouper species retention restrictions for captains and crew of vessels with a South Atlantic for-hire snapper-grouper permit; modifies the South Atlantic Snapper-Grouper FMP framework procedure; and removes blue runner from the South Atlantic Snapper-Grouper FMP.

The Magnuson-Stevens Act provides the statutory basis for this final rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this final rule. Accordingly, this final rule does not implicate the Paperwork Reduction Act.

NMFS expects the final rule to directly affect commercial fishermen and for-hire vessel operators in the South Atlantic snapper-grouper fishery. The Small Business Administration (SBA) recently modified the small entity size criteria for all major industry sectors in the U.S., including fish harvesters. A business involved in finfish harvesting is classified as a small business if independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts are not in excess of $19.0 million (NAICS code 114111, finfish fishing) for all of its affiliated operations worldwide. For for-hire vessels, all qualifiers apply except that the annual receipts threshold is $7.0 million (NAICS code 487210, recreational industries). The SBA periodically reviews and changes, as appropriate, these size criteria. On June 20, 2013, the SBA issued a final rule revising the small business size standards for several industries effective July 22, 2013 (78 FR 37398). This rule increased the size standard for commercial finfish harvesters from $4.0 million to $19.0 million. Neither this rule, nor other recent SBA rules, changed the size standard for for-hire vessels.

From 2007 through 2011, an annual average of 336 vessels with valid commercial South Atlantic snapper-grouper permits landed at least 1 lb (0.45 kg) of blue runner. These vessels generated dockside revenues of approximately $2.1 million (2011) from all species caught in the same trips as blue runner, of which $111,000 (2011 dollars) were from sales of blue runner. Each vessel, therefore, generated an average of approximately $6,250 in gross revenues, of which $330 were from blue runner. Vessels in the coastal migratory pelagics fishery also harvested blue runner on some of their trips harvesting Spanish or king mackerel. In 2007–2011, an average of 176 vessels harvested at least 1 lb (0.45 kg) of king mackerel and 1 lb (0.45 kg) of blue runner. These vessels generated an average of about $799,000 from sales of king mackerel and $57,000 from sales of blue runner. For the same period, an average of 219 vessels harvested at least 1 lb (0.45 kg) of Spanish mackerel and 1 lb (0.45 kg) of blue runner. These vessels generated about $352,000 from sales of Spanish mackerel and $33,000 from sales of blue runner.

For more than two decades, the commercial and recreational harvest of Nassau grouper in the South Atlantic and Gulf has been prohibited, so no revenue information on commercial vessels dependent on Nassau grouper is available. Based on the revenue information presented above, all commercial vessels that will be affected by the rule can be considered small entities.

From 2007 through 2011, an annual average of 1,813 vessels had valid South Atlantic charter vessel/headboat (for-hire) snapper-grouper permits. As of January 22, 2013, 1,462 vessels held South Atlantic for-hire snapper-grouper permits, and about 75 are estimated to have operated as headboats in 2013. The for-hire fleet consists of charter vessels, which charge a fee on a vessel basis, and headboats, which charge a fee on an

individual angler (head) basis. Average annual revenues (2011 dollars) per charter vessel are estimated to be $126,032 for Florida vessels, $53,443 for Georgia vessels, $100,823 for South Carolina vessels, and $101,959 for North Carolina vessels. For headboats, the corresponding per vessel estimates are $209,507 for Florida vessels and $153,848 for vessels in the other states. Revenue figures for headboats in states other than Florida are aggregated for confidentiality reasons. Based on these average revenue figures, all for-hire operations that will be affected by the rule can be considered small entities.

NMFS expects the final rule to directly affect all federally permitted commercial vessels harvesting blue runner and for-hire vessels that operate in the South Atlantic snapper-grouper fishery. All directly affected entities have been determined, for the purpose of this analysis, to be small entities. Therefore, NMFS has determined that this rule will affect a substantial number of small entities. In addition, the issue of disproportional effects on small versus large entities does not arise in the present case.

Extending the South Atlantic Council's jurisdictional authority for management of Nassau grouper has no direct effects on the profits of commercial and for-hire vessels, because there are no accompanying changes to the management measures for this species. Any future changes to the management for Nassau grouper in the Gulf or South Atlantic EEZ will pass through the usual regulatory process, although in the future it will be solely under the South Atlantic Council's regulatory process.

Increasing the maximum number of crew members on any dual-permitted vessel that is operating commercially from three to four will generally affect only those vessels that opt to bring on board an additional crew member. Vessel owners/operators will likely weigh the additional costs and benefits of such an action. Direct costs will be in the form of compensation to the additional crew member. Benefits could come in the form of better safety conditions, especially on trips that involve diving. The net effect of this action is relatively unknown in the short term. This action will make the South Atlantic regulation on the maximum crew size of dual-permitted vessels consistent with the Gulf regulation. Preliminary reports for the Gulf for-hire sector appear to indicate that safety-at-sea has improved when vessels started adding crew members.

Removing the snapper-grouper bag limit retention restrictions for the captains and crew of for-hire vessels (*i.e.*, allowing the captains and crew to possess bag limits for all snapper-grouper species with allowable bag limits) could potentially increase the profits of for-hire vessels. These extra bag limits could be used as part of crew compensation, which would lower overall cost, or as a marketing tool to attract additional angler trips, which could bring in additional revenues. It is likely, however, that profit increases will be relatively minimal because of the small number of additional fish that could be kept if the retention restriction were removed. The total extra fish in a year that will result from allowing the captains and crew of for-hire vessels to keep bag limits is estimated to be about 51 fish on all charter trips and 138 fish on all headboat trips. From an enforcement perspective, this action will reduce confusion regarding which snapper-grouper species may be retained by the captains and crew of for-hire vessels.

Modifying the FMP framework procedure has no direct effects on commercial and for-hire vessel profits. This modification will allow for faster implementation of changes in the ABCs, ACLs, and ACTs for any snapper-grouper species based on the most recent stock assessment. The effects of those changes will be analyzed once they are considered by the South Atlantic Council.

Removing blue runner from the FMP will leave this species relatively unregulated in the South Atlantic EEZ, where 24 percent of the landings occurred from 2005–2011. As a result, commercial vessels could harvest as many blue runner as they can, using whatever gear is most efficient for their operations. In principle, therefore, this action can be expected to result in overall profit increases to commercial vessels in the short term. Historically, however, blue runner has not been a major species targeted or landed by commercial snapper-grouper or coastal migratory pelagic vessels. During 2007–2011, revenues from blue runner accounted for an average of about 5 percent of total revenues generated by snapper-grouper commercial vessels that landed at least 1 lb (0.45 kg) of blue runner. These vessels will generate additional profits mainly if they increase their effort in harvesting blue runner. This will require some changes in their harvesting strategies that may only increase fishing costs. Many vessel operators may have deemed this cost increase not worth expending, as partly evidenced by the relatively small share that sales of blue runner contribute to total vessel revenues.

The case with commercial vessels targeting mainly Spanish or king mackerel is different from that with vessels mainly dependent on snapper-grouper species. Under the no action alternative, a commercial snapper-grouper permit is required to possess and land blue runner. In addition, allowable gear types for harvesting any snapper-grouper species exclude gillnets, which are a gear type used in harvesting king and Spanish mackerel. Vessels which harvest king or Spanish mackerel, but do not possess a commercial snapper-grouper permit, must discard their catches of blue runner; or, even if they have the necessary commercial snapper-grouper permit, they may not use gillnets to harvest blue runner along with king and Spanish mackerel. For commercial vessels landing at least 1 lb (0.45 kg) of Spanish mackerel and 1 lb (0.45 kg) of blue runner, revenues from blue runner were about 10 percent of revenues from Spanish mackerel in 2007–2011; and for commercial vessels landing at least 1 lb (0.45 kg) of king mackerel and 1 lb (0.45 kg) of blue runner, revenues from blue runner were about 5 percent of revenues from king mackerel in 2007–2011. Removing blue runner from the FMP will allow these vessels to legally maintain their revenues and profits at current levels. However, some of these vessels' revenues may be forgone if Florida extends its gillnet ban into the EEZ.

Similar to commercial vessels, for-hire vessels will, in principle, benefit from removing blue runner from the FMP. These vessels may take as many trips targeting blue runner as they can. However, charter vessels and headboats accounted for only 2.4 percent and 2.5 percent, respectively, of total recreational landings of blue runner during 2007–2011. In addition, there is no record of target trips for blue runner by charter vessels, and target trips for blue runner by headboats are unknown. Given this information on landings and target trips, removing blue runner from the FMP will likely have minimal effects on the profits of for-hire vessels.

The long-term effects of removing blue runner from the FMP on commercial and for-hire vessel profits depend on whether the harvest of blue runner is sustainable in the absence of Federal management of the species. Should blue runner undergo overfishing or become overfished, commercial and for-hire vessel catches of blue runner would decline and so would their profits. However, it should be noted that about 99 percent of blue runner are caught off Florida, so with blue runner being removed from the FMP, Florida

could extend its fishing regulations into the EEZ. This could allow for continued sustainable management of the species. In addition, the South Atlantic Council expressed its intention to continue monitoring trends and landings of blue runner for possible future management actions affecting the species, should the need arise.

The following discussion analyzes the alternatives that were not preferred by the South Atlantic Council, or alternatives for which the South Atlantic Council chose the no action alternative.

Two alternatives, including the preferred alternative, were considered for extending the South Atlantic Council's jurisdictional authority for management of Nassau grouper. The only other alternative is the no action alternative. The South Atlantic Council decided two alternatives were sufficient, since the Secretary of Commerce has already designated the South Atlantic Council as the responsible fishery management council to manage Nassau grouper in the Gulf. These two alternatives are administrative in nature and therefore would have no direct effects on the profits of commercial and for-hire vessels.

Three alternatives, including the preferred alternative, were considered for modifying the crew size restriction for dual-permitted snapper-grouper vessels. The first alternative, the no action alternative, would maintain the commercial crew size limit of three persons. This alternative would have no effects on vessel profits, but it would not address safety issues particularly related to diving trips..The second alternative would remove entirely the commercial crew size limit on dual-permitted snapper-grouper vessels. This alternative would afford vessel owners/operators more flexibility in selecting the optimal crew size for every fishing trip, and thus may be expected to result in higher profits than any of the other alternatives. However, this alternative would tend to complicate the enforcement of fishing rules that differentiate between a commercial and a for-hire fishing trip. Under the alternative, dual-permitted vessels could take a for-hire trip with every angler practically considered a crew member, and then sell their catch as if a commercial vessel trip was taken. In addition to being illegal, this practice could pose problems in tracking recreational versus commercial landings of snapper-grouper species for purposes of ACL monitoring. Moreover, accountability measures could be unduly imposed on one sector if sector ACLs could not be properly monitored.

Three alternatives, including the preferred alternative, were considered for modifying the bag limit restriction on snapper-grouper species for the captains and crew of permitted for-hire vessels. The first alternative, the no action alternative, would maintain the prohibition on captains and crew of for-hire vessels from retaining bag limit quantities of the following species: Gag, black grouper, red grouper, scamp, red hind, rock hind, coney, graysby, yellowfin grouper, yellowmouth grouper, yellowedge grouper, snowy grouper, misty grouper, vermilion snapper, sand tilefish, blueline tilefish, and golden tilefish. This alternative would not change the profits of for-hire vessels, but would also forgo any potential profit that could result from the preferred alternative. The second alternative would establish a bag limit of zero for the captains and crew of permitted for-hire vessels for all species included in the FMP. Under this alternative, captains and crew of for-hire vessels would tend to forgo annually about 275 fish in charter trips, and 4,291 fish in headboat trips. If these fish were used as part of crew compensation, losing them would increase the cost of fishing; if these fish were used as a marketing tool to attract additional angler trips, those trips and associated revenues would likely not occur in the future. There is, therefore, a substantial likelihood that this alternative would adversely affect the profits of for-hire vessels, although the magnitude of effects would be relatively small.

Two alternatives, including the preferred alternative, were considered for modifying the FMP framework procedure. The only other alternative is the no action alternative. These two alternatives are administrative in nature and therefore would have no direct effects on the profits of commercial and for-hire vessels. Only one alternative was considered by the Council that would meet the purpose of this amendment and at same time address the concerns raised by NOAA General Counsel (NOAA GC). The Council had initially proposed amending the framework procedure to allow for adjustments to ACLs via publication of a notice in the **Federal Register**. However, NOAA GC advised the Council that such a process would not meet current legal requirements and NMFS would likely disapprove it. Subsequently, the Council revised the alternative to incorporate NOAA GC suggestions.

Three alternatives, including the preferred alternative, were considered for modifying the placement of blue runner in a fishery management unit and/or modifying management measures for blue runner. The first alternative, the no action alternative, would have no effect on the profits of commercial and for-hire vessels in the snapper-grouper fishery. However, commercial vessels in the coastal migratory pelagics fishery that do not possess a commercial snapper-grouper permit would have to discard their catches of blue runner unless they secure the necessary permit. Without the necessary permit, they would experience revenue and profit reductions from discarding blue runner. If they wanted to continue their practice of harvesting and selling blue runner, they would have to purchase a commercial snapper-grouper permit. Their cost would increase especially because the commercial snapper-grouper permit is under a limited access program, and the likely purchase price of a commercial snapper-grouper permit would be substantially higher than the administrative cost of securing an open access permit or renewing a commercial snapper-grouper permit. The second alternative would retain blue runner in the FMP, but would allow commercial harvest and sale of blue runner for vessels with a South Atlantic commercial Spanish mackerel permit. In addition, gillnets would be an allowable gear in the snapper-grouper fishery, although only for harvesting blue runner. This alternative would tend to maintain the current profitability of commercial vessels, especially in the coastal migratory pelagics fishery as these vessels would be allowed to harvest and sell blue runner without incurring additional costs through the purchase of commercial snapper-grouper permits. The third alternative would retain blue runner in the FMP, but would exempt the species from the commercial snapper-grouper permit requirement for purchase, harvest, and sale of snapper or grouper. This alternative would have the same effects on the profits of commercial vessels as the second alternative.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Headboat, Reporting and recordkeeping requirements, South Atlantic.

Dated: December 20, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.1, paragraph (d), Table 1, the entry for "FMP for the Snapper-Grouper Fishery of the South Atlantic Region" is revised and footnote 6 is added to read as follows:

§ 622.1 Purpose and scope.

* * * * *

(d) * * *

TABLE 1—FMPS IMPLEMENTED UNDER PART 622

FMP title	Responsible fishery management council(s)	Geographical area
FMP for the Snapper-Grouper Fishery of the South Atlantic Region	SAFMC	South Atlantic[6]

[6] Nassau grouper in the South Atlantic EEZ and the Gulf EEZ are managed under the FMP.

* * * * *

■ 3. In § 622.2, the definition for "Charter vessel" is revised to read as follows:

§ 622.2 Definitions and acronyms.

* * * * *

Charter vessel means a vessel less than 100 gross tons (90.8 mt) that is subject to the requirements of the USCG to carry six or fewer passengers for hire and that engages in charter fishing at any time during the calendar year. A charter vessel with a commercial permit, as required under § 622.4(a)(2), is considered to be operating as a charter vessel when it carries a passenger who pays a fee or when there are more than three persons aboard, including operator and crew, except for a charter vessel with a commercial vessel permit for Gulf reef fish or South Atlantic snapper-grouper. A charter vessel that has a charter vessel permit for Gulf reef fish and a commercial vessel permit for Gulf reef fish or a charter vessel permit for South Atlantic snapper-grouper and a commercial permit for South Atlantic snapper-grouper (either a South Atlantic snapper-grouper unlimited permit or a 225-lb (102.1-kg) trip limited permit for South Atlantic snapper-grouper) is considered to be operating as a charter vessel when it carries a passenger who pays a fee or when there are more than four persons aboard, including operator and crew. A charter vessel that has a charter vessel permit for Gulf reef fish, a commercial vessel permit for Gulf reef fish, and a valid Certificate of Inspection (COI) issued by the USCG to carry passengers for hire will not be considered to be operating as a charter vessel provided—

(1) It is not carrying a passenger who pays a fee; and

(2) When underway for more than 12 hours, that vessel meets, but does not exceed the minimum manning requirements outlined in its COI for vessels underway over 12 hours; or when underway for not more than 12 hours, that vessel meets the minimum manning requirements outlined in its COI for vessels underway for not more than 12-hours (if any), and does not exceed the minimum manning requirements outlined in its COI for vessels that are underway for more than 12 hours.

* * * * *

■ 4. In § 622.33, a sentence is added at the end of paragraph (a) and paragraph (c) is removed and reserved.

The addition reads as follows:

§ 622.33 Prohibited species.

(a) * * * (Note: Nassau grouper in the Gulf EEZ may not be harvested or possessed, as specified in § 622.181(b)(1).)

* * * * *

■ 5. In § 622.38, paragraph (b)(2) is revised to read as follows:

§ 622.38 Bag and possession limits.

* * * * *

(b) * * *

(2) *Groupers, combined, excluding goliath grouper*—4 per person per day, but not to exceed 1 speckled hind or 1 warsaw grouper per vessel per day, or 2 gag per person per day. However, no grouper may be retained by the captain or crew of a vessel operating as a charter vessel or headboat. The bag limit for such captain and crew is zero. (Note: Nassau grouper in the Gulf EEZ may not be harvested or possessed, as specified in § 622.181(b)(4).)

* * * * *

■ 6. In § 622.181, paragraph (b)(1) is revised and paragraph (b)(4) is added to read as follows:

§ 622.181 Prohibited and limited-harvest species.

* * * * *

(b) * * *

(1) Goliath grouper may not be harvested or possessed in the South Atlantic EEZ. Goliath grouper taken in the South Atlantic EEZ incidentally by hook-and-line must be released immediately by cutting the line without removing the fish from the water.

* * * * *

(4) Nassau grouper may not be harvested or possessed in the South Atlantic EEZ or the Gulf EEZ. Nassau grouper taken in the South Atlantic EEZ or the Gulf EEZ incidentally by hook-and-line must be released immediately by cutting the line without removing the fish from the water.

* * * * *

■ 7. In § 622.187, paragraphs (b)(2), (b)(5), and (b)(8) are revised to read as follows:

§ 622.187 Bag and possession limits.

* * * * *

(b) * * *

(2) *Grouper and tilefish, combined*—3. Within the 3-fish aggregate bag limit:

(i) No more than one fish may be gag or black grouper, combined;

(ii) No more than one fish per vessel may be a snowy grouper;

(iii) No more than one fish may be a golden tilefish; and

(iv) No goliath grouper or Nassau grouper may be retained.

* * * * *

(5) *Vermilion snapper*—5.

* * * * *

(8) *South Atlantic snapper-grouper, combined*—20. However, excluded from this 20-fish bag limit are tomtate, South Atlantic snapper-grouper ecosystem component species (specified in Table 4 of Appendix A to part 622), and those specified in paragraphs (b)(1) through (7) and paragraphs (b)(9) and (10) of this section.

* * * * *

§ 622.193 [Amended]

■ 7. In § 622.193, paragraph (s) is removed and reserved.

■ 8. In Appendix A to part 622, Table 4 is revised to read as follows:

Appendix A to part 622—Species Tables

* * * * *

TABLE 4 OF APPENDIX A TO PART 622—SOUTH ATLANTIC SNAPPER-GROUPER

Balistidae—Triggerfishes
Gray triggerfish, *Balistes capriscus*
Carangidae—Jacks
Bar jack, *Caranx ruber*
Greater amberjack, *Seriola dumerili*
Lesser amberjack, *Seriola fasciata*
Almaco jack, *Seriola rivoliana*
Banded rudderfish, *Seriola zonata*
Ephippidae—Spadefishes
Spadefish, *Chaetodipterus faber*
Haemulidae—Grunts
Margate, *Haemulon album*
Tomtate, *Haemulon aurolineatum*
Sailor's choice, *Haemulon parrai*
White grunt, *Haemulon plumieri*
Labridae—Wrasses
Hogfish, *Lachnolaimus maximus*
Lutjanidae—Snappers
Black snapper, *Apsilus dentatus*
Queen snapper, *Etelis oculatus*
Mutton snapper, *Lutjanus analis*
Blackfin snapper, *Lutjanus buccanella*
Red snapper, *Lutjanus campechanus*
Cubera snapper, *Lutjanus cyanopterus*
Gray snapper, *Lutjanus griseus*
Mahogany snapper, *Lutjanus mahogoni*
Dog snapper, *Lutjanus jocu*
Lane snapper, *Lutjanus synagris*
Silk snapper, *Lutjanus vivanus*
Yellowtail snapper, *Ocyurus chrysurus*
Vermilion snapper, *Rhomboplites aurorubens*
Malacanthidae—Tilefishes
Blueline tilefish, *Caulolatilus microps*
Golden tilefish, *Lopholatilus chamaeleonticeps*
Sand tilefish, *Malacanthus plumieri*
Percichthyidae—Temperate basses
Wreckfish, *Polyprion americanus*
Serranidae—Groupers
Rock hind, *Epinephelus adscensionis*
Graysby, *Epinephelus cruentatus*
Speckled hind, *Epinephelus drummondhayi*
Yellowedge grouper, *Epinephelus flavolimbatus*
Coney, *Epinephelus fulvus*
Red hind, *Epinephelus guttatus*
Goliath grouper, *Epinephelus itajara*
Red grouper, *Epinephelus morio*
Misty grouper, *Epinephelus mystacinus*
Warsaw grouper, *Epinephelus nigritus*
Snowy grouper, *Epinephelus niveatus*
Nassau grouper, *Epinephelus striatus*
Black grouper, *Mycteroperca bonaci*
Yellowmouth grouper, *Mycteroperca interstitialis*
Gag, *Mycteroperca microlepis*
Scamp, *Mycteroperca phenax*
Yellowfin grouper, *Mycteroperca venenosa*
Serranidae—Sea Basses
Black sea bass, *Centropristis striata*
Sparidae—Porgies
Jolthead porgy, *Calamus bajonado*
Saucereye porgy, *Calamus calamus*
Whitebone porgy, *Calamus leucosteus*
Knobbed porgy, *Calamus nodosus*
Red porgy, *Pagrus pagrus*
Scup, *Stenotomus chrysops*
The following species are designated as ecosystem component species:
Cottonwick, *Haemulon melanurum*
Bank sea bass, *Centropristis ocyurus*
Rock sea bass, *Centropristis philadelphica*
Longspine porgy, *Stenotomus caprinus*
Ocean triggerfish, *Canthidermis sufflamen*
Schoolmaster, *Lutjanus apodus*

* * * * *

[FR Doc. 2013–30943 Filed 12–26–13; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130710605–3999–02]
RIN 0648–BD41

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery of the Gulf of Mexico; Establish Funding Responsibilities for the Electronic Logbook Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final changes to management measures.

SUMMARY: NMFS establishes funding responsibilities for an upgrade to the shrimp electronic logbook (ELB) program as described in a framework action to the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico (Gulf) Fishery Management Council (Council). Newer and more efficient ELB units have been purchased by NMFS for the Gulf shrimp fleet and are available for installation on Gulf shrimp vessels. Therefore, NMFS establishes a cost-sharing program to fund the ELB program. NMFS will pay for the software development, data storage, effort estimation analysis, and archival activities for the new ELB units, and selected vessel permit holders in the Gulf shrimp fishery will pay for installation and maintenance of the new ELB units and for the data transmission from the ELB units to a NOAA server. The purpose of these changes is to ensure that management of the shrimp fishery is based upon the best scientific information available and that bycatch is minimized to the extent practicable.

DATES: These final changes to management measures are effective January 27, 2014.

ADDRESSES: Electronic copies of the framework action, which includes a Regulatory Flexibility Act analysis and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/shrimp/index.html*.

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained herein may be submitted in writing to Anik Clemens, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701; and OMB, by email at *OIRA Submission@omb.eop.gov*, or by fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Susan Gerhart; Southeast Regional Office, NMFS, telephone: 727–824–5305; email: *Susan.Gerhart@noaa.gov*.

SUPPLEMENTARY INFORMATION: The shrimp fishery of the Gulf is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On October 22, 2013, NMFS published the proposed changes to management measures for the ELB program for the Gulf shrimp fishery and requested public comment (78 FR 62579). The proposed changes to management measures and the framework action outline the rationale for the actions contained herein. A summary of the actions implemented by the framework action is provided below.

These final changes in management measures require vessel permit holders in the Gulf shrimp fishery to share in the cost of the ELB program. NMFS will inform vessel owners that they have been selected to participate in this program, and that they have a total of 90 days to comply with the regulations to install and activate their new ELB units (30 days to activate a wireless account and 60 days to install the new ELB unit) after it has been shipped by NMFS and received by the vessel owner. Vessel owners selected to participate in the ELB program must

contact Verizon Wireless, the wireless provider, by email at *VZWGulfCoastELB@VerizonWireless.com*, or by phone: 888–211–3258, to initiate service for the new ELB unit.

The changes to the management measures are being published pursuant to section 304(b)(3) of the Magnuson-Stevens Act.

Changes From the Proposed Changes to Management Measures

As was proposed, selected vessel permit holders in the Gulf shrimp fishery will cover the costs of installing and maintaining the ELB units and the cost of data transmission from the units to a NOAA server. The cost of data transfer, however, which is the major cost to the vessel permit holders in the Gulf shrimp fishery, was previously estimated to be $720 per vessel annually. Recent negotiations with the wireless provider have substantially reduced this cost to approximately $240 per vessel annually.

Comments and Responses

NMFS received a total of nine public comments on the proposed changes to management measures; one from an organization and the remainder from individuals. Some commenters submitted suggestions for the Gulf shrimp fishery that were outside the scope of the framework action, including comments regarding monitoring catch. Seven commenters were against the framework action, one was in favor of the framework action, and one expressed no position for or against the changes but was in support of using modern vessel monitoring system (VMS) type technology. Specific comments related to the actions contained in the framework action, as well as NMFS' respective responses, are summarized below.

Comment 1: The cost sharing program will impose a financial burden on fishermen who already have high expenses because of increased operating costs and a depressed economy.

Response: The Council considered several funding alternatives for continuing the ELB program, and NMFS agrees with the Council's choice to implement the cost-sharing program. The Council and NMFS recognize the burden of the cost-sharing program on the vessel permit holders in the Gulf shrimp fishery. As analyzed in the framework action, NMFS will cover the cost of the ELB equipment, software development, data storage, effort estimation analysis, and archival activities. Vessel permit holders in the Gulf shrimp fishery selected to participate in the ELB program will cover the costs of installing and maintaining the ELB units and the cost of data transmission from the units to a NOAA server. The installation cost of approximately $200 per vessel is a one-time cost; maintenance costs are periodic; and the data transfer cost is annual. The cost of data transfer, which is the major cost to the vessel permit holders in the Gulf shrimp fishery selected to participate in the ELB program, was previously estimated at $720 per vessel annually. Recent negotiations with the wireless provider have substantially reduced this cost to approximately $240 per vessel annually to receive the same service. The division of cost is similar to that for the Gulf reef fish VMS program. NMFS will constantly evaluate the ELB program, including its costs, particularly with respect to the burden on the vessel permit holders in the Gulf shrimp fishery.

Comment 2: Fishermen should not be required to reveal where they fish. Information provided by the ELB unit transmissions should be confidential.

Response: The new ELB program collects the same data as the prior ELB program. NMFS adheres to strict confidentiality guidelines with regards to its various data collection programs, including the ELB program. To date, there have been no reported issues related to the confidentiality of information collected through the ELB program. NMFS will work with the wireless provider to ensure that data transmission under the new ELB program is secure, as in the VMS program for the Gulf reef fish fishery.

Comment 3: The new ELB units are not ready to be implemented and will not work.

Response: The new ELB units have been tested on several vessels that also have the prior ELB units. The new ELB units are functioning and the data collected by both units match. It is expected that some issues may arise with the implementation of a new system. However, NMFS is confident that any issues that arise regarding the functioning of the ELB units can be efficiently resolved.

Comment 4: The prior ELB program worked so it should be continued. NOAA should not be involved in the ELB program and should let the previous contractor continue the program.

Response: Continuing the prior ELB program would necessarily result in either NMFS or vessel permit holders in the Gulf shrimp fishery being required to cover the full cost of the program. Funding for the prior ELB program through the current contractor will cease at the end of 2013 (the end of the contract), and no new Federal money is expected to be forthcoming. Therefore, NMFS does not have the means to cover the full cost of the ELB program at this time. Additionally, NMFS recognizes that it would be very burdensome for vessel permit holders in the Gulf shrimp fishery to bear the full cost of the ELB program. Unless NMFS or the vessel permit holders in the Gulf shrimp fishery can secure outside funding, a cost-sharing program is the most appropriate funding option, and is therefore the option that the Council chose to implement at this time. NMFS' direct administration of the new ELB program is expected to reduce the cost of the ELB program and allow for a more efficient method of retrieving, archiving, and analyzing the data. The total annual cost of the new ELB program (after the first year) will be $434,000 for 500 vessels, which is substantially less than the $975,000 annual cost for the prior ELB program, for 500 vessels. If all 1,500 vessels with Federal permits are selected to participate in the new ELB program, the cost would still be less than that of the prior ELB program, at $674,000. As needed, NMFS will consult with experts, including the current contractor for the prior ELB program, in administering the program.

Comment 5: NOAA should fund the entire program. NOAA should have put the ELB program in the budget and could use BP funds to support it.

Response: As noted above, NMFS does not have the resources to fund the entire ELB program. NMFS' current budget is restricted from adding new programs for funding. Just because a program is not placed within the Federal budget, it does not lessen its importance to the government mission. There are many high priority programs which the Federal government oversees that may not have appropriations to fully fund them on an annual basis. Cost-sharing with user groups is one method that is used to fund high priority programs that do not have enough appropriations to be implemented solely under the Federal budget. Further, no funding has been made available for this program as a result of the Deepwater Horizon MC252 incident. If outside funding becomes available in the future to cover the cost of the entire ELB program, cost-sharing may not be needed. If additional funding is acquired that is less than the total cost of the new ELB program, the vessel permit holders in the Gulf shrimp fishery's portion could be covered or reduced with that funding.

Comment 6: Data from the ELB program are important for future management of the Gulf shrimp fishery, however, there might be a less expensive way to obtain it.

Response: Since before the creation of the existing program, the Council and NMFS have explored numerous options for data collection in the Gulf shrimp fishery. During the development of Amendment 13 to the Gulf Shrimp FMP, which originally established the existing ELB requirement, the Council and NMFS determined that the ELB program was an accurate and cost effective means for collecting the necessary information from the fishery. Requiring industry to bear a portion of the costs of the program does not undermine these prior determinations relative to the program. Further, NMFS has determined that these modifications to the program best achieve the Council's objectives, while minimizing, to the extent practicable, the associated burdens on industry. Should more cost effective means of collecting the information be developed in the future, industry and the public at large are encouraged to recommend these innovations to the Council and NMFS for future implementation.

Classification

The Regional Administrator, Southeast Region, NMFS has determined that these final changes to management measures are necessary for the conservation and management of Gulf shrimp and is consistent with the FMP, the Magnuson-Stevens Act, and other applicable law.

This rule has been determined to be not significant for purposes of Executive Order 12866.

A Final Regulatory Flexibility Analysis (FRFA) was prepared for this action. The FRFA incorporates the Initial Regulatory Flexibility Analysis (IRFA), a summary of the significant economic issues raised by public comment, NMFS' responses to those comments, and a summary of the analyses completed to support the action. The FRFA follows.

No public comments specific to the IRFA were received. However, some comments regarding the cost burden of the new ELB program were received, and these are addressed in the comments and responses section, specifically Comments 1 and 5. No changes in management measures were made in response to public comments.

NMFS agrees that the Council's choice of preferred alternative would best achieve the Council's objectives for the framework action to the FMP while minimizing, to the extent practicable, the adverse effects on fishers, support industries, and associated communities. The preamble for these final changes to management measures provides a statement of the need for and objectives of the management measures in the framework action.

The Magnuson-Stevens Act provides the statutory basis for the final changes to the management measures. No duplicative, overlapping, or conflicting Federal rules have been identified.

The prior ELB program for the Gulf shrimp fishery, established through the final rule to implement Amendment 13 to the FMP in 2006, required selected vessels to carry ELB units. These final changes to the management measures require selected vessels to carry new ELB units that are more modern and technologically advanced. From the standpoint of technical and professional skills needed, the new ELB units do not materially differ from the current ELB units. In fact, the new ELB units no longer require a technician to meet vessels to pull and program the memory card. Data collected by ELB units will be automatically transmitted to NMFS servers via a cellular phone connection activated when the vessel is within non-roaming cellular range. A key feature introduced by the final changes is that the vessel permit holders in the Gulf shrimp fishery will share the cost of the ELB program, whereas currently all costs of the ELB program are borne by the Federal government. Each federally permitted shrimp vessel selected to participate will be responsible for the one-time cost of installing the ELB unit ($200) and the annual cost of data transmission ($240) through a contract with the service provider. The vessel permit holders will also be responsible for the cost of repairing or replacing the ELB unit. The replacement of one ELB unit is estimated at about $425.

NMFS expects the final changes to management measures to directly affect commercial fishermen with valid or renewable Federal Gulf shrimp permits for harvesting penaeid shrimp in the Gulf exclusive economic zone (EEZ). The Small Business Administration (SBA) has established small entity size criteria for all major industry sectors in the United States, including fish harvesters. A business involved in fish harvesting is classified as a small business if independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts are not in excess of $19.0 million from finfish fishing (NAICS code 114111), or $5.0 million from shellfish fishing (NAICS code 114112), or $7 million from other marine fishing (NAICS code 114119) for all of its affiliated operations worldwide. For for-hire vessels, all qualifiers apply except that the annual receipts threshold is $7.0 million (NAICS code 487210, recreational industries). The SBA periodically reviews and changes, as appropriate, these size criteria. On June 20, 2013, the SBA issued a final rule revising the small business size standards for several industries effective July 22, 2013 (78 FR 37398). This rule increased the size standard for commercial finfish harvesters from $4.0 million to $19.0 million and commercial shellfish harvesters from $4.0 million to $5.0 million. Neither this rule, nor other recent SBA rules, changed the size standard for for-hire vessels.

The Federal Gulf shrimp permit has been placed under a moratorium since 2007. At the start of the moratorium, 1,915 vessels qualified and received Gulf shrimp permits. Over time, the number of permitted shrimp vessels declined, and in 2012 there were 1,582 such permitted vessels. According to the Southeast Regional Office Web site, the Constituency Services Branch (Permits) unofficially listed 1,431 holders of Gulf shrimp permits as of June 25, 2013.

During the period from 2006 through 2010, an average of 4,582 vessels fished for shrimp in the Gulf EEZ and state waters, of which 20 percent held Gulf shrimp permits. Despite being a minority of the total number, vessels with Gulf shrimp permits accounted for an average of 67 percent of total shrimp landings and 77 percent of total ex-vessel revenues. Of all the vessels with Gulf shrimp permits, 73 percent were active and 27 percent were inactive (*i.e.*, did not commercially fish).

During the period from 2006 through 2010, an average federally permitted shrimp vessel generated revenues from commercial fishing ranging from around $205,000 to $244,000. An average active federally permitted vessel had revenues from commercial fishing ranging from around $233,000 to $274,000. As may be expected, revenues from commercial fishing for an average inactive permitted vessel were practically none.

Based on the revenue figures above, all federally permitted shrimp vessels are expected to be directly affected by the final changes to the management measures and are determined for the purpose of this analysis to be small business entities. Hence, NMFS determined that the action would affect a substantial number of small entities.

Because NMFS determined that all entities expected to be affected by the final changes to the management measures are small entities, the issue of disproportional effects on small versus

large entities does not arise in the present case.

The vessel permit holders' share of the cost of the new ELB program consists of a one-time cost of installing the ELB unit, an annual cost of transmitting data from the ELB unit to NMFS servers, and a periodic cost of repairing or replacing defective ELB units. On a per vessel basis, the installation cost is $200 and the annual data transmission cost is $240. In the event of equipment failure, the cost of repair could run from a de minimis amount to $425, which is the cost of replacing an ELB unit.

During the period from 2006 through 2010, an average permitted shrimp vessel had negative net operating revenues in all years, except 2009. Its net profits (*i.e.*, net operating revenues plus net receipts from non-operating activities, such as government payments) were positive in 2006 ($2,961), 2009 ($1,238), and 2010 ($94,279). However, it should be noted that the 2010 profits came mainly from earnings associated with the Deepwater Horizon MC252 (DWH) oil spill in the form of damage claims and revenues from the vessel's participation in BP's clean-up program. Without these oil spill related revenues, net profits in 2010 would have been negative $2,480.

For active federally permitted shrimp vessels, net operating revenues were negative in all years from 2006 through 2010. In addition, profits in all of those years were negative, except in 2010. Again, the positive net profits in 2010 were due to revenues associated with the DWH oil spill. The situation is worse for inactive permitted shrimp vessels, with net revenues and profits (except for 2010) being more negative than those of active permitted shrimp vessels. The average inactive permitted shrimp vessel had higher net profit in 2010 than the average active permitted shrimp vessel.

The cost of the new ELB program will impose a significant impact on the profits of an average permitted shrimp vessel. The effects will be even more significant for vessels that are not active in the fishery. It is noted that there are some vessels that are substantially more profitable than the average vessel, and thus will be able to absorb the per vessel cost of the ELB program. However, there are other vessels that are only slightly more profitable than the average vessel, and very likely the impacts on their profits will be significant.

The following discussion analyzes the alternatives that were not selected as preferred by the Council.

The management measures contained in the framework action continue the ELB program. Being adjudged and proven to be very effective in collecting shrimp effort data in the Gulf EEZ, continuation of the ELB program has been deemed necessary so that NMFS can effectively carry out its mandate to base conservation and management measures on the best scientific information available and to minimize bycatch to the extent practicable. To date, no other means of collecting shrimp effort data have been developed and tested that would be more technically and economically effective than the ELB. Therefore, no other alternative to collect shrimp effort data was considered.

However, three alternatives, including the preferred alternative, were considered for funding the ELB program. As noted above, the preferred alternative will provide for cost sharing between NMFS and the vessel permit holders in the Gulf shrimp fishery. The second alternative will require NMFS to bear the entire cost of the ELB program. NMFS recognizes the vital role that the ELB program has played in estimating shrimp effort in the Gulf, but due to budget constraints, NMFS cannot fully fund the ELB program. The third alternative will require the Gulf shrimp vessel permit holders to fund the entire cost of the ELB program. For several years now, the Gulf shrimp industry has been in relatively dire financial condition. Thus the Gulf shrimp fishery indicated that it could not possibly fund the entire cost of the ELB.

These final changes to management measures contain collection-of-information requirements subject to the requirements of the Paperwork Reduction Act (PRA), which have been approved by Office of Management and Budget (OMB) under control number 0648–0543. NMFS estimates the requirement for the Gulf shrimp fishery to share in the costs of the new ELB units, which includes installation ($200) and data transmission ($240), to average 1 hour and $440 per response for the first year. After the first year, NMFS estimates the requirement for vessel permit holders in the Gulf shrimp fishery to share in the costs of the new ELB units, which includes data transmission, to average 1 hour and $240 per response. These estimates of the public reporting burden include the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection-of-information.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection-of-information subject to the requirements of the PRA, unless that collection-of-information displays a currently valid OMB control number.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 20, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2013–30949 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130409354–3999–02]

RIN 0648–BD21

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Revisions to Headboat Reporting Requirements for Species Managed by the South Atlantic Fishery Management Council

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement the Joint South Atlantic/Gulf of Mexico Generic Charter Vessel/Headboat Reporting in the South Atlantic Amendment (For-Hire Reporting Amendment). The For-Hire Reporting Amendment amends the following Fishery Management Plans (FMPs): the Snapper-Grouper Fishery of the South Atlantic Region and the Dolphin and Wahoo Fishery of the Atlantic, as prepared by the South Atlantic Fishery Management Council (South Atlantic Council); and the Coastal Migratory Pelagic (CMP) Resources of the Atlantic and Gulf of Mexico (Gulf), as prepared by the Gulf of Mexico Fishery Management Council (Gulf Council) and the South Atlantic Council. This final rule modifies the recordkeeping and reporting requirements for headboat owners and operators who fish for species managed by the South Atlantic Council through the previously mentioned FMPs. These revisions require fishing records to be submitted electronically (via computer or internet) on a weekly basis or at intervals shorter than a week if notified by the NMFS' Southeast Fisheries Science Center (SEFSC) Science and Research Director (SRD), and prohibits

headboats from continuing to fish if they are delinquent in submitting reports. The purpose of this final rule is to obtain timelier fishing information from headboats to better monitor recreational annual catch limits (ACLs), improve stock assessments, and to help obtain 100 percent compliance with reporting in South Atlantic fisheries.

DATES: This rule is effective January 27, 2014.

ADDRESSES: Electronic copies of the For-Hire Reporting Amendment, which includes an environmental assessment and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov*.

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted in writing to Anik Clemens, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701; and Office of Management and Budget (OMB), by email at *OIRA_Submission@omb.eop.gov*, or by fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Karla Gore, Southeast Regional Office, NMFS, telephone 727–824–5305; email: *Karla.Gore@noaa.gov*.

SUPPLEMENTARY INFORMATION: NMFS and the Councils manage the fisheries for South Atlantic Snapper-Grouper, Atlantic Dolphin and Wahoo, and Gulf and South Atlantic CMP under their respective FMPs. The FMPs were prepared by the Gulf and South Atlantic Councils and are implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On September 18, 2013, NMFS published a notice of availability for the For-Hire Reporting Amendment and requested public comment (78 FR 57339). On September 27, 2013, NMFS published a proposed rule for the For-Hire Reporting Amendment and requested public comment (78 FR 59641). NMFS approved the For-Hire Reporting Amendment on December 16, 2013. The proposed rule and the For-Hire Reporting Amendment outline the rationale for the actions contained in this final rule. A summary of the actions implemented by the For-Hire Reporting Amendment and this final rule is provided below.

This final rule requires electronic reporting for headboat vessels in the South Atlantic snapper-grouper, Atlantic dolphin and wahoo, and South Atlantic CMP fisheries, increases the reporting frequency for the headboat vessels in these fisheries, and prohibits headboats from continuing to fish if they are delinquent in submitting their reports.

Comments and Responses

NMFS received a total of 6 comments on the For-Hire Reporting Amendment and the proposed rule, which included comments from private citizens, fishermen, non-governmental organizations, and fishermen associations. Four comments were in support of the action contained in the amendment. Three comments provided recommendations that were outside the scope of the amendment and rulemaking. Two comments expressed concern with the requirement for increased reporting frequency. These two comments are summarized into one comment which is responded to below.

Comment: The requirement to report weekly instead of monthly is too burdensome on fishermen.

Response: NMFS estimates the requirement for headboat owners and operators to report more frequently (weekly instead of monthly) does not create more burden on headboat owners and operators. Keeping accurate records is essential to successful business operation. As a result, recording trips as they are completed, or as soon as is practical, is expected to be the common business practice. Electronic recording and reporting is expected to support additional labor and business management efficiencies because it is expected to allow better data storage, retrieval, and production of annual performance summaries for use in business planning. Therefore, the increase in the frequency of reporting is expected to require little, if any, change in business practices or associated operational costs. Headboat owners and operators will still be reporting the same amount of information; they will just be clicking the send button to transmit the data more frequently. Currently, 95 percent of headboats are reporting electronically, and 80 to 90 percent of these headboats are submitting their monthly reports on time. This requirement is intended to obtain timelier fishing information from headboats to better monitor recreational ACLs, improve stock assessments, and to help obtain 100 percent compliance with reporting in South Atlantic fisheries.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined that this final rule is necessary for the management of the South Atlantic snapper-grouper, dolphin and wahoo, and CMP fisheries and is consistent with the For-Hire Reporting Amendment, the FMPs, the Magnuson-Stevens Act and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. No comments were received regarding the certification and NMFS has not received any new information that would affect its determination. As a result, a final regulatory flexibility analysis was not required and none was prepared.

This final rule contains collection-of-information requirements subject to the requirements of the Paperwork Reduction Act (PRA), which have been approved by OMB under control number 0648–0016. NMFS estimates the requirement for South Atlantic headboat owners and operators to report electronically results in a net zero effect on the reporting burden under OMB control number 0648–0016, because headboat owners and operators will continue to report all species harvested, however, now electronically instead of by paper. NMFS estimates the requirement for headboat owners and operators to report more frequently (weekly instead of monthly) does not create more burden on headboat owners and operators, because the headboat owners and operators will still be reporting the same amount of information; they will just be clicking the send button to transmit the data more frequently. Keeping accurate records is essential to successful business operation. As a result, recording trips as they are completed, or as soon as is practical, is expected to be the common business practice. These estimates of the public reporting burden include the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection-of-information.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection-of-information subject to the requirements of the PRA, unless that collection-of-information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Headboat, Reporting and recordkeeping requirements, South Atlantic.

Dated: December 20, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, Performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.13, paragraph (g) is added to read as follows:

§ 622.13 Prohibitions—general.

* * * * *

(g) Harvest or possess fish if the required headboat reports have not been submitted in accordance with this part.

* * * * *

■ 3. In § 622.176, paragraph (b) is revised to read as follows:

§ 622.176 Recordkeeping and reporting.

* * * * *

(b) *Charter vessel/headboat owners and operators*—(1) *General reporting requirement*—(i) *Charter vessels.* The owner or operator of a charter vessel for which a charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, as required under § 622.170(b)(1), or whose vessel fishes for or lands such snapper-grouper in or from state waters adjoining the South Atlantic EEZ, who is selected to report by the SRD must maintain a fishing record for each trip, or a portion of such trips as specified by the SRD, on forms provided by the SRD and must submit such record as specified in paragraph (b)(2) of this section.

(ii) *Headboats.* The owner or operator of a headboat for which a charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, as required under § 622.170(b)(1), or whose vessel fishes for or lands such snapper-grouper in or from state waters adjoining the South Atlantic EEZ, who is selected to report by the SRD must submit an electronic fishing record for each trip of all fish harvested within the time period specified in paragraph (b)(2)(ii) of this section, via the Southeast Region Headboat Survey.

(iii) *Electronic logbook/video monitoring reporting.* The owner or operator of a vessel for which a charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, as required under § 622.170(b)(1), or whose vessel fishes for or lands such snapper-grouper in or from state waters adjoining the South Atlantic EEZ, who is selected to report by the SRD must participate in the NMFS-sponsored electronic logbook and/or video monitoring program as directed by the SRD. Compliance with the reporting requirements of this paragraph (b)(1)(iii) is required for permit renewal.

(2) *Reporting deadlines*—(i) *Charter vessels.* Completed fishing records required by paragraph (b)(1)(i) of this section for charter vessels must be submitted to the SRD weekly, postmarked no later than 7 days after the end of each week (Sunday). Completed fishing records required by paragraph (b)(1)(iii) of this section for charter vessels may be required weekly or daily, as directed by the SRD. Information to be reported is indicated on the form and its accompanying instructions.

(ii) *Headboats.* Electronic fishing records required by paragraph (b)(1)(ii) of this section for headboats must be submitted at weekly intervals (or intervals shorter than a week if notified by the SRD) by 11:59 p.m., local time, the Sunday following a reporting week. If no fishing activity occurred during a reporting week, an electronic report so stating must be submitted for that reporting week by 11:59 p.m., local time, the Sunday following a reporting week.

(3) *Catastrophic conditions.* During catastrophic conditions only, NMFS provides for use of paper forms for basic required functions as a backup to the electronic reports required by paragraph (b)(1)(ii) of this section. The RA will determine when catastrophic conditions exist, the duration of the catastrophic conditions, and which participants or geographic areas are deemed affected by the catastrophic conditions. The RA will provide timely notice to affected participants via publication of notification in the **Federal Register,** NOAA weather radio, fishery bulletins, and other appropriate means and will authorize the affected participants' use of paper forms for the duration of the catastrophic conditions. The paper forms will be available from NMFS. During catastrophic conditions, the RA has the authority to waive or modify reporting time requirements.

(4) *Compliance requirement.* Electronic reports required by paragraph (b)(1)(ii) of this section must be submitted and received by NMFS according to the reporting requirements under this section. A report not received within the time specified in paragraph (b)(2)(ii) of this section is delinquent. A delinquent report automatically results in the owner and operator of a headboat for which a charter vessel/headboat permit for South Atlantic snapper-grouper has been issued being prohibited from harvesting or possessing such species, regardless of any additional notification to the delinquent owner and operator by NMFS. The owner and operator who are prohibited from harvesting or possessing such species due to delinquent reports are authorized to harvest or possess such species only after all required and delinquent reports have been submitted and received by NMFS according to the reporting requirements under this section.

* * * * *

■ 4. In § 622.271, paragraph (b) is revised to read as follows:

§ 622.271 Recordkeeping and reporting.

* * * * *

(b) *Charter vessel/headboat owners and operators*—(1) *General reporting requirement*—(i) *Charter vessels.* The owner or operator of a charter vessel for which a charter vessel/headboat permit for Atlantic dolphin and wahoo has been issued, as required under § 622.270(b)(1), or whose vessel fishes for or lands Atlantic dolphin or wahoo in or from state waters adjoining the Atlantic EEZ, who is selected to report by the SRD must maintain a fishing record for each trip, or a portion of such trips as specified by the SRD, on forms provided by the SRD and must submit such record as specified in paragraph (b)(2) of this section.

(ii) *Headboats.* The owner or operator of a headboat for which a charter vessel/headboat permit for Atlantic dolphin and wahoo has been issued, as required under § 622.270(b)(1), or whose vessel fishes for or lands Atlantic dolphin or wahoo in or from state waters adjoining the South Atlantic EEZ, who is selected to report by the SRD must submit an electronic fishing record for each trip of all fish harvested within the time period specified in paragraph (b)(2)(ii) of this section, via the Southeast Region Headboat Survey.

(2) *Reporting deadlines*—(i) *Charter vessels.* Completed fishing records required by paragraph (b)(1)(i) of this section for charter vessels must be submitted to the SRD weekly, postmarked no later than 7 days after the end of each week (Sunday).

Information to be reported is indicated on the form and its accompanying instructions.

(ii) *Headboats.* Electronic fishing records required by paragraph (b)(1)(ii) of this section for headboats must be submitted at weekly intervals (or intervals shorter than a week if notified by the SRD) by 11:59 p.m., local time, the Sunday following a reporting week. If no fishing activity occurred during a reporting week, an electronic report so stating must be submitted for that reporting week by 11:59 p.m., local time, the Sunday following a reporting week.

(3) *Catastrophic conditions.* During catastrophic conditions only, NMFS provides for use of paper forms for basic required functions as a backup to the electronic fishing records required by paragraph (b)(1)(ii) of this section. The RA will determine when catastrophic conditions exist, the duration of the catastrophic conditions, and which participants or geographic areas are deemed affected by the catastrophic conditions. The RA will provide timely notice to affected participants via publication of notification in the **Federal Register**, NOAA weather radio, fishery bulletins, and other appropriate means and will authorize the affected participants' use of paper forms for the duration of the catastrophic conditions. The paper forms will be available from NMFS. During catastrophic conditions, the RA has the authority to waive or modify reporting time requirements.

(4) *Compliance requirement.* Electronic reports required by paragraph (b)(1)(ii) of this section must be submitted and received by NMFS according to the reporting requirements under this section. A report not received within the time specified in paragraph (b)(2)(ii) of this section is delinquent. A delinquent report automatically results in the owner and operator of a headboat for which a charter vessel/headboat permit for Atlantic dolphin and wahoo has been issued being prohibited from harvesting or possessing such species, regardless of any additional notification to the delinquent owner and operator by NMFS. The owner and operator who are prohibited from harvesting or possessing such species due to delinquent reports are authorized to harvest or possess such species only after all required and delinquent reports have been submitted and received by NMFS according to the reporting requirements under this section.

* * * * *

■ 5. In § 622.374, paragraph (b) is revised to read as follows:

§ 622.374 Recordkeeping and reporting.

* * * * *

(b) *Charter vessel/headboat owners and operators*—(1) *General reporting requirement*—(i) *Charter vessels.* The owner or operator of a charter vessel for which a charter vessel/headboat permit for Gulf coastal migratory pelagic fish or South Atlantic coastal migratory pelagic fish has been issued, as required under § 622.370(b)(1), or whose vessel fishes for or lands Gulf or South Atlantic coastal migratory pelagic fish in or from state waters adjoining the Gulf or South Atlantic EEZ, who is selected to report by the SRD must maintain a fishing record for each trip, or a portion of such trips as specified by the SRD, on forms provided by the SRD and must submit such record as specified in paragraph (b)(2)(i) of this section.

(ii) *South Atlantic headboats.* The owner or operator of a headboat for which a charter vessel/headboat permit for South Atlantic coastal migratory fish has been issued, as required under § 622.370(b)(1), or whose vessel fishes for or lands South Atlantic coastal migratory pelagic fish in or from state waters adjoining the South Atlantic EEZ, who is selected to report by the SRD must submit an electronic fishing record of each trip of all fish harvested within the time period specified in paragraph (b)(2)(ii) of this section, via the Southeast Region Headboat Survey.

(iii) *Gulf headboats.* The owner or operator of a headboat for which a charter vessel/headboat permit for Gulf coastal migratory pelagic fish has been issued, as required under § 622.370(b)(1), or whose vessel fishes for or lands Gulf coastal migratory fish in or from state waters adjoining the Gulf EEZ, who is selected to report by the SRD must maintain a fishing record for each trip, or a portion of such trips as specified by the SRD, on forms provided by the SRD and must submit such record as specified in paragraph (b)(2)(iii) of this section.

(2) *Reporting deadlines*—(i) *Charter vessels.* Completed fishing records required by paragraph (b)(1)(i) of this section for charter vessels must be submitted to the SRD weekly, postmarked no later than 7 days after the end of each week (Sunday). Information to be reported is indicated on the form and its accompanying instructions.

(ii) *South Atlantic headboats.* Electronic fishing records required by paragraph (b)(1)(ii) of this section for South Atlantic headboats must be submitted at weekly intervals (or intervals shorter than a week if notified by the SRD) by 11:59 p.m., local time, the Sunday following a reporting week. If no fishing activity occurred during a reporting week, an electronic report so stating must be submitted for that reporting week by 11:59 p.m., local time, the Sunday following a reporting week.

(iii) *Gulf headboats.* Completed fishing records required by paragraph (b)(1)(iii) of this section for Gulf headboats must be submitted to the SRD monthly and must be made available to an authorized statistical reporting agent or be postmarked no later than 7 days after the end of each month. Information to be reported is indicated on the form and its accompanying instructions.

(3) *Catastrophic conditions.* During catastrophic conditions only, NMFS provides for use of paper forms for basic required functions as a backup to the electronic reports required by paragraph (b)(1)(ii) of this section. The RA will determine when catastrophic conditions exist, the duration of the catastrophic conditions, and which participants or geographic areas are deemed affected by the catastrophic conditions. The RA will provide timely notice to affected participants via publication of notification in the **Federal Register**, NOAA weather radio, fishery bulletins, and other appropriate means and will authorize the affected participants' use of paper forms for the duration of the catastrophic conditions. The paper forms will be available from NMFS. During catastrophic conditions, the RA has the authority to waive or modify reporting time requirements.

(4) *Compliance requirement.* Electronic reports required by paragraph (b)(1)(ii) of this section must be submitted and received by NMFS according to the reporting requirements under this section. A report not received within the time specified in paragraph (b)(2)(ii) of this section is delinquent. A delinquent report automatically results in the owner and operator of a headboat for which a charter vessel/headboat permit for South Atlantic coastal migratory pelagic fish has been issued being prohibited from harvesting or possessing such species, regardless of any additional notification to the delinquent owner and operator by NMFS. The owner and operator who are prohibited from harvesting or possessing such species due to delinquent reports are authorized to harvest or possess such species only after all required and delinquent reports have been submitted and received by NMFS according to the reporting requirements under this section.

* * * * *

[FR Doc. 2013–31069 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 131212999–3999–01]

RIN 0648–BD84

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Extension of Emergency Fishery Closure Due to the Presence of the Toxin That Causes Paralytic Shellfish Poisoning

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; emergency action; extension of effective period and expansion; request for comments.

SUMMARY: This temporary rule extends a closure of Federal waters for one year, through December 31, 2014. It also expands the list of species prohibited for harvest under this closure to include gastropods, commonly referred to as whelks, conchs, and snails. This temporary rule, first published in 2005, has been subsequently extended several times at the request of the U.S. Food and Drug Administration. This action also includes a correction to exclude the Federal waters west of 70 degrees West longitude.

DATES: This action extends the closure for one year, effective January 1, 2014, through December 31, 2014. Comments must be received on any part of this action by January 27, 2014.

ADDRESSES: You may submit comments, identified by NOAA-NMFS-2011-0260, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2011-0260*, click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Fax:* (978) 281–9177, Attn: Jason Berthiaume.
- *Mail:* John K. Bullard, Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope: "Comments on PSP Closure."

Instructions: All comments received are part of the public record and will generally be posted to *www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted via Microsoft Word, Microsoft Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Jason Berthiaume, Fishery Management Specialist, phone: (978) 281–9177, fax: (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Background

On June 10, 2005, the U.S. Food and Drug Administration (FDA) requested that NMFS close an area of Federal waters off the coasts of New Hampshire and Massachusetts to fishing for bivalve shellfish intended for human consumption due to the presence in those waters of toxins (saxotoxins) that cause Paralytic Shellfish Poisoning (PSP). These toxins are produced by the alga *Alexandrium fundyense,* which can form blooms commonly referred to as red tides. Red tide blooms, also known as harmful algal blooms (HABs), can produce toxins that accumulate in filter-feeding shellfish. Shellfish contaminated with the toxin, if eaten in large enough quantity, can cause illness or death from PSP.

On June 16, 2005, NMFS published an emergency rule (70 FR 35047) closing the area recommended by the FDA (i.e., the Temporary PSP Closure Area). Since 2005, the closure has been extended several times and the area has been expanded and divided into northern and southern components. The Northern Temporary PSP Closure Area remained closed to the harvest of all bivalve molluscan shellfish, while the Southern Temporary PSP Closure Area was reopened to the harvest of Atlantic surfclams, ocean quahogs, and sea scallop adductor muscles harvested and shucked at sea. The current closure will expire on December 31, 2013, and this action extends this closure for one additional year, through December 31, 2014.

In addition, this emergency rule also prohibits the harvest of gastropods from the Temporary PSP Closure Areas. As discussed above, these areas are currently closed to the harvest of bivalves, but the closure does not include gastropods. Gastropods include carnivorous snails, conchs, and whelks that feed on bivalves. The bivalves, if contaminated with the toxin that causes PSP, transfer the toxins on to the gastropod. While there are few data available on how susceptible gastropods are to PSP, the available evidence suggests that gastropods typically have higher levels of the PSP toxin and retain it longer than bivalves taken from the same waters.

NMFS has recently received information that there is a developing Federal waters whelk fishery seeking to target the northern component of the Temporary PSP Closure to harvest whelks. While there has been a state waters whelk fishery in recent past, there have been few available data regarding a Federal waters fishery. The data that are available indicate that there is a Federal waters fishery, primarily Massachusetts based, where the PSP Closed Areas cover a large portion of the Massachusetts coast line. The FDA, in collaboration with the Commonwealth of Massachusetts Division of Marine Fisheries and Department of Public Health, have been actively investigating this issue, and, on October 29, 2013, the FDA and the Massachusetts Division of Marine Fisheries and Department of Public Health advised NMFS to expand the Temporary PSP Closures to also include a prohibition on the harvest of gastropods while the matter is being researched. On November 26, 2013, NMFS received a letter from the FDA, formalizing its request that NMFS modify the Temporary PSP Closures to also include a prohibition on the harvest of gastropods. Based on these recommendations, this action will prohibit the harvest and possession of gastropods from the areas currently defined as the Temporary PSP Closed Areas. The FDA is actively working on this and they have informed NMFS that they will continue to look into this issue. Therefore, until NMFS is directed otherwise by the FDA, the Temporary PSP Closed Areas will also include a prohibition on gastropod harvesting. As such, NMFS is seeking comments on the gastropod fishery, the PSP closure, and the susceptibility of gastropods and PSP.

The boundaries of the northern component of the Temporary PSP Closure Area comprise Federal waters bounded by the following coordinates specified in Table 1 below. Under this emergency rule, this area remains closed to the harvest of Atlantic surfclams, ocean quahogs, and whole or roe-on scallops, and also now includes gastropods.

TABLE 1—COORDINATES FOR THE NORTHERN TEMPORARY PSP CLOSURE AREA

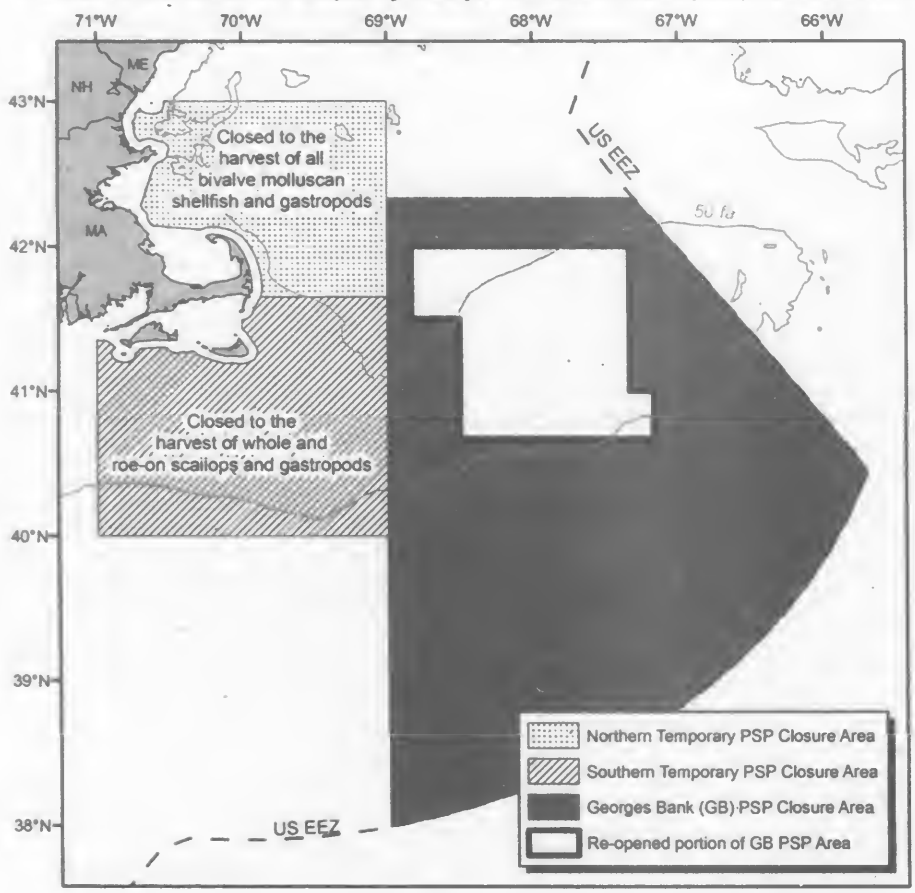
Point	Latitude	Longitude
1	43°00′ N	71°00′ W
2	43°00′ N	69°00′ W
3	41°39′ N	69°00′ W
4	41°39′ N	71°00′ W
5	43°00′ N	71°00′ W

The boundaries of the southern component of the Temporary PSP Closure Area comprise Federal waters bound by the following coordinates specified in Table 2. Under this emergency rule, the Southern Temporary PSP Closure Area remains closed to the harvest of whole or roe-on scallops, and now also includes gastropods.

TABLE 2—COORDINATES FOR THE SOUTHERN TEMPORARY PSP CLOSURE AREA

Point	Latitude	Longitude
1	41°39′ N	71°00′ W
2	41°39′ N	69°00′ W
3	40°00′ N	69°00′ W
4	40°00′ N	71°00′ W
5	41°39′ N	71°00′ W

Northern and Southern Temporary Paralytic Shellfish Poison (PSP) Closure Areas



This notice also corrects and clarifies the coordinates in the regulatory text to exclude the area known as Nantucket Shoals (also referred to as pocket waters) from the closure. The Magnuson-Stevens Fishery

Conservation and Management Act provides the Commonwealth of Massachusetts with the authority to manage the Federal waters in this area west of the 70 degrees West longitude. This change is a technical correction and will have no effects on fisheries because Massachusetts already exercises its authority in this area.

Classification

Pursuant to section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1855(c) the Assistant Administrator for Fisheries, NOAA, has determined that this emergency action is consistent with the provisions of the Magnuson-Stevens Act, and other applicable law. Section 305 of the Magnuson-Stevens Act authorizes the Secretary to act if (1) the Secretary finds that an emergency involving a fishery exists; or (2) the Secretary finds that interim measures are needed to reduce overfishing in any fishery; or (3) if the Council finds one of those factors exists and requests that the Secretary act; or (4) to respond to a public health emergency or an oil spill. Where such circumstances exist, the Secretary may promulgate emergency rules or interim measures "to address the emergency or overfishing" (16 U.S.C. 1855(c)(1) and (2)). The Secretary has delegated this authority to NMFS. Further, NMFS has issued guidance defining when "an emergency" involving a fishery exists (62 FR 44421; August 21, 1997). This guidance defines an emergency as a situation that (1) arose from recent, unforeseen events, (2) presents a serious management problem in the fishery, and (3) can be addressed through interim emergency regulations for which the immediate benefits outweigh the value of advance notice, public comment, and the deliberative consideration of the impacts on participants to the same extent as would be expected under the formal rulemaking process. Therefore, the rationale for an emergency as provided in the preamble of this rule, justifies this rule as an emergency and interim action according to the statutes and guidance as cited above.

Pursuant to section 5 U.S.C. 553(b)(B) of the Administrative Procedure Act, the Assistant Administrator for Fisheries finds there is good cause to waive prior notice and an opportunity for public comment on this action as notice and comment would be impracticable and contrary to the public interest due to a public health emergency. This action prohibits the harvest and possession of gastropods from the areas referred to as the Temporary PSP Closed Areas, which have been closed to bivalve fishing since 2005. NMFS has recently received information that the whelk fishery is a new and potentially expanding fishery in Federal waters, possibly targeting the northern component of the Temporary PSP Closure Area to harvest whelks. Based on available data, whelk are susceptible to PSP as they can ingest bivalves contaminated with the toxins that cause PSP, transferring the toxins on to the gastropod. As such, since the current closure does not include gastropods, there is risk of gastropods contaminated with PSP entering the market for human consumption. As such, to protect public health it is in the best interest of the public as well as the developing whelk fishery to have this action in place as soon as possible. Thus, there is good cause to waive prior notice and an opportunity for public comment on this action as notice and comment would be impracticable and contrary to the public interest due to a public health emergency.

In regards to the closure extension, public comment has been solicited concurrently with each of the extensions of this action, as detailed and responded to below. Under section 553(d)(3), there is good cause to waive the 30-day delay in effectiveness due to a public health emergency. The original emergency closure was in response to a public health emergency. Toxic algal blooms are responsible for the marine toxin that causes PSP in persons consuming affected shellfish. People have become seriously ill and some have died from consuming affected shellfish under similar circumstances. Pursuant to section 305(c)(3)(C) of the Magnuson-Stevens Act, the closure to the harvest of shellfish, as modified on September 9, 2005, and re-instated on October 18, 2005, may remain in effect until the circumstances that created the emergency no longer exist, provided the public has had an opportunity to comment after the regulation was published, and, in the case of a public health emergency, the Secretary of Health and Human Services concurs with the Commerce Secretary's action. During the initial comment period, June 16, 2005, through August 1, 2005, no comments were received. Two comments were received after the re-opening of the southern component of the Temporary PSP Closure Area on September 9, 2005. One commenter described the overall poor quality of water in Boston Harbor, but provided no evidence to back these claims. The other commenter expressed reluctance to re-opening a portion of the closure area without seeing the results of the FDA tests. Data used to make determinations regarding closing and opening of areas to certain types of fishing activity are collected from Federal, state, and private laboratories. NOAA maintains a Red Tide Information Center (*http://oceanservice.noaa.gov/redtide*) which can be accessed directly or through the Web site listed in the **ADDRESSES** section. Information on test results, modeling of algal bloom movement, and general background on red tides can be accessed through this information center. While NMFS is the agency with the authority to promulgate the emergency regulations, NMFS defers to the FDA in promulgating such regulations when in regard to public health. The FDA requested that NMFS lift a portion of the closure after the FDA determined that the area was safe. Based on this recommendation, NMFS lifted a portion of the closure on September 9, 2005. If necessary, the regulations may be terminated at an earlier date, pursuant to section 305(c)(3)(D) of the Magnuson-Stevens Act, by publication in the **Federal Register** of a notice of termination, or extended further to ensure the safety of human health.

This emergency action is exempt from the procedures of the Regulatory Flexibility Act because the rule is issued without opportunity for prior notice and opportunity for public comment.

This rule is not significant for the purposes of Executive Order 12866.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: December 20, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is amended to read as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.14, paragraphs (a)(10)(iii) and (iv) are added to read as follows:

§ 648.14 Prohibitions.

(a) * * *

(10) * * *

(iii) Fish for, harvest, catch, possess or attempt to fish for, harvest, catch, or possess any bivalve shellfish, including

Atlantic surfclams, ocean quahogs, and mussels, with the exception of sea scallops harvested only for adductor muscles and shucked at sea, and any gastropods, including whelks, conchs, and carnivorous snails, unless issued and possessing on board a Letter of Authorization (LOA) from the Regional Administrator authorizing the collection of shellfish and/or gastropods for biological sampling and operating under the terms and conditions of said LOA, in the area of the U.S. Exclusive Economic Zone bound by the following coordinates in the order stated:

(A) 43°00′ N. lat., 71°00′ W. long.;
(B) 43°00′ N. lat., 69°00′ W. long.;
(C) 41°39′ N. lat., 69°00′ W. long.;
(D) 41°39′ N. lat., 71°00′ W. long.; and then ending at the first point.

(iv) Fish for, harvest, catch, possess, or attempt to fish for, harvest, catch, or possess any sea scallops, except for sea scallops harvested only for adductor muscles and shucked at sea, and any gastropods, including whelks, conchs, and carnivorous snails, unless issued and possessing on board a Letter of Authorization (LOA) from the Regional Administrator authorizing collection of shellfish and/or gastropods for biological sampling and operating under the terms and conditions of said LOA, in the area of the U.S. Exclusive Economic Zone bound by the following coordinates in the order stated below, excluding the Federal waters of Nantucket Sound west of 70° 00′ W. Longitude:

(A) 41°39′ N. lat., 71°00′W. long.;
(B) 41°39′ N. lat., 69°00′ W. long.;
(C) 40°00′ N. lat., 69°00′ W. long.:
(D) 40°00′ N. lat., 71°00′ W. long.; and then ending at the first point.

* * * * *

[FR Doc. 2013–30945 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 121009528–2729–02]

RIN 0648–XD026

Fisheries of the Northeastern United States; 2014 Commercial Summer Flounder Quota Adjustments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Announcement of 2014 commercial summer flounder state quotas.

SUMMARY: NMFS is announcing the commercial summer flounder state quotas for fishing year 2014. The 2014 summer flounder specifications were established in December 2012. This notice incorporates any previously unaccounted for overages from fishing year 2012 and any known overages to date from fishing year 2013. These commercial state quotas may change as a result of a recent stock assessment and a recommendation by the Mid-Atlantic Fishery Management Council.

DATES: Effective January 1, 2014, through December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Moira Kelly, Fishery Policy Analyst, (978) 281–9218.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council (Council) and the Atlantic States Marine Fisheries Commission cooperatively manage the summer flounder, scup, and black sea bass fisheries. Specifications in these fisheries include the acceptable biological catch (ABC) limit, various catch and landing subdivisions (such as the commercial and recreational sector annual catch limits (ACLs)), annual catch targets (ACTs), sector-specific landing limits (i.e., the commercial fishery quota and recreational harvest limit (RHL)), and research set-aside (RSA) established for the upcoming fishing year. Typically, these specifications are set on an annual basis and announced in the **Federal Register** in December of each year. Because the summer flounder stock assessment was scheduled for July 2013 and the normal specification schedule would be delayed, the Council established specifications for the 2014 summer flounder fishery in December 2012 (December 31, 2012; 77 FR 76942). These specifications included the initial state allocations, as well as the state allocations after adjusting for RSA.

An important component of the annual specifications rulemaking is the notification of the commercial summer flounder state quota and overages. Overages are calculated using final landings data from the previous fishing year and landings from the current fishing year through October 31. In this case, previously unaccounted for overages from fishing year 2012 are combined with known overages from fishing year 2013, through October 31, 2013. As a result, the 2014 summer flounder state quotas, adjusted for RSA and overages, are as follows:

TABLE 1—2014 COMMERCIAL SUMMER FLOUNDER STATE QUOTAS, AS ADJUSTED BY OVERAGES AND RSA

State	FMP percent share	2014 Initial quota		2014 Initial quota, less RSA		Quota overages (through 10/31/13)		Adjusted 2014 quota, less RSA and overages	
		lb	kg	lb	kg	lb	kg	lb	kg
ME	0.04756	5,579	2,533	5,417	2,457	0	0	5,417	2,457
NH	0.00046	54	24	52	24	0	0	52	24
MA	6.82046	800,091	363,242	776,788	352,345	28,199	12,791	748,589	339,554
RI	15.68298	1,839,732	835,240	1,786,147	810,183	0	0	1,786,147	810,183
CT	2.25708	264,772	120,207	257,061	116,601	0	0	257,061	116,601
NY	7.64699	897,050	407,261	870,922	395,044	79,355	35,995	791,587	359,058
NJ	16.72499	1,961,967	890,735	1,904,823	864,013	0	0	1,904,823	864,013
DE	0.01779	2,087	947	2,026	919	52,384	23,760	−50,358	−22,842
MD	2.03910	239,202	108,598	232,235	105,340	0	0	232,235	105,340
VA	21.31676	2,500,616	1,135,282	2,427,783	1,101,224	0	0	2,427,783	1,101,224
NC	27.44584	3,219,604	1,461,703	3,125,829	1,417,852	0	0	3,125,829	1,417,852
Total	100.00	11,730,754	5,326,000	11,389,082	5,166,000	155,376	70,476	11,284,065	5,118,366

On October 9, 2013, the Council met to discuss whether adjustments to the previously established 2014 specifications were necessary as a result of the updated stock assessment, and to establish fishing year 2015

specifications for the summer flounder, scup, and black sea bass fisheries. The Council determined that an adjustment was necessary for the 2014 summer flounder specifications. Table 2 below summarizes the established 2014 summer flounder specifications, as well as the specifications that the Council voted to recommend in October 2013. The Council has not yet submitted the specifications package to be reviewed by NMFS; nor has NMFS made a determination that these adjustments would be implemented. The state quotas listed in Table 1 will be in effect until and unless otherwise changed through proposed and final rulemaking.

TABLE 2—SUMMER FLOUNDER 2014 SPECIFICATIONS AND COUNCIL RECOMMENDED 2014 SPECIFICATIONS

	2014 Specifications		October 2013 council recommended 2014 specifications	
	million lb	mt	million lb	mt
ABC	22.24	10,088	21.94	9,950
Commercial ACL	12.05	5,467	12.87	5,837
Recreational ACL	10.19	4,621	9.07	4,113
Commercial ACT	12.05	5,467	12.87	5,837
Recreational ACT	10.19	4,621	9.07	4,113
Comm. Quota (less 3% for RSA)	11.39	5,166	10.51	4,767
RHL (less 3% for RSA)	7.59	3,444	7.01	3,178

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 23, 2013.

Emily H. Menashes,

Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–31070 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 78, No. 249
Friday, December 27, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 15d

RIN 0503–AA52

Nondiscrimination in Programs or Activities Conducted by the United States Department of Agriculture

AGENCY: United States Department of Agriculture.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Department of Agriculture (USDA or Department) proposes to amend its regulation on nondiscrimination in programs or activities conducted by the Department. The changes are proposed to clarify the roles and responsibilities of USDA's Office of the Assistant Secretary for Civil Rights (OASCR) and USDA agencies in enforcing nondiscrimination in programs or activities conducted by the Department and to strengthen USDA's civil rights compliance and complaint processing activities to better protect the rights of USDA customers. OASCR's compliance activities are detailed, and a requirement is included that each agency shall, for civil rights compliance purposes, collect, maintain, and annually compile data on the race, ethnicity, and gender of all conducted program applicants and participants by county and State. Applicants and program participants will provide the race, ethnicity, and gender data on a voluntary basis. The proposed amendment also provides that OASCR shall offer Alternative Dispute Resolution (ADR) services to complainants where appropriate. This amendment is intended to encourage the early resolution of customer complaints. Finally, USDA proposes to amend its regulation to add protection from discrimination in programs or activities conducted by the Department with respect to two new protected bases: political beliefs and gender identity. This amendment is meant to make explicit protections against discrimination based on USDA program customers' political beliefs or gender identity. Gender identity includes USDA program customers' gender expression, including how USDA program customers act, dress, perceive themselves, or otherwise express their gender.

DATES: Submit comments on or before January 27, 2014. Submit comments on the Paperwork Reduction Act package on or before February 25, 2014.

ADDRESSES: Submit comments on the proposed regulation to Anna G. Stroman, Chief, Policy Division, by mail at Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington DC, 20250. Please send written comments on the information collection or recordkeeping requirements included in this proposal to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), attention: Desk Officer for Agriculture, Washington, DC 20503.

Please state that your comments refer to Docket No. 0503–AA52. Please send a copy of your comments to: Docket No. 0503–AA52, Anna G. Stroman, Chief, Policy Division, by mail at the Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington DC, 20250. Comments on the Paperwork Reduction Act section are best assured of having their full effect if OMB receives them within 60 days of publication of this proposed rule.

FOR FURTHER INFORMATION CONTACT: Anna Stroman on (202) 205–5953 or at *anna.stroman@ascr.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The USDA proposes to amend its regulation on nondiscrimination in programs or activities conducted by the Department. In 1964, USDA extended the nondiscrimination principles found in Title VI of the Civil Rights Act of 1964 to apply to its own federally conducted activities by prohibiting discrimination on the basis of race, color, and national origin. (See 29 **Federal Register** (FR) 16966, creating 7 CFR part 15, subpart b, referring to nondiscrimination in direct USDA programs and activities, now found at 7 CFR part 15d). Subsequently, USDA expanded the protected bases for its conducted programs to include religion, sex, age, marital status, familial status, sexual orientation, disability, and whether any portion of a person's income is derived from public assistance programs. The Secretary's intention is to hold the Department and its employees accountable for a nondiscrimination standard equal to or greater than the standard recipients of Federal financial assistance must follow.

The regulation was last revised in 1999 (64 FR 66709, Nov 30, 1999). The changes are proposed to clarify the roles and responsibilities of OASCR and USDA agencies in enforcing nondiscrimination in programs or activities conducted by the Department ("conducted programs") and to strengthen USDA's civil rights compliance and complaint processing activities to better protect the rights of USDA customers. This regulation does not address those programs for which the Department provides Federal financial assistance [1] ("federally assisted programs"), which are covered under 7 CFR parts 15, 15a and 15b.

Highlights of Changes to the Regulation

The proposed regulation outlines three specific changes to current activities. First, the proposed regulation includes a requirement that each agency shall, for civil rights compliance purposes, collect, maintain, and annually compile, by county and State, data on the race, ethnicity, and gender of all applicants and participants of programs and activities conducted by USDA. Applicants and program participants of these programs will provide this data on a voluntary basis. Although USDA first established a policy for collecting data on race, ethnicity, and gender in 1969, there is currently no uniform requirement for reporting and tabulating this data across USDA's diverse program areas. The four USDA agencies that administer the majority of USDA's conducted programs—the Farm Services Agency (FSA), the Natural Resources Conservation Service (NRCS), Rural

[1] Federally assisted programs are programs and activities receiving financial assistance through a third party such as a State or municipal government, university, or organization. Federally conducted programs, which are those programs covered in this regulation, are programs and activities receiving assistance directly from USDA.

Development (RD), and the Forest Service—already collect this data from individuals. FSA, NRCS, and RD (the "field-based agencies") collect this data under the requirements of section 14006 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill), which requires collection of this data for each program that serves agricultural producers and landowners. This data allows USDA to track application and participation rates for socially disadvantaged and limited resources applicants and participants. Together, these four agencies capture more than 90 percent of the contacts USDA has with the public through its conducted programs. This proposed regulation will standardize the recordkeeping requirement across the Department to all programs conducted by USDA that deliver benefits to the public.

Second, the rule would require that OASCR offer ADR services to complainants where appropriate. This amendment is intended to encourage the early resolution of customer complaints and is in accordance with the Secretary of Agriculture's Blueprint for Stronger Service. Offering ADR will expand the use of techniques currently applied in the employment context that facilitate complaint resolution and shorten resolution time. It will provide a cost-effective opportunity for early complaint resolution. USDA anticipates that this measure will reduce costs associated with complaint processing while also enhancing customer experience with the Department.

Finally, USDA proposes to amend its regulation to add protection from discrimination in programs or activities conducted by the Department with respect to two new protected bases, political beliefs and gender identity. Discrimination by USDA employees on these grounds is already prohibited in USDA's nondiscrimination statement. This amendment is meant to formalize protections against discrimination based on USDA program customers' political beliefs or gender identity, which will strengthen USDA's ability to ensure that all USDA customers receive fair and consistent treatment, and align the regulations with USDA's civil rights goals. Gender identity includes USDA program customers' gender expression, including how USDA program customers act, dress, perceive themselves, or otherwise express their gender.

The inclusion of political beliefs will prohibit discrimination consistent with the Food Stamp Act of 1964, Public Law 88–525, 78 Stat. 703–709 (Aug. 31, 1964), the Civil Service Reform Act of 1978 (which covers political affiliation), and the Secretary of Agriculture's civil rights policy statements.

The inclusion of gender identity will ensure equal treatment of transgender and other gender nonconforming individuals in USDA's conducted programs and activities. For the purpose of this regulation, gender identity includes USDA program customers' gender expression, including how USDA program customers act, dress, perceive themselves, or otherwise express their gender. The inclusion of gender identity as a separate category is not intended to undermine existing protections for transgender and other nonconforming individuals under laws that prohibit sex discrimination.

The change proposed will allow USDA customers of conducted programs who believe that they have been discriminated against on the basis of political beliefs or gender identity to take advantage of USDA's existing mechanisms to file an administrative complaint and receive a response. USDA's response could include recommending additional training for USDA employees or outreach in appropriate cases, procedures which already take place and can continue to take place within existing resources. The change proposed applies only to USDA's internal administrative complaint mechanism and does not, in and of itself, create any new legal rights to bring suit against USDA, or expand the class of cases where USDA is authorized to pay money in connection with civil rights complaints.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

The proposed rule has been determined to be significant for the purposes of Executive Order 12866 by the OMB. Executive Order 12866, "Regulatory Planning and Review," and Executive Order 13563, "Improving Regulation and Regulatory Review," direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

The Regulatory Flexibility Act (RFA) requires agencies to consider the impact of their rules on small entities and to evaluate alternatives that would accomplish the same objectives without undue burden when the rules impose a significant economic impact on a substantial number of small entities.

Regulatory Impact Analysis—Benefits and Costs

The proposed changes to 7 CFR part 15d will clarify the roles and responsibilities of the United States Department of Agriculture's (USDA) Office of the Assistant Secretary for Civil Rights (OASCR) and USDA agencies in enforcing nondiscrimination in programs or activities conducted by the Department. They will also strengthen USDA's civil rights compliance and complaint processing activities to better protect the rights of USDA's customers.

Impact of Changes

This regulation will afford several benefits. First, requiring the collection of data in a standardized fashion of applicants and participants of those programs in which USDA directly provides to the public services, benefits, or resources (i.e. conducted programs) will conform with the requirements of the 2008 Farm Bill. Second, it will strengthen USDA's ability to monitor agency compliance with civil rights requirements. Third, the expansion of Alternative Dispute Resolution Services will enhance USDA's ability to resolve complaints against USDA conducted programs, and result in a small net annual savings to USDA. The expansion of protections against discrimination in the delivery of conducted programs will improve the protection of USDA customers' rights by ensuring that USDA conducted programs are delivered fairly and consistently.

These changes will impose a small, time-related cost on the public who are served by USDA's conducted programs through the data collection requirement, should they volunteer to provide the data. This data collection requirement will benefit USDA by enabling it to better monitor whether USDA programs and services are meeting the needs of all populations served by USDA. USDA does not anticipate that the proposed changes will otherwise significantly add to USDA's program costs.

The proposed changes do not affect programs administered by States, local governments, or other third-party recipients of Federal assistance from USDA, which are covered under 7 CFR parts 15, 15a and 15b. The benefits and costs of each of the three proposed changes to the rule are discussed below.

Collection of Voluntary Data on Race, Ethnicity, and Gender

The proposed rule requires that each USDA agency collect, maintain, and annually compile data on the race, ethnicity, and gender of all program

applicants and participants of conducted programs by county and State. Program users' responses will be voluntary. This will create a standard collection of data on race, ethnicity, and gender from applicants and beneficiaries of USDA-conducted programs. USDA anticipates that this expanded data collection will include additional data regarding customers who are and are not receiving USDA benefits, improve the design of USDA programs, and ultimately reduce the number of complaints of discrimination filed against USDA. While it is difficult to quantify the impact of these improvements in advance of implementation, improvements in outreach and monitoring adopted since 2009 led to a measurable drop in complaints received.

As described below, the proposed additional collection of voluntary data will impose a small new cost on the public in the form of time needed to complete the form. USDA estimates that the cost to the USDA agency to process the collection of the additional data on race, ethnicity, and gender proposed in the rule will be low. As previously described, the three field-based agencies and the Forest Service account for more than 90 percent of contacts with the public in USDA-conducted programs. However, these agencies are already collecting the data required under this rule, and USDA has already incurred the associated costs. Three additional USDA agencies currently have conducted programs that will be covered by the proposed rule, and the passage of this rule will require new data collection efforts. These three agencies are the Animal and Plant Health Inspection Service (APHIS), the Foreign Agricultural Service (FAS), and the Food and Nutrition Service (FNS). These three agencies will collect voluntary data from individuals who apply, participate in, or receive benefits from their various conducted programs. Collectively, collection of voluntary data at these three agencies will impact an estimated 1,349 additional program users per year. USDA estimates that it will take each participant 3 minutes to respond, and using a conservative 100-percent response rate, USDA estimates that the total new impact to the public from this requirement will be 68 additional burden hours to program users (Table 1). For comparison, the existing collection requirements under FSA, NRCS, RD, and the Forest Service involve a burden of about 82,800 hours. Considering USDA agency costs, USDA estimates the total cost of the additional data collection to be $5,289 (Table 2).

TABLE 1—ESTIMATED BURDEN HOURS TO PUBLIC FROM NEW DATA COLLECTION REQUIRED BY PROPOSED RULE

Agency	Contacts with program users per year [1]	Annual burden hours at 3 min. per form [2]
APHIS	1,100	55
FAS	90	5
FNS	159	8
Total	1,349	68

Source:
[1] Individual USDA Agency estimates of the number of program participants engaging in conducted programs
[2] Annual burden hours are calculated based on the unit of time needed to complete the form: 3 min./60 min. = 0.05hours per form, which is multiplied by the number of agency program users.

TABLE 2—ESTIMATED PUBLIC AND AGENCY COST OF NEW DATA COLLECTION REQUIRED BY PROPOSED RULE

Agency	Number of contacts with program users per year [1]	Estimated cost to public in time required to complete form at $0.84 per contact [2]	Cost to USDA to collect and report data at $3.08 per contact [3]	Total costs
APHIS	1,100	$924	$3388	$4312
FAS	90	76	277	353
FNS	159	134	490	624
Total [4]	1,349	1,134	4,155	5,289

Sources:
[1] Individual USDA Agency estimates of the number of program participants engaging in conducted programs.
[2] Estimated cost to the public in the time required to complete the form is estimated based on the Department of Labor Occupation Employment Survey data, which shows that for all occupations, the median wage rate is $16.71/hr. This rate equals $0.28 per minute, or $.84 per 3-minute contact. This figure is multiplied by the number of agency program users.
[3] Estimated cost to process each form is based on the assumption that the data from one contact will take 10 minutes to process by an employee at a GS–7 Step 5 salary. The Office of Personnel Management states that this salary is $18.45/hr. This rate equals $0.308 per minute, or $3.08 per 10-minute contact. This figure is multiplied by the number of agency program users.

Alternative Dispute Resolution Services Offered to Program Complainants

The proposed amendment provides that OASCR shall offer ADR services to complainants where appropriate. This amendment is intended to encourage the early resolution of customer complaints. The outcome from early resolution should improve customers' experience with the complaint process and result in reduced costs to complainants and the Department.

The proposed change to ADR will not impose or result in any costs to the public served by USDA's conducted programs. USDA anticipates that this expansion of ADR services to complainants of USDA's conducted programs will provide a small net yearly savings to USDA. USDA receives, on

average, approximately 1,055 [2] complaints from participants of all USDA programs per year; of these, 160 are under USDA's conducted programs and would be covered by this rule.

Even assuming an additional 160 program complaints per year through ADR, USDA has existing infrastructure to process these complaints. An average of 16.7 hours of staff time will be required to provide ADR in each case. Based on an hourly wage rate of $46 per hour for this staff, OASCR estimates an annual estimated cost of program ADR of $122,912.

Historically, the ADR rate of resolution for Equal Employment Opportunity cases is 16.5 percent. Should this rate be realized for program resolution, approximately 26 cases per year would be resolved through ADR. Complaints successfully resolved through ADR will allow the avoidance of several additional, costly steps currently required to resolve complaints, such as an Agency response, fact finding, investigation, adjudication, or review. OASCR estimates that avoiding these steps would save an average of 250 hours of staff time per complaint successfully resolved through ADR. Resolving 26 cases through ADR would save the agency approximately 6,500 hours in processing time. These savings amount to $299,000, yielding net savings of about $176,000 per year by implementing ADR for program complaints.

Adding Explicit Protections Against Discrimination Based on Political Beliefs and Gender Identity

Finally, USDA proposes to amend its regulation to add protection from discrimination in programs or activities conducted by the Department with respect to two new protected bases, political beliefs and gender identity. Discrimination by USDA employees on these grounds is already prohibited in USDA's nondiscrimination statement. Making these protections explicit in the governing regulations will benefit the public by strengthening USDA's ability to ensure that all USDA customers receive fair and consistent treatment, and will bring the regulations into alignment with USDA's nondiscrimination goals. The proposed change will impose no new costs on the public served by USDA-conducted programs, and USDA does not expect any significant increase in operational costs to USDA.

[2] Estimated complaints average based on data from FY 2009–2011. FY 2009–2011 Farm Bill Reports are posted on OASCR Web site.

The change proposed will allow USDA customers of conducted programs who believe that they have been discriminated against based on their political beliefs or gender identity to take advantage of USDA's existing mechanisms to file an administrative complaint and receive a response. USDA's response could include recommending additional training for USDA employees or outreach in appropriate cases, procedures that already take place within existing resources. The change proposed applies only to USDA's internal administrative complaint mechanism and does not create any new legal rights to bring suit against USDA, or expand the class of cases where USDA is authorized to pay money in connection with civil rights complaints. The inclusion of gender identity also is not intended to undermine existing protections against transgender discrimination under laws that prohibit sex discrimination.

USDA does not anticipate a significant increase in operational costs to result from specifying that discrimination based on political beliefs and gender identity may be the bases for complaints in conducted programs. Based on USDA's complaint inventory, and the experience of the Department of Housing and Urban Development (HUD) in adopting similar protections, USDA does not anticipate a significant increase in the number of complaints, and therefore the cost of processing these complaints, as a result of extending the requirement that USDA program customers are treated fairly and without bias. Any additional administrative costs to process these complaints will be offset by the benefits of extending these protections to USDA customers.

For additional context, in February 2012, HUD amended its regulations to extend protections against discrimination based on gender identity (see FR Vol. 77, No. 23 at 5662 *et seq.*). The public comment period for the HUD-proposed rule resulted in approximately 376 public comments received from a variety of commenters, including individuals, advocacy groups, legal aid offices, tenant and fair housing organizations, realtors and their representatives, law school clinics, public housing authorities, local government officials, and members of Congress. The overwhelming majority of comments were supportive of the rule, stating that it was long overdue and noting that HUD, as the Nation's housing agency, should lead the efforts to prevent discrimination against Lesbian, Gay, Bisexual, and Transgender persons in housing. Moreover, HUD's rule has not created a significant increase in complaints received. USDA expects that its rule will be similarly received.

OASCR believes that the benefits of this rule exceed its cost, but OASCR invites comments on the analysis, and is interested in receiving further information that could be used to quantify further the benefits and costs of this proposed rule.

Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis" that will "describe the impact of the proposed rule on small entities." (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

7 CFR part 15d clarifies the roles and responsibilities of the USDA OASCR and USDA agencies in enforcing nondiscrimination in programs or activities conducted by the Department. The proposed regulation was last revised in 1999 (64 FR 66709, Nov 30, 1999). The changes also strengthen USDA's civil rights compliance and complaint processing activities to better protect the rights of USDA customers. As stated previously, the proposed data collection is in line with the requirements of section 14006 of the 2008 Farm Bill. The inclusion of political beliefs as a protected basis will prohibit discrimination in accordance with current civil rights laws, the Food Stamp Act of 1964, Public Law 88–525, 78 Stat. 703–709 (Aug. 31, 1964) and the Civil Service Reform Act of 1978 (which covers political affiliation) and the Secretary of Agriculture's civil rights policy statements.

The proposed rule may affect entities such as grocery and related product merchant wholesalers, establishments that export their goods on their own account that fall into category 4244 of the North American Industry Classification System (NAICS). Merchant wholesale establishments typically maintain their own warehouse, where they receive and handle goods for their customers. Goods are generally sold without transformation but may include integral functions, such as sorting, packaging, labeling, and other marketing services.

For the purpose of this analysis and following the Small Business Administration (SBA) guidelines, the potentially affected entities are classified within the following

industries: General Line Grocery Merchant Wholesalers (NAICS 424410); Packaged Frozen Food Merchant Wholesalers (NAICS 424420); Dairy Product (except Dried or Canned) Merchant Wholesalers (NAICS 424430); Poultry and Poultry Product Merchant Wholesalers (NAICS 424440); Confectionery Merchant Wholesalers (NAICS 424450); Fish and Seafood Merchant Wholesalers (NAICS 424460); Meat and Meat Product Merchant Wholesalers (NAICS 424470); Fresh Fruit and Vegetable Merchant Wholesalers (NAICS 424480); and Other Grocery and Related Products Merchant Wholesalers (NAICS 424490).

Establishments in the categories listed above are considered small by SBA standards if their employee base is less than 100 employees. According to the U.S. Census data, there are 46,272 grocery and related product merchant wholesalers that are considered small.

Based on USDA program data, it is expected that the proposed data collection requirements on those who apply, participate in, or receive benefits from various conducted programs may affect 90 participants who fall in the above cited categories. These are participants in FAS programs (Table 1). The remaining 1,259 contacts are private individuals.

USDA estimates that it will take each participant 3 minutes to respond. The race, ethnicity, and gender information will be voluntarily collected from individual applicants. Assuming an upper bound, 100-percent response rate of all 1,349 contacts, USDA estimates that the total new impact to the public from this requirement will be 68 additional burden hours per year at an estimated cost of about $1,100 (Table 2), or less than $1 per respondent should they choose to report.

The offer of ADR to program customers is not expected to have an adverse impact on small businesses. ADR will reduce the number of complaints filed, thereby reducing costs to the agency.

The inclusion of political beliefs and gender identity as protected bases is also not expected to have any adverse effect on small businesses. Instead, it will ensure that USDA is operating in accordance with the requirements of current civil rights laws and regulations and should not add additional costs to small businesses that are not participating in discriminatory activities or practices.

USDA considered the alternative of not updating its nondiscrimination regulations, however, without this rule, no additional assurances of nondiscrimination protections will be realized.

Based on the above discussion, the Assistant Secretary for Civil Rights certifies that this rule will not have a significant economic impact on a substantial number of small entities. USDA invites comment from members of the public who believe there will be a significant impact, and requests information to better inform the analysis of benefits and costs.

The 2008 Farm Bill, section 14006 requires the collection of application and participation rate data regarding socially disadvantaged farmers or ranchers. OMB has approved a form for this data collection, and the field-based agencies have already implemented it. This existing data collection already meets the requirements proposed in this rule, and therefore, the proposed rule imposes no new data collection requirements on the three field-based agencies and will not cause duplication or conflict with the 2008 Farm Bill requirements. USDA is unaware of any other Federal rules that duplicate, overlap, or conflict with the proposed rule.

Executive Order 12372

Executive Order 12372, "Intergovernmental Review of Federal Programs", requires consultation with State and local officials. The objectives of the Executive Order are to foster an intergovernmental partnership and a strengthened Federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance and direct Federal development. This rule neither provides Federal financial assistance nor direct Federal development. It does not provide either grants or cooperative agreements. Therefore, this program is not subject to Executive Order 12372.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988, "Civil Justice Reform." This rule would not preempt State and or local laws, and regulations, or policies unless they present an irreconcilable conflict with this rule. Before any judicial action may be brought regarding the provisions of this rule, the administrative appeal provisions of 7 CFR parts 11 and 780 must be exhausted.

Executive Order 13175

This rule has been reviewed for compliance with Executive Order 13175, "Consultation and Coordination with Indian Tribal governments." The review reveals that this rule will not have substantial and direct effects on Tribal Governments and will not have significant Tribal implications. OASCR consulted with the USDA Office of Tribal Relations in development of this proposed rule and believes that it will not impact or have direct effects on Tribal governments and will not have significant Tribal implications. OASCR continues to consult with the USDA Office of Tribal Relations to collaborate meaningfully to develop and strengthen departmental regulations.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandate Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions on State, local, or Tribal governments or the private sector. Agencies generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures of $100 million or more in any one year for State, local, or Tribal governments, in the aggregate, or to the private sector. The UMRA generally requires agencies to consider alternatives and adopt the more cost-effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandate as defined by Title II of UMRA for State, local, or Tribal governments or for the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Paperwork Reduction Act of 1995

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et* seq.), the information collection or recordkeeping requirements included in this proposed rule will be submitted for approval to OMB. Please send written comments to the Office of Information and Regulatory Affairs, OMB, attention: Desk Officer for the Office of the Assistant Secretary for Civil Rights, Washington, DC 20503. Please state that your comments refer to Docket No. 0503–AA52. Please send a copy of your comments to: Docket No. 0503–AA52, Anna G. Stroman, Chief, Policy Division, by mail, at the Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington DC, 20250. Comments on the Paperwork Reduction Act section are best assured of having their full effect if OMB receives them within 60 days of publication of this proposed rule.

The proposed rule outlines USDA's compliance activities in greater detail, including a requirement that each agency shall, for civil rights compliance

purposes, collect, maintain, and annually compile data on the race, ethnicity, and gender of all applicants and participants of programs and activities conducted by USDA, by county and State. This requirement would not apply to programs conducted by state or local governments or other private entities that receive Federal funding from USDA. While USDA agencies will be required to seek this data, program users' responses will be voluntary. USDA estimates that it will take program users who participate no more than 3 minutes to respond.

Four USDA agencies already collect and report this data; this regulation will not impact their existing data collections. The field-based agencies, FSA, NRCS, and RD, track participation rates for socially disadvantaged limited resources applicants and participants. Collection by these three agencies is required by Section 14006 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill). OMB has approved a form for data collection by the three field-based agencies, and USDA has already implemented collection efforts (Approved OMB No. 0503–0019). In addition, the Forest Service also has an OMB-approved form in place to collect this data through a survey (Approved OMB No. 0596–0110). The proposed regulation will standardize the recordkeeping requirement across the Department to all other programs conducted by USDA. FSA, NRCS, RD, and the Forest Service will continue to use the existing forms that OMB has approved for their data collections. Other program areas will adopt the form that has already been approved by OMB for the three field-based agencies, under control number OMB No. 0503–0019. Therefore, the provisions of this rule require no revision to the information collection requirements that were previously approved by OMB under control number 0503 0019.

There is no paperwork collection associated with the other changes in this rule.

USDA is soliciting comments from the public concerning the proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of the agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses).

Title of the Collection: 7 CFR part 15 subpart D—Data Collection Requirement

OMB Control Number: 0503–NEW

Estimate of burden hours: Public reporting burden for this collection of information is estimated to average 3 minutes per response.

Respondents: Applicant and program participants of USDA federally conducted programs.

Estimated annual number of Respondents: 1,349.

Estimated annual number of Responses per Respondent: 1.

Estimated annual number of Responses: 1,349.

Estimated total annual burden on Respondents: 68 hours.

Copies of this information collection can be obtained from: Clearance Officer, OCIO, USDA, Room 405W, 1400 Independence Avenue SW., Washington, DC 20250.

E-Government Act Compliance

OASCR is committed to complying with the E-Government Act, which requires Government Agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

List of Subjects in 7 CFR Part 15d

Civil rights, Equal employment opportunity, Grant programs-education, Individuals with disabilities.

For the reasons set forth in the preamble, USDA proposes to revise 7 CFR Part 15d to read as follows:

PART 15d—NONDISCRIMINATION IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE UNITED STATES DEPARTMENT OF AGRICULTURE

Sec.

Authority: 5 U.S.C. 301.

§ 15d.1 Purpose.

The purpose of this part is to set forth the nondiscrimination policy of the United States Department of Agriculture (USDA) in programs or activities conducted by the Department, including such programs and activities in which the Department or any agency thereof makes available any benefit directly to persons under such programs and activities.

§ 15d.2 Definitions.

For the purpose of this section, the below terms are defined as follows:

(a) *Agency* means a major organizational unit of the Department with delegated authority to deliver programs, activities, benefits, and services. Heads of Agencies receive their delegated authority as prescribed in 7 CFR Part 2.

(b) *Agency Head Assessment* means the annual Agency Civil Rights Performance Plan and Accomplishment Report conducted by the Office of the Assistant Secretary for Civil Rights (OASCR). It is an evaluation tool used by OASCR to assess USDA Agency Heads and Staff Office Directors on their civil rights activities and accomplishments to ensure accountability throughout the Department on these issues.

(c) *Alternative Dispute Resolution* or *ADR* means any number of conflict resolution procedures in which parties agree to use a third-party neutral to resolve complaints or issues in controversy. ADR methods include, but are not limited to, mediation, facilitation, fact finding, arbitration, use of ombuds, or any combination thereof.

(d) *Assistant Secretary for Civil Rights* or *ASCR* means the civil rights officer for USDA responsible for the performance and oversight of all civil rights functions within USDA, and who retains the authority to delegate civil rights functions to heads of USDA agencies and offices. The ASCR is also responsible for evaluating agency heads on their performance of civil rights functions.

(e) *Complaint* means a written statement that contains the complainant's name and address and describes an agency's alleged discriminatory action in sufficient detail to inform the ASCR of the nature and date of an alleged civil rights violation. The statement must be signed by the complainant(s) or someone authorized to sign on behalf of the complainant(s). To accommodate the needs of people with disabilities, special needs, or who have Limited English Proficiency, a complaint may be in an alternative format.

(f) *Compliance report* means a written review of an agency's compliance with civil rights requirements, to be prepared by OASCR and to identify each finding of non-compliance or other civil rights-

related issue. The review is conducted at the discretion of OASCR or if there has been a formal finding of non-compliance.

(g) *Conducted programs and activities* means the program services, benefits, or resources delivered directly to the public by USDA.

(h) *Days* mean calendar days, not business days.

(i) *Department (used interchangeably with USDA)* means the Department of Agriculture and includes each of its operating agencies and other organizational units.

(j) *Discrimination* means unlawful treatment or denial of benefits, services, rights, or privileges to a person or persons based on race, color, national origin, religion, sex (including gender identity), sexual orientation, disability, age, marital status, sexual orientation, familial status, parental status, income derived from a public assistance program, political beliefs, or gender identity.

(k) *Secretary* means the Secretary of Agriculture or any officer or employee of the Department whom the Secretary has heretofore delegated, or whom the Secretary may hereafter delegate, the authority to act in his or her stead under the regulations in this part.

§ 15d.3 Discrimination prohibited.

(a) No agency, officer, or employee of USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by USDA.

(b) No person shall be subjected to reprisal for opposing any practice(s) prohibited by this part, for filing a complaint, or for participating in any other manner in a proceeding under this part.

§ 15d.4 Compliance.

(a) *Compliance program.* OASCR shall evaluate each agency's efforts to comply with this part and shall make recommendations for improving such efforts.

(1) OASCR shall oversee the compliance reviews and evaluations, and issue compliance reports that monitor compliance efforts to ensure that there is equitable and fair treatment in conducted programs.

(2) OASCR shall monitor all settlement agreements pertaining to program complaints for compliance to ensure full implementation and enforcement.

(3) OASCR shall oversee Agency Head Assessments to ensure that Agency Heads are in compliance with civil rights laws and regulations.

(4) OASCR shall monitor all findings of non-compliance to ensure that compliance is achieved.

(5) OASCR shall require agencies to collect the race, ethnicity, and gender of applicants and program participants, who choose to provide such information on a voluntary basis, in USDA-conducted programs, for purposes of civil rights compliance, oversight, and evaluation.

(b) *Agency data collection and compliance reports.* (1) Each Agency shall, for civil rights compliance, collect, maintain, and annually compile data on all program applicants and participants in conducted programs by county and State, including but not limited to, application and participation rate data regarding socially disadvantaged and limited resources applicants and participants. At a minimum, the data should include:

(i) Numbers of applicants and participants by race, ethnicity, and gender, subject to appropriate privacy protections, as determined by the Secretary and in accordance with law; and

(ii) The application and participation rate, by race, ethnicity, and gender, as a percentage of the total participation rate.

(2) Each Agency shall submit to OASCR timely, complete, and accurate program application and participation reports containing the information described in paragraph (b)(1) of this section, on an annual basis, and upon the request of OASCR independently of the annual requirement.

(c) *Complaint reporting compliance.* OASCR shall ensure compliance with mandated complaint reporting requirements, such as those required by section 14006 of the Food, Conservation, and Energy Act of 2008 (PL 110–246).

§ 15d.5 Complaints.

(a) Any person who believes that he or she (or any specific class of individuals) has been, or is being, subjected to practices prohibited by this part may file (or file through an authorized representative) a written complaint alleging such discrimination. The written complaint must be filed within 180 calendar days from the date the person knew or reasonably should have known of the alleged discrimination, unless the time is extended for good cause by ASCR or the designee. Any person who complains of discrimination under this part in any fashion shall be advised of the right to file a complaint as herein provided.

(b) All complaints under this part should be filed with the Office of the Assistant Secretary for Civil Rights (ASCR), 1400 Independence Ave SW., U.S. Department of Agriculture, Washington, DC 20250, who will investigate the complaints. The ASCR will make final determinations as to the merits of complaints under this part and as to the corrective actions required to resolve program complaints. The complainant will be notified of the final determination on the complaint.

(c) Any complaint filed under this part alleging discrimination on the basis of disability will be processed under 7 CFR part 15e.

(d) For complaints OASCR deems appropriate for ADR, OASCR shall offer ADR services to complainants.

Dated: December 19, 2013.

Krysta Harden,

Deputy Secretary.

[FR Doc. 2013–30812 Filed 12–26–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2013–0957; Airspace Docket No. 13–AWP–18]

Proposed Establishment of Class E Airspace; Flagstaff, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at the Flagstaff VHF Omni-Directional Radio Range/Distance Measuring Equipment (VOR/DME) navigation aid, Flagstaff, AZ, to facilitate vectoring of Instrument Flight Rules (IFR) aircraft under control of Albuquerque Air Route Traffic Control Center (ARTCC). The FAA is proposing this action to enhance the safety and management of aircraft operations within the National Airspace System.

DATES: Comments must be received on or before February 10, 2014.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA

Docket No. FAA–2013–0957; Airspace Docket No. 13–AWP–18, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2013–0957 and Airspace Docket No. 13–AWP–18) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2013–0957 and Airspace Docket No. 13–AWP–18". The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E en route domestic airspace extending upward from 1,200 feet above the surface at the Flagstaff VOR/DME navigation aid, Flagstaff, AZ. This action would contain aircraft while in IFR conditions under control of Albuquerque ARTCC by vectoring aircraft from en route airspace to terminal areas.

Class E airspace designations are published in paragraph 6006, of FAA Order 7400.9X, dated August 7, 2013, and effective September 15, 2013, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish controlled airspace at the Flagstaff VOR/DME navigation aid, Flagstaff, AZ.

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9X, Airspace Designations and Reporting Points, dated August 7, 2013, and effective September 15, 2013 is amended as follows:

Paragraph 6006 En route domestic airspace areas

* * * * *

AWP AZ E6 Flagstaff, AZ [New]

Flagstaff VOR/DME, AZ
(Lat. 35°08′50″ N., long. 111°40′27″ W.)

That airspace extending upward from 1,200 feet above the surface within an area bounded by lat. 35°51′00″ N., long. 109°19′00″ W.; to lat. 35°41′00″ N., long. 109°38′30″ W.; to lat. 34°47′52″ N., long.

110°18'52" W.; to lat. 34°30'00" N., long. 109°35'00" W.; to lat. 34°00'00" N., long. 108°53'00" W.; to lat. 33°52'30" N., long. 108°45'00" W.; to lat. 32°29'30" N., long. 110°45'45" W.; to lat. 33°33'12" N., long. 111°51'21" W.; to lat. 34°01'00" N., long. 114°00'00" W.; to lat. 34°40'00" N., long. 114°00'00" W.; to lat. 34°52'00" N., long. 113°42'00" W.; to lat. 34°55'00" N., long. 113°37'00" W.; to lat. 35°15'20" N., long. 112°55'40" W.; to lat. 35°23'00" N., long. 112°40'00" W.; to lat. 35°23'48" N., long. 112°09'11" W.; to lat. 35°24'00" N., long. 112°00'00" W.; to lat. 35°46'00" N., long. 111°50'30" W.; to lat. 35°42'00" N., long. 110°14'00" W., thence to the point of beginning.

Issued in Seattle, Washington, on December 11, 2013.

Christopher Ramirez,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2013–31093 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. FDA–2013–N–0500]

RIN 0910–AG94

Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Correction and Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction and extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is correcting, and extending the comment period for, the proposed rule that appeared in the **Federal Register** of November 13, 2013. In the proposed rule, FDA requested comments on the proposal to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. The proposed rule published without a reference or a link to the accompanying Regulatory Impact Analysis. The Agency is taking this action to correct this omission and to extend the comment period in response to requests for an extension to allow interested persons additional time to submit comments on the proposed rule.

DATES: FDA is extending the comment period on the proposed rule published November 13, 2013, at 78 FR 67985, and on information collection issues under the Paperwork Reduction Act of 1995. Submit either electronic or written comments on the proposed rule by March 13, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 11, 2014 (see the "Paperwork Reduction Act of 1995" section of the proposed rule).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0500 and/or Regulatory Information Number (RIN) 0910–AG94, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of the proposed rule.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0500 and RIN 0910–AG94 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 13, 2013 (78 FR 67985), FDA published a proposed rule with a 60-day comment period to request comments on the proposal to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. Comments on the proposal to permit holders of abbreviated new drug applications to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug upon submission of a "changes being effected" supplement will inform FDA's rulemaking.

The proposed rule published without reference or a link to the accompanying Regulatory Impact Analysis. Accordingly, the following corrections are made to FR Doc. 2013–26799, appearing on page 67985, in the **Federal Register** of November 13, 2013:

1. On page 67996, in the first column, at the end of section IV. Analysis of Impacts, the following is added as a third full paragraph: "The full discussion of economic impacts is available in docket FDA–2013–N–0500 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 3)."

2. On page 67997, in the third column, the following is added as a third reference: "3. Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*"

The Agency has received requests for a 60-day extension of the comment period for the proposed rule. These requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 60 days, until March 13, 2014. FDA also is extending the comment period for information collection issues under the Paperwork

Reduction Act of 1995 for 60 days, until February 11, 2014. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues..

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30881 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2011–0834; FRL–9904–90–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Second Ten-Year PM_{10} Maintenance Plan for Pagosa Springs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to partially approve and partially disapprove State Implementation Plan (SIP) revisions submitted by the State of Colorado. On March 31, 2010, the Governor of Colorado's designee submitted to EPA a revised maintenance plan for the Pagosa Springs area for the National Ambient Air Quality Standards (NAAQS) for particulate matter with an aerodynamic diameter less than or equal to 10 microns (PM_{10}). The State adopted the revised maintenance plan on November 19, 2009. As required by Clean Air Act (CAA) section 175A(b), this revised maintenance plan addresses maintenance of the PM_{10} standard for a second 10-year period beyond the area's original redesignation to attainment for the PM_{10} NAAQS. EPA is proposing to approve the revised maintenance plan with the exception of one aspect of the plan's contingency measures. EPA's proposed approval includes the revised maintenance plan's 2021 transportation conformity motor vehicle emissions budget for PM_{10}. In proposing to approve the revised maintenance plan, we are proposing to exclude from use in determining that Pagosa Springs continues to attain the PM_{10} NAAQS, exceedances of the PM_{10} NAAQS that were recorded at the Pagosa Springs PM_{10} monitor on March 22, 2009, April 3, 2009, April 5, 2010, April 28, 2010, April 29, 2010, May 11, 2010, and May 22, 2010 because the exceedances meet the criteria for exceptional events caused by high wind natural events. This action is being taken under sections 110 and 175A of the CAA.

DATES: Written comments must be received on or before January 27, 2014.

ADDRESSES: Submit your comments, identified by Docket number EPA–R08–OAR–2011–0834, by one of the following methods:

- *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- Email: *olson.kyle@epa.gov*.
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** section if you are faxing comments).
- Mail: Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- Hand Delivery: Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

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Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kyle Olson, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6002, *olson.kyle@epa.gov*.

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

i. The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.
ii. The initials *APCD* mean or refer to the Colorado Air Pollution Control Division.
iii. The initials *AQCC* mean or refer to the Colorado Air Quality Control Commission.

iv. The words *CMB* mean or refer to chemical mass balance.
v. The words *Colorado* and *State* mean or refer to the State of Colorado.
vi. The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.
vii. The initials *MVEB* mean or refer to motor vehicle emissions budget.
viii. The initials *NAAQS* mean or refer to National Ambient Air Quality Standard.
ix. The initials PM_{10} mean or refer to particulate matter with an aerodynamic diameter of less than or equal to 10 micrometers (coarse particulate matter).
x. The initials *RTP* mean or refer to the Regional Transportation Plan.
xi. The initials *SIP* mean or refer to State Implementation Plan.
xii. The initials *TIP* mean or refer to the Transportation Improvement Program.
xiii. The initials *TSD* mean or refer to technical support document.

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I. General Information

1. *Submitting CBI.* Do not submit CBI to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. Background

The Pagosa Springs area was designated nonattainment for PM_{10} and classified as moderate by operation of law upon enactment of the CAA Amendments of 1990. See 56 FR 56694, 56705, 56736 (November 6, 1991). EPA approved Colorado's nonattainment area SIP for the Pagosa Springs PM_{10} nonattainment area on May 19, 1994 (59 FR 26126).

On May 10, 2000, the Governor of Colorado submitted a request to EPA to redesignate the Pagosa Springs moderate PM_{10} nonattainment area to attainment for the 1987 PM_{10} NAAQS. Along with this request, the State submitted a maintenance plan, which demonstrated that the area was expected to remain in attainment of the PM_{10} NAAQS through 2012. EPA approved the Pagosa Springs maintenance plan and redesignation to attainment on June 15, 2001 (66 FR 32556).

Eight years after an area is redesignated to attainment, CAA section 175A(b) requires the state to submit a subsequent maintenance plan to EPA, covering a second 10-year period.[1] This second 10-year maintenance plan must demonstrate continued maintenance of the applicable NAAQS during this second 10-year period. To fulfill this requirement of the Act, the Governor of Colorado's designee submitted the second 10-year update of the PM_{10} maintenance plan to EPA on March 31, 2010 (hereafter, "revised Pagosa Springs PM_{10} Maintenance Plan").

As described in 40 CFR 50.6, the level of the national primary and secondary 24-hour ambient air quality standards for PM_{10} is 150 micrograms per cubic meter ($\mu g/m^3$). An area attains the 24-hour PM_{10} standard when the expected number of days per calendar year with a 24-hour concentration in excess of the standard (referred to herein as "exceedance"), as determined in accordance with 40 CFR part 50, appendix K, is equal to or less than one, averaged over a three-year period.[2] See 40 CFR 50.6 and 40 CFR part 50, appendix K.

Table 1 below shows the maximum monitored 24-hour PM_{10} values for the Pagosa Springs PM_{10} maintenance area for 1998 through 2012, excluding seven values the State flagged as being caused by exceptional events. The table reflects that most of the values for the Pagosa Springs area were below the PM_{10} NAAQS of 150 $\mu g/m^3$. In 2000 the area experienced an exceedance measured at 165 $\mu g/m^3$, and in 2009 exceedances measured at 182 and 188 $\mu g/m^3$.[3] These exceedances did not cause a violation of the PM_{10} NAAQS.

40 CFR 50.1(j) defines an exceptional event as an event which affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Exceptional events do not include stagnation of air masses or meteorological inversions, meteorological events involving high temperatures or lack of precipitation, or air pollution relating to source noncompliance. 40 CFR 50.14(b) states that EPA shall exclude data from use in determinations of exceedances and NAAQS violations where a state demonstrates to EPA's satisfaction that an exceptional event caused a specific air pollution concentration in excess of one or more NAAQS at a particular air quality monitoring location and

[1] In this case, the initial maintenance period described in CAA section 175A(a) was required to extend for at least 10 years after the redesignation to attainment, which was effective on August 14, 2001. See 66 FR 32556. Therefore, the first maintenance plan was required to show maintenance through 2011. CAA section 175A(b) requires that the second 10-year maintenance plan maintain the NAAQS for "10 years after the expiration of the 10-year period referred to in [section 175A(a)]." Thus, for the Pagosa Springs area, the second 10-year period ends in 2021.

[2] An exceedance is defined as a daily value that is above the level of the 24-hour standard, 150 $\mu g/m^3$, after rounding to the nearest 10 $\mu g/m^3$ (i.e., values ending in five or greater are to be rounded up). Thus, a recorded value of 154 $\mu g/m^3$ would not be an exceedance since it would be rounded to 150 $\mu g/m^3$; whereas, a recorded value of 155 $\mu g/m^3$ would be an exceedance since it would be rounded to 160 $\mu g/m^3$. See 40 CFR part 50, appendix K, section 1.0.

[3] The State flagged the exceedance of 188 $\mu g/m^3$ from April 25, 2009 as being caused by an exceptional event but, due to an administrative oversight, did not demonstrate that it was caused by an exceptional event by the June 30, 2012 regulatory deadline (see 40 CFR 50.14). Thus, EPA was unable to concur on the flag for that exceedance. In addition, it is thought that the exceedance of 182 $\mu g/m^3$ was recorded during a regional dust storm on April 8, 2009 but that the site operator mistakenly gave the filter a date of April 6, 2009. Since this supposition could not be proved, the State was unable to flag the April 6 exceedance of 182 $\mu g/m^3$.

otherwise satisfies the requirements of section 50.14.

On March 29 and 30, 2012, the State submitted exceptional events packages for two exceedances of the PM_{10} NAAQS in Pagosa Springs that measured 255 µg/m³ on March 22, 2009, and 225 µg/m³ on April 3, 2009. On June 28, 2013, the State submitted four exceptional events packages for five exceedances of the PM_{10} NAAQS in Pagosa Springs that measured 349 µg/m³ on April 5, 2010, 181 µg/m³ on April 28, 2010, 162 µg/m³ on April 29, 2010, 200 µg/m³ on May 11, 2010, and 187 µg/m³ on May 22, 2010. The Colorado Air Pollution Control Division (APCD) flagged these seven exceedances as exceptional events in EPA's Air Quality System, which is EPA's repository for ambient air quality data. EPA concurred on the APCD's flags in August, September, and November of 2013 because the State successfully demonstrated that the exceedances were caused by natural high wind exceptional events blowing desert dust from upwind natural desert areas of Arizona, Utah, New Mexico, and southwest Colorado into the Pagosa Springs area. Thus, we are proposing to exclude from use in determining that Pagosa Springs continues to attain the 24-hour PM_{10} NAAQS the exceedances of the 24-hour PM_{10} NAAQS that were recorded at the Pagosa Springs PM_{10} monitor on the seven dates listed above. See 40 CFR 50.14(b) and (c)(2)(ii).

TABLE 1—PAGOSA SPRINGS PM_{10} MAXIMUM 24-HOUR VALUES (THERE ARE TWO 2001 VALUES DUE TO THE MONITOR BEING MOVED THAT YEAR FROM THE TOWN HALL TO HIGH SCHOOL LOCATION) BASED ON DATA FROM TOWN HALL AND HIGH SCHOOL MONITORING SITES, AQS IDENTIFICATION NUMBER 08–007–0001

Year	Maximum value (µg/m³)	2nd Maximum concentration (µg/m³)	Monitoring site
1998	66	66	Town Hall.
1999	138	82	Town Hall.
2000	165	87	Town Hall.
2001	123	121	Town Hall.
2001	66	61	High School.
2002	107	82	High School.
2003	123	111	High School.
2004	79	61	High School.
2005	82	77	High School.
2006	122	53	High School.
2007	102	59	High School.
2008	149	74	High School.
2009	[4] 188	[4] 182	High School.
2010	[5] 117	73	High School.
2011	109	81	High School.
2012	147	93	High School.

Table 2 below shows the estimated number of exceedances for the Pagosa Springs PM_{10} maintenance area for the three-year periods of 1998 through 2000, 1999 through 2001, 2000 through 2002, 2001 through 2003, 2002 through 2004, 2003 through 2005, 2004 through 2006, 2005 through 2007, 2006 through 2008, 2007 through 2009, 2008 through 2010, 2009 through 2011, and 2010 through 2012. To attain the standard, the three-year average number of expected exceedances (values greater than 150 µg/m³) must be less than or equal to one. The table reflects continuous attainment of the PM_{10} NAAQS.

[4] As noted above, it is believed that these two exceedances were impacted by regional dust storms in Pagosa Springs in 2009. Also, as noted above, exceedances that occurred on March 22 and April 3, 2009 were flagged by Colorado as exceptional events and received concurrence from EPA. Colorado also flagged a value of 100 µg/m³ that was recorded on March 29, 2009. A dust storm on that date caused one exceedance of the PM_{10} NAAQS elsewhere in western Colorado. However, the 100 µg/m³ value in Pagosa Springs was not eligible for consideration under EPA's exceptional events rule because it was not an exceedance of the NAAQS. The highest two samples in 2009 not identified by Colorado to be impacted by regional dust storms were samples of 75 and 73 µg/m³.

TABLE 2—PAGOSA SPRINGS PM_{10} ESTIMATED EXCEEDANCES BASED ON DATA FROM TOWN HALL AND HIGH SCHOOL MONITORING SITES, AQS IDENTIFICATION NUMBER 08–007–0001

Design value period	3-Year estimated number of exceedances
1998–2000	0
1999–2001	0
2000–2002	0.33
2001–2003	0
2002–2004	0
2003–2005	0
2004–2006	0
2005–2007	0
2006–2008	0
2007–2009	0.7
2008–2010	0.7
2009–2011	0.7
2010–2012	0

[5] The 117 µg/m³ value recorded on March 31, 2010 was flagged by Colorado as impacted by a regional dust storm. Since it was not an exceedance of the NAAQS, it was not eligible for consideration under EPA's exceptional events rule.

III. What was the State's process?

Section 110(a)(2) of the CAA requires that a state provide reasonable notice and public hearing before adopting a SIP revision and submitting it to EPA.

The Colorado Air Quality Control Commission (AQCC) held a public hearing for the revised Pagosa Springs PM_{10} Maintenance Plan on November 19, 2009. The AQCC approved and adopted the revised Pagosa Springs PM_{10} Maintenance Plan during this hearing. The Governor's designee submitted the revised plan to EPA on March 31, 2010.

We have evaluated the revised maintenance plan and have determined that the State met the requirements for reasonable public notice and public hearing under section 110(a)(2) of the CAA. On September 30, 2010, by operation of law under CAA section 110(k)(1)(B), the revised maintenance plan was deemed to have met the minimum "completeness" criteria found in 40 CFR part 51, appendix V.

IV. EPA's Evaluation of the Revised Pagosa Springs PM_{10} Maintenance Plan

The following are the key elements of a maintenance plan for PM_{10}: Emission Inventory, Maintenance Demonstration, Monitoring Network/Verification of Continued Attainment, Contingency Plan, and Transportation Conformity Requirements/Motor Vehicle Emission Budget for PM_{10}. Below, we describe our evaluation of these elements as they pertain to the revised Pagosa Springs PM_{10} Maintenance Plan.

A. Emission Inventory

The revised Pagosa Springs PM_{10} Maintenance Plan includes three inventories of daily PM_{10} emissions for the Pagosa Springs area, one for 2007 as the base year, one interim inventory for 2015, and one inventory for 2021 as the maintenance year. The APCD developed these emission inventories using EPA-approved emissions modeling methods and updated transportation and demographics data. Each emission inventory lists estimated PM_{10} emissions for individual source categories within the Pagosa Springs PM_{10} maintenance area. A more detailed description of the 2007, 2015 and 2021 inventories and information on model assumptions and parameters for each source category are contained in the State's PM_{10} maintenance plan Technical Support Document (TSD). The inventories include the following source categories: Commercial cooking, construction, fuel combustion, non-road, structure fires, wood burning, unpaved road dust, paved road dust, highway vehicles, and agriculture. We find that Colorado has prepared adequate emission inventories for the area.

B. Maintenance Demonstration

The revised Pagosa Springs PM_{10} Maintenance Plan uses emission roll-forward modeling combined with chemical mass balance (CMB) analysis to demonstrate maintenance of the 24-hour PM_{10} NAAQS through 2021. The State's CMB analysis examined the chemical composition of material on filters from Pagosa Springs air quality monitors to determine the relative contribution from the following source categories: Geologic, burning, nitrate, sulfate, and unknown. The State collected CMB data on five days in 1994, 2006, and 2008 when ambient PM_{10} concentrations exceeded 100 $\mu g/m^3$. The State then averaged the data for the source categories to create a "design day apportionment" for each category, as follows: Geologic—79.0%; burning—7.3%; nitrate—1.0%; sulfate—1.6%; and unknown—11.1%. After subtracting background (8 $\mu g/m^3$) from the design day concentration (102 $\mu g/m^3$),[6] the State applied the CMB apportionments to apportion the design day concentration by source category. For example, the State apportioned 74.3 $\mu g/m^3$ of a total of 94 $\mu g/m^3$ to the geologic source category (94 $\mu g/m^3$ x 0.790 = 74.3 $\mu g/m^3$).

Using assumptions about the inventory source categories that contributed to the CMB categories, the State applied the percent change in emissions for the relevant inventory source categories between 2007 and 2021 to "roll-forward" the CMB apportionments to 2021. For example, the State determined that the inventory source categories of unpaved road dust, paved road dust, and highway vehicles contribute all of the geologic emissions accounted for in the CMB analysis. The State's inventories reflect that emissions from these source categories are estimated to grow by 54.9% between 2007 and 2021. Applying this growth factor, the State estimated that the 74.3 $\mu g/m^3$ of PM_{10} resulting from geologic materials would grow to 115.1 $\mu g/m^3$ in 2021.

Applying this methodology, the State projected a total concentration of PM_{10} in 2021 of 146.3 $\mu g/m^3$, which includes background. This value is below the PM_{10} NAAQS of 150 $\mu g/m^3$ and, thus, is consistent with maintenance.

To account for new data acquired since the submission of the State's Plan, we evaluated the 2010–2012 data in AQS to determine whether maintenance would be demonstrated using a more recent design value as a starting point. Excluding the exceedances in 2010 that were caused by high wind exceptional events, the third high concentration in 2010–2012 was 109 $\mu g/m^3$, which was recorded on March 21, 2011. As noted, the State's emissions inventories contain emissions estimates for 2007, 2015, and 2021. An examination of these inventories reveals that total emissions in 2015 represent a point on a line of near linear growth from 2007 to 2021.

Acknowledging that the State's analysis is complete, we used a simpler total emissions roll-forward analysis rather than the CMB-apportioned analysis the State used in projecting 2006–2008 data in order to estimate emissions growth from 2011 to 2021 and ensure that growth in emissions would result in PM_{10} remaining below the NAAQS. We did this to evaluate future maintenance in light of the somewhat higher 2010–2012 design value, compared to the 2006–2008 design value Colorado evaluated. The total emissions roll-forward approach produces a higher projected concentration than does the State's CMB-apportioned method. We first removed the 8 $\mu g/m^3$ background concentration from the 109 $\mu g/m^3$, which left 101 $\mu g/m^3$. Next, relying on the linear growth in emissions, we estimated 2011 emissions would grow 32.9 percent by 2021.[7] Using this factor, we projected the 101 $\mu g/m^3$ from 2011 forward to 2021 to arrive at a concentration of 134.2 $\mu g/m^3$. We then added the 8 $\mu g/m^3$ of background to this value to predict a total concentration in 2021 of 142.2 $\mu g/m^3$. This value is below the PM_{10} NAAQS of 150 $\mu g/m^3$ and, thus, is consistent with maintenance.

C. Monitoring Network/Verification of Continued Attainment

In the revised Pagosa Springs PM_{10} Maintenance Plan, the State commits to continue to operate an air quality monitoring network in accordance with 40 CFR part 58 and the EPA-approved Colorado Monitoring SIP Element to verify continued attainment of the PM_{10} NAAQS. This includes the continued operation of a PM_{10} monitor in the Pagosa Springs area, which the State will rely on to track PM_{10} emissions in the maintenance area. We are proposing to approve this commitment as satisfying the relevant requirements.

D. Contingency Plan

Section 175A(d) of the CAA requires that a maintenance plan include contingency provisions to promptly correct any violation of the NAAQS that occurs after redesignation of an area. To meet this requirement the State has identified contingency measures along with a schedule for the development and implementation of such measures. The revised Pagosa Springs PM_{10} Maintenance Plan indicates that, upon notification of an exceedance of the PM_{10} NAAQS, the APCD and local government staff in the Pagosa Springs

[6] Based on EPA guidance, the State determined the design day concentration to be the third highest 24-hour maximum PM_{10} value recorded in the Pagosa Springs area from 2006–2008. It was recorded in 2007.

[7] Total emissions in 2007 were 184.3 tons/year, while total emissions were projected to be 236.1 tons/year in 2015 and 282.1 tons/year in 2021; these values are nearly collinear. Updating the roll forward for growth from a 2011 monitored value to 2021 requires a projection of the growth in emissions from 2011 to 2021. Linear emissions growth from 2007 to 2011 is (282.1 tons/year—184.3 tons/year)*(2011–2007)/(2021–2007), or 27.9 tons, bringing 2011 emissions to (184.3 + 27.9) = 212.2 tons. Growth from 2011 to 2021, therefore, is (282.1 tons/year—212.24 tons/year)/212.2 tons/year * 100% = 32.9%.

area will develop appropriate contingency measures intended to prevent or correct a violation of the PM_{10} standard. According to the plan, notification to EPA and local governments of any exceedance will occur no later than 45 days and the process will be completed within six months of the notification. Upon a violation, a public hearing process at the State and local level will begin. The AQCC may endorse or approve local measures, or it may adopt State enforceable measures. The revised Pagosa Springs PM_{10} Maintenance Plan states that contingency measures will be adopted and fully implemented within one year of a violation.

The State identifies the following as potential contingency measures in the revised Pagosa Springs PM_{10} Maintenance Plan: (1) Increased street sweeping requirements; (2) additional road paving requirements; (3) more stringent street sand specifications; (4) voluntary or mandatory coal and/or wood burning curtailment; (5) bans on all coal and/or wood burning; (6) expanded use of alternative de-icers; (7) re-establishing new source review permitting requirements for stationary sources; (8) transportation control measures designed to reduce vehicle miles traveled; and (9) other emission control measures appropriate for the area based on the following considerations: cost effectiveness, PM_{10} emission reduction potential, economic and social concerns, and/or other factors.

We find that the contingency measures provided in the revised Pagosa Springs PM_{10} Maintenance Plan are sufficient and meet the requirements of section 175A(d) of the CAA, with the exception of "voluntary coal and/or wood burning curtailment." While we have not required that potential contingency measures be effective without further action by the State, we interpret the CAA as requiring measures that will be enforceable. Voluntary measures may not be widely implemented and, thus, cannot be relied on to ensure prompt emission reductions to correct a violation. Thus, we are proposing to disapprove the listing of "voluntary coal and/or wood burning curtailment" as a potential contingency measure.

E. Transportation Conformity Requirements: Motor Vehicle Emission Budget for PM_{10}

Transportation conformity is required by section 176(c) of the CAA. EPA's conformity rule at 40 CFR part 93 requires that transportation plans, programs, and projects conform to SIPs and establishes the criteria and procedures for determining whether or not they conform. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS. To effectuate its purpose, the conformity rule requires a demonstration that emissions from the Regional Transportation Plan (RTP) and the Transportation Improvement Program (TIP) are consistent with the motor vehicle emissions budget(s) (MVEB(s)) contained in a control strategy SIP revision or maintenance plan (40 CFR 93.101, 93.118, and 93.124). An MVEB is defined as the level of mobile source emissions of a pollutant relied upon in the attainment or maintenance demonstration to attain or maintain compliance with the NAAQS in the nonattainment or maintenance area. Further information concerning EPA's interpretations regarding MVEBs can be found in the preamble to EPA's November 24, 1993, transportation conformity rule (see 58 FR 62193–62196).

The revised Pagosa Springs PM_{10} Maintenance Plan contains a single MVEB of 946 lbs/day of PM_{10} for the year 2021, the maintenance year. Once the State submitted the revised plan with the 2021 MVEB to EPA for approval, 40 CFR 93.118 required that EPA determine whether the MVEB was adequate.

Our criteria for determining whether a SIP's MVEB is adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4), which was promulgated August 15, 1997 (see 62 FR 43780). Our process for determining adequacy is described in our July 1, 2004 Transportation Conformity Rule Amendments (see 69 FR 40004) and in relevant guidance.[8] We used these resources in making our adequacy determination described below.

On November 22, 2010, EPA announced the availability of the revised Pagosa Springs PM_{10} Maintenance Plan, and the PM_{10} MVEB, on EPA's transportation conformity adequacy Web site. EPA solicited public comment on the MVEB, and the public comment period closed on December 22, 2010. We did not receive any comments. This information is available at EPA's conformity Web site: *http://www.epa.gov/otaq/stateresources/transconf/reg8sips.htm#co*

By letter to the Colorado Department of Public Health and Environment dated March 17, 2011, EPA found that the revised Pagosa Springs PM_{10} Maintenance Plan and the 2021 PM_{10} MVEB were adequate for transportation conformity purposes.[9] However, we noted in our letter that the revised Pagosa Springs PM_{10} Maintenance Plan did not discuss the PM_{10} MVEB for 2012 of 7,486 lbs/day from the original PM_{10} maintenance plan that EPA approved in 2001 (see 66 FR 32556, June 15, 2001).

According to 40 CFR 93.118(e)(1), the EPA-approved 2012 PM_{10} MVEB must continue to be used for analysis years 2012 through 2020 (as long as such years are within the timeframe of the transportation plan), unless the State elects to submit a SIP revision to revise the 2012 PM_{10} MVEB and EPA approves the SIP revision. The revised Pagosa Springs PM_{10} Maintenance Plan did not revise the previously-approved 2012 PM_{10} MVEB nor establish a new MVEB for 2012. Accordingly, the MVEB ". . . for the most recent prior year . . ." (i.e., 2012) from the original maintenance plan must continue to be used (see 40 CFR 93.118(b)(1)(ii) and (b)(2)(iv)).

We note that there is a considerable difference between the 2021 and 2012 budgets—946 lbs/day versus 7,486 lbs/day. This is largely an artifact of changes in the methods, models, and emission factors used to estimate mobile source emissions. The 2021 MVEB is consistent with the State's 2021 emissions inventory for vehicle exhaust and road dust, and, thus, is consistent with the State's maintenance demonstration for 2021.

The discrepancy between the 2012 and 2021 MVEBs is not a significant issue for several reasons. As a practical matter, the 2021 MVEB of 946 lbs/day of PM_{10} would be controlling for any conformity determination involving the relevant years because conformity would have to be shown to both the 2012 MVEB and the 2021 MVEB. Also, for any maintenance plan like the revised Pagosa Springs PM_{10} Maintenance Plan that only establishes a MVEB for the last year of the maintenance plan, 40 CFR 93.118(b)(2)(i) requires that the demonstration of consistency with the budget be accompanied by a qualitative finding that there are no factors that would cause or contribute to a new violation or exacerbate an existing violation in the years before the last year

[8] "Companion Guidance for the July 1, 2004 Final Transportation Conformity Rule, Conformity Implementation in Multi-Jurisdictional Nonattainment and Maintenance Areas for Existing and New Air Quality Standards" (EPA420–B–04–012 July, 2004).

[9] In a **Federal Register** notice dated August 2, 2011, we notified the public of our finding (see 76 FR 46288). This adequacy determination became effective on August 17, 2011.

of the maintenance plan. Therefore, when a conformity determination is prepared which assesses conformity for the years before 2021, the 2021 MVEB and the underlying assumptions supporting it would have to be considered. Finally, 40 CFR 93.110 requires the use of the latest planning assumptions in conformity determinations. Thus, the most current motor vehicle and road dust emission factors would need to be used, and we expect the analysis would show greatly reduced PM_{10} motor vehicle and road dust emissions from those calculated in the first maintenance plan. In view of the above, EPA is proposing to approve the 2021 PM_{10} MVEB of 946 lbs/day.

V. Proposed Action

We are proposing to approve the revised Pagosa Springs PM_{10} Maintenance Plan that was submitted to us on March 31, 2010, with one exception. We are proposing to disapprove the listing of "voluntary coal and/or wood burning curtailment" as a potential contingency measure in section 5.F.3 of the revised Pagosa Springs PM_{10} Maintenance Plan. We are proposing to approve the remainder of the revised maintenance plan because it demonstrates maintenance through 2021 as required by CAA section 175A(b), retains the control measures from the initial PM_{10} maintenance plan that EPA approved on June 15, 2001, and meets other CAA requirements for a section 175A maintenance plan. We are proposing to exclude from use in determining that Pagosa Springs continues to attain the 24-hour PM_{10} NAAQS exceedances of the 24-hour PM_{10} NAAQS that were recorded at the Pagosa Springs PM_{10} monitor on March 22, 2009, April 3, 2009, April 5, 2010, April 28, 2010, April 29, 2010, May 11, 2010, and May 22, 2010 because they meet the criteria for exceptional events caused by high wind natural events. We are also proposing to approve the revised maintenance plan's 2021 transportation conformity MVEB for PM_{10} of 946 lbs/day.

VI. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k), 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This proposed action merely proposes to approve state law as meeting federal requirements and does not propose to impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 USC 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 USC 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 USC 272 note) because application of those requirements would be inconsistent with the CAA; and,
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP would not be approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile Organic Compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 16, 2013.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2013–31110 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–6055–P]

RIN 0938–AS03

Medicare Program; Right of Appeal for Medicare Secondary Payer Determination Relating to Liability Insurance (Including Self-Insurance), No Fault Insurance, and Workers' Compensation Laws and Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement provisions of the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act) which require us to provide a right of appeal and an appeal process for liability insurance (including self-insurance), no-fault insurance, and workers' compensation laws or plans when Medicare pursues a Medicare Secondary Payer (MSP) recovery claim directly from the liability insurance (including self-insurance), no fault insurance, or workers' compensation law or plan.

DATES: To be assured consideration, comments must be received at one of the addresses provided, no later than 5 p.m. on February 25, 2014.

ADDRESSES: In commenting, please refer to file code CMS–6055–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed).

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6055–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6055–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Barbara Wright, (410) 786–4292.
Cynthia Ginsburg, (410) 786–2579.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please phone 1–800–743–3951.

I. Overview and Background

A. Overview

When the Medicare program was enacted in 1965, Medicare was the primary payer for all medically necessary covered and otherwise reimbursable items and services, with the exception of those items and services covered and payable by workers' compensation. In 1980, the Congress enacted the Medicare Secondary Payer (MSP) provisions of the Social Security Act (the Act), which added section 1862(b) to the Act and established Medicare as the secondary payer to certain primary plans. Primary plan, as defined in section 1862(b)(2)(A) of the Act, means a group health plan or large group health plan, workers' compensation law or plan, automobile or liability insurance policy or plan (including self-insured plan) or no fault insurance.

Section 1862(b)(2) of the Act, in part, prohibits Medicare from making payment where payment has been made or can reasonably be expected to be made by a primary plan. If payment has not been made or cannot reasonably be expected to be made by a primary plan, Medicare may make conditional payments with the expectation that the payments will be reimbursed to the appropriate Medicare Trust Fund. That is, Medicare may pay for medical claims with the expectation that it will be repaid if the beneficiary obtains a settlement, judgment, award, or other payment (hereafter referred to as "settlement"). Section 1862(b)(2)(B) of the Act provides authority for Medicare to make conditional payments and requires the primary plan, if it is responsible for the payment, to reimburse Medicare. A primary plan and any entity that receives payment from a primary plan shall reimburse the appropriate Medicare Trust Fund for Medicare's payments for items and services if it is demonstrated that such primary plan has or had responsibility to make payment with respect to such items and services.

The responsibility for payment on the part of workers' compensation, liability insurance (including self-insurance), and no-fault insurance is generally demonstrated by "settlements." When a "settlement" occurs, the "settlement" is subject to the Act's MSP provisions because a "payment has been made" with respect to medical care of a beneficiary related to that "settlement." Section 1862(b)(2)(B)(iv) of the Act provides the Federal government subrogation rights to any right under MSP of an individual or any other entity to payment for items or services under a primary plan, to the extent Medicare payments were made for such medical items and services. Moreover, section 1862(b)(2)(B)(iii) of the Act provides the Federal government a direct right of action to recover conditional payments made by Medicare. This direct right of action, which is separate and independent from Medicare's statutory subrogation rights, may be brought to recover conditional payments against any or all entities that are or were responsible for making payment for the items and services under a primary plan. Under the direct right of action, the Federal government may also recover from any entity that has received payment from a primary plan or the proceeds of a primary plan's payment to any entity.

B. Background

The Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act) was signed into law by President Obama on January 10, 2013, and amends the Act's MSP provisions (found at 42 U.S.C. 1395y(b)). Specifically, section 201 of the SMART Act added subparagraph (viii) to section 1862(b)(2)(B) of the Social Security Act. This new clause requires Medicare to promulgate regulations establishing a right of appeal and an appeals process, with respect to any determination for which the Secretary is seeking to recover payments from an applicable plan (as defined in the MSP provisions), under which the applicable plan involved, or an attorney, agent, or third-party administrator on behalf of the applicable plan, may appeal such a determination. Further, the individual furnished such an item and/or service shall be notified of the applicable plan's intent to appeal such a determination. For purposes of this provision, the term applicable plan refers to liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan as defined at section 1862(b)(8)(F) of the Act. (We note that the industry has expressed interest in an appeal process for determinations regarding proposed Workers' Compensation Medicare Set-

Aside Arrangement (WCMSA) amounts. This proposed rule does not address this issue. It will be addressed separately.)

Currently, if an MSP recovery demand is issued to the beneficiary as the identified debtor, the beneficiary has formal administrative appeal rights and eventual judicial review as set forth in subpart I of part 405. If the recovery demand is issued to the applicable plan as the identified debtor, currently the applicable plan has no formal administrative appeal rights or judicial review. CMS' recovery contractor addresses any dispute raised by the applicable plan, but there is no multilevel formal appeal process.

Subpart I of part 405, provides for a multilevel process including a redetermination by the contractor issuing the recovery demand, a reconsideration by a Qualified Independent Contractor (QIC), an Administrative Law Judge (ALJ) hearing, a review by the Departmental Appeals Board's (DAB) Medicare Appeals Council (MAC), and eventual judicial review. The regulations set forth details on the process including filing requirements, amount in controversy requirements, and other requirements, as appropriate. We propose to include appeals for applicable plans where Medicare is pursuing recovery directly from the applicable plan in this process. The debts at issue involve recovery of the same conditional payments that would be at issue if recovery were directed at the beneficiary. Given this, we believe it is appropriate to utilize the same multilevel appeals process for applicable plans.

II. Provisions of the Proposed Regulations

After review of the existing regulations in subpart I of 42 CFR Part 405, we are proposing the following changes, as appropriate, in order to include the applicable plan as a party when we pursue recovery directly from the applicable plan.

We propose to amend § 405.900, Basis and Scope, by revising paragraph (a) to add section 1862(b)(2)(B)(viii) of the Act as part of the statutory basis for Subpart I. Section 1862(b)(2)(B)(viii) of the Act requires an appeals process for applicable plans when Medicare pursues recovery directly from the applicable plan.

In § 405.902, Definitions, we propose to add a definition of the term "applicable plan" for purposes of Subpart I. We would adopt the statutory definition of "applicable plan" in section 1862(b)(8)(F) of the Act, which states that an applicable plan means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan.

We propose to amend § 405.906, Parties to initial determinations, redeterminations, reconsiderations, hearings and reviews by adding § 405.906(a)(4) to include the applicable plan as a party for an initial determination where Medicare is pursuing recovery directly from the applicable plan. By "pursuing recovery directly from the applicable plan," we mean that the applicable plan would be the identified debtor, with a recovery demand letter requiring repayment issued to the applicable plan (or its agent or representative). Sending an applicable plan a courtesy copy of a recovery demand letter issued to a beneficiary does not qualify as "pursuing recovery directly from the applicable plan" and does not confer party status on the applicable plan. We are also proposing a technical change in the section heading for § 405.906 (adding a comma before the phrase "and reviews").

Based upon this proposed change to § 405.906, the applicable plan's party status would continue at subsequent levels of appeal. Consistent with section 1862(b)(2)(B)(viii) of the Act, the beneficiary, provider, and/or supplier are not considered parties to an appeal by an applicable plan. Thus, we propose to remove the beneficiary, as well as the provider or supplier, as a party at the redetermination level where Medicare is pursuing recovery directly from the applicable plan. This would also, in effect, remove the beneficiary and the provider or supplier as a party at subsequent levels of appeal where Medicare is pursuing recovery directly from the applicable plan. To implement our proposed changes, we would revise § 405.906 (a) to specify: (1) The circumstances under which an applicable plan is a party to an initial determination; and (2) when an applicable plan is a party to an initial determination, it is the sole party with respect to that determination. Finally, as providers and suppliers would specifically be excluded from party status for an initial determination with respect to an applicable plan, we would make it clear that the special rule for provider or supplier party status in § 405.906(c) does not apply to an initial determination with respect to an applicable plan.

In proposed § 405.910, Appointed representatives, we would add a new paragraph (e)(4) to provide the applicable plan with parallel rights to a beneficiary's rights or a provider or supplier's rights regarding the duration of an appointment of representation with respect to an MSP recovery claim. We also propose to revise § 405.910(i)(4) so that the special provision that beneficiaries as well as their representatives must receive notices or requests in a MSP recovery case continues to apply only to beneficiaries. For all other parties, including an applicable plan, we would continue to follow the regulatory provisions in § 405.910(i)(1) through (3).

In § 405.921, Notice of initial determination, we propose to add a paragraph (c) to provide specific language regarding requirements for notice to an applicable plan. This language would parallel the existing language in this section regarding the notice to beneficiaries. In addition to these changes, for consistency we have made a number of technical and formatting changes.

In order for an action to be subject to the appeal process set forth in subpart I of 42 CFR Part 405, there must be an "initial determination." We propose, in § 405.924, Actions that are initial determinations, to add a new paragraph § 405.924(b)(15) providing that a determination that Medicare has a recovery claim where Medicare is pursuing recovery directly from an applicable plan is an initial determination with respect to the amount of or existence of the MSP recovery claim. This addition would generally parallel the existing provisions in § 405.924(b)(14) addressing pursuing MSP recovery claims from a beneficiary, provider or supplier. In addition to these changes, for consistency we have made a number of technical and formatting changes.

The MSP provisions in section 1862(b) of the Act establish that Medicare has a direct right of recovery against a primary payer. Currently under § 405.926(k), determinations under these provisions that Medicare has a recovery against a particular primary payer, are not initial determinations for purposes of part 405 subpart I. Consequently, although the primary payer may dispute the recovery claim where Medicare pursues recovery against the applicable plan, it has no formal appeal rights. We propose to revise § 405.926(k) by creating an exception to the broad rule in § 405.926(k) to reflect the proposed addition of § 405.924(b)(15). The proposed revision would provide an exception to § 405.926(k) where there is an initial determination under § 405.924(b)(15) (where Medicare is pursuing recovery directly from an applicable plan). We also propose to add a new § 405.926(a)(3) to clarify that Medicare's determination regarding

who/what entity it will pursue with respect to an MSP recovery claim is not an initial determination for purposes of part 405 subpart I. Because Medicare has the right to recover conditional payments from the beneficiary, the primary payer, or any other entity that has the proceeds from payment by the primary plan, Medicare's decision regarding who/what entity it is pursuing recovery from is not subject to appeal. We also propose to add the word "facilitates" to the existing "sponsors or contributes to" language in § 405.926(k) in recognition of our longstanding position that the concept of employer sponsorship or contribution has always included facilitation efforts. Finally for consistency, we are proposing several technical changes.

We propose to add a new § 405.947, Notice to the beneficiary of an applicable plan's request for a redetermination, to add language satisfying the requirement at section 1862(b)(2)(B)(viii) of the Act that the beneficiary receive notice of the applicable plan's intent to appeal where Medicare is pursuing recovery directly from the applicable plan. As the beneficiary would not be a party to the appeal at the redetermination level or subsequent levels of appeal, we believe that a single notice at the redetermination level satisfies the intent of this provision. We also propose that the required notice be issued by the contractor adjudicating the redetermination request in order to ensure clarity and consistency in the wording of the notice.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that the effect of this proposed rule on the economy and the Medicare program is not economically significant. The proposed rule would provide a formal administrative appeal process for MSP recovery claims where the applicable plan is the identified debtor, as opposed to the current process which requires a CMS contractor to consider any defense submitted by an applicable plan but does not provide formal administrative appeal rights.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million to $35.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined and we certify that this proposed rule would not have a significant economic impact on a substantial number of small entities because there is and will be no change in the administration of the MSP provisions. The proposed changes would simply expand or formalize existing rights with respect to MSP recovery claims pursued directly from an applicable plan. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 for proposed rules of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We have determined that this proposed rule would not have a significant effect on the operations of a substantial number of small rural hospitals because it would simply expand and/or formalize existing rights with respect to MSP recovery claims pursued directly from an applicable plan. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This proposed rule has no consequential effect on State, local, or tribal governments or on the private sector because it would simply expand and/or formalize existing rights with respect to MSP recovery claims pursued directly from an applicable plan.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Part 405 as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 reads as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, 1886(k) of the Social Security Act (42 U.S.C. 405(a),

1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a)

■ 2. Amend § 405.900 by revising paragraph (a) to read as follows:

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the following provisions of the Act:

(1) Section 1869(a) through (e) and (g) of the Act.

(2) Section 1862(b)(2)(B)(viii) of the Act.

* * * * *

■ 3. Amend § 405.902 by adding the definition "Applicable plan" in alphabetical order to read as follows:

§ 405.902 Definitions.

* * * * *

Applicable plan means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan.

* * * * *

■ 4. Amend § 405.906 as follows:

■ A. Revising the section heading.

■ B. Adding new paragraph (a)(4).

■ C. Amending paragraph (c) by adding a sentence at the end of the paragraph.

The additions and revision read as follows:

§ 405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews.

(a) * * *

(4) An applicable plan for an initial determination under § 405.924(b)(15) where Medicare is pursuing recovery directly from the applicable plan. The applicable plan is the sole party to an initial determination under § 405.924(b)(15) (that is, where Medicare is pursuing recovery directly from the applicable plan).

* * * * *

(c) * * *. This paragraph (c) does not apply to an initial determination with respect to an applicable plan under § 405.924(b)(15).

■ 4. Amend § 405.910 as follows:

■ A. Adding paragraph (e)(4).

■ B. Revising paragraph (i)(4).

The addition and revision read as follows:

§ 405.910 Appointed representatives.

* * * * *

(e) * * *

(4) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed by an applicable plan which has party status in accordance with § 405.906(a)(1)(iv) is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

* * * * *

(i) * * *

(4) For initial determinations and appeals involving Medicare Secondary Payer recovery claims where the beneficiary is a party, the adjudicator sends notices and requests to both the beneficiary and the beneficiary's representative, if the beneficiary has a representative.

* * * * *

■ 5. Amend § 405.921 as follows:

■ A. In paragraph (a)(1), removing ";" and adding in its place "."

■ B. In paragraph (a)(2) introductory text, removing the phrase "must contain—" and adding in its place the phrase "must contain all of the following:"

■ C. In paragraphs (a)(2)(i) and (a)(2)(ii), removing ";" and adding in its place "."

■ D. In paragraph (a)(2)(iii), removing "; and" and adding in its place "."

■ E. Redesignating the second and third sentences of paragraph (b)(1) as paragraph (b)(1)(i) and (ii), respectively.

■ F. In paragraph (b)(2) introductory text, removing the phrase "must contain:" and adding in its place the phrase "must contain all of the following:"

■ G. In paragraphs (b)(2)(i) through (b)(2)(iv), removing ";" and add in its place "."

■ H. In paragraph (b)(2)(v), removing "; and" and add in its place "."

■ I. Adding paragraph (c) to read as follows:

§ 405.921 Notice of initial determination.

* * * * *

(c) *Notice of initial determination sent to an applicable plan*—(1) *Content of the notice.* The notice of initial determination under § 405.924(b)(15) must contain all of the following:

(i) The reasons for the determination.

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.

(iii) Information on the right to a redetermination if the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.

(iv) Any other requirements specified by CMS.

(2) [Reserved]

■ 6. Amend § 405.924 as follows:

■ A. In paragraph (b) introductory text, removing the phrase "with respect to:" and add in its place the phrase "with respect to any of the following:"

■ B. In paragraph (b)(1) through (b)(11) removing ";" and adding in its place "."

■ D. In paragraph (b)(12) introductory text, removing the ":" and adding in its place "—".

■ C. Adding paragraph (b)(15).

The addition reads as follows:

§ 405.924 Actions that are initial determinations.

* * * * *

(b) * * *

(15) Under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery claim if Medicare is pursuing recovery directly from an applicable plan. That is, there is an initial determination with respect to the amount and existence of the recovery claim.

* * * * *

■ 7. Amend § 405.926 as follows:

■ A. In the introductory text, removing the phrase "not limited to –" and adding in its place the phrase "not limited to the following:"

■ B. In the introductory text of paragraph (a), removing the phrase "for example –" and adding in its place the phrase "for example one of the following:"

■ C. In paragraphs (a)(1) and (a)(2), removing ";" and adding in its place "."

■ D. Adding paragraph (a)(3).

■ E. In paragraphs (b) through (j), removing ";" and adding in its place "."

■ F. Revising paragraph (k).

■ G. In paragraphs (l) through (q), removing ";" and adding in its place "."

■ H. In paragraph (r), removing "; and" and adding in its place "."

The addition and revision read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(a) * * *

(3) Determination under the Medicare Secondary Payer provisions of section 1862(b) of the Act of the debtor for a particular recovery claim.

* * * * *

(k) Except as specified in § 405.924(b)(15), determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery against an entity that was or is required or responsible (directly, as an insurer or self-insurer; as a third party administrator; as an employer that sponsors, contributes to or facilitates a group health plan or a large group health plan; or otherwise) to make payment for services or items that were

already reimbursed by the Medicare program.

* * * * *

■ 8. Add a new § 405.947 to subpart I to read as follows:

§ 405.947 Notice to the beneficiary of applicable plan's request for a redetermination.

(a) The contractor adjudicating the redetermination request must send notice of the applicable plan's appeal to the beneficiary.

(b) Issuance and content of the notice must comply with CMS instructions.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 29, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 12, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–30661 Filed 12–26–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 25, 2014.

ADDRESSES: In commenting, please refer to file code OIG–122–N. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at *http://www.regulations.gov.*

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Patrice Drew, Office of Inspector General, Congressional and Regulatory Affairs, Department of Health and Human Services, Attention: OIG–122–N, Room 5541C, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 330 Independence Avenue SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–1368. For information on viewing public comments, please see the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Patrice Drew, Congressional and Regulatory Affairs Liaison, Office of Inspector General, (202) 619–1368.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on recommendations for developing new or revised safe harbors and Special Fraud Alerts. Please assist us by referencing the file code OIG–122–N.

Inspection of Public Comments: All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on *http://www.regulations.gov* as soon as possible after they have been received. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday from 9:30 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619–1368.

I. Background

A. OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward business reimbursable under the Federal health care programs. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), or exclusion from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 § 14, the Act, § 1128B(b), 42 U.S.C. 1320a–7b(b), specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, specifying various payment and business practices that, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. OIG safe harbor provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements" (56 FR 35952, July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices will not be subject to liability under the anti-kickback statute or related administrative authorities. The OIG safe harbor regulations are found at 42 CFR 1001.952.

B. OIG Special Fraud Alerts

OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices OIG finds potentially fraudulent or abusive. The Special Fraud Alerts encourage industry compliance by giving providers guidance that can be applied to their own practices. OIG Special Fraud Alerts

are intended for extensive distribution directly to the health care provider community, as well as to those charged with administering the Federal health care programs.

In developing Special Fraud Alerts, OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within OIG, other agencies of the Department, other Federal and State agencies, and those in the health care industry.

C. Section 205 of the Health Insurance Portability and Accountability Act of 1996

Section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191 § 205, the Act, § 1128D, 42 U.S.C. 1320a–7d, requires the Department to develop and publish an annual notice in the **Federal Register** formally soliciting proposals for modifying existing safe harbors to the anti-kickback statute and for developing new safe harbors and Special Fraud Alerts.

In developing safe harbors for a criminal statute, OIG is required to engage in a thorough review of the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover potential opportunities for fraud and abuse. Only then can OIG determine, in consultation with the Department of Justice, whether it can effectively develop regulatory limitations and controls that will permit beneficial and innocuous arrangements within a subject area while, at the same time, protecting the Federal health care programs and their beneficiaries from abusive practices.

II. Solicitation of Additional New Recommendations and Proposals

In accordance with the requirements of section 205 of HIPAA, OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 28, 2012 (77 FR 76434). As required under section 205, a status report of the public comments related to safe harbors received in response to that notice is set forth in Appendix F to the OIG's Semiannual Report to Congress covering the period April 1, 2013, through September 30, 2013.[1] OIG is not seeking additional public comment on the proposals listed in Appendix F at this time. Rather, this notice seeks additional recommendations regarding the development of new or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix F.

A detailed explanation of justifications for, or empirical data supporting, a suggestion for a safe harbor or Special Fraud Alert would be helpful and should, if possible, be included in any response to this solicitation.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider a number of factors in reviewing proposals for new or modified safe harbor provisions, such as the extent to which the proposals would affect an increase or decrease in:

- Access to health care services,
- the quality of health care services,
- patient freedom of choice among health care providers,
- competition among health care providers,
- the cost to Federal health care programs,
- the potential overutilization of health care services, and
- the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will also take into consideration other factors, including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may be taken into account in their decisions whether to (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider.

B. Criteria for Developing Special Fraud Alerts

In determining whether to issue additional Special Fraud Alerts, we will consider whether, and to what extent, the practices that would be identified in a new Special Fraud Alert may result in any of the consequences set forth above, as well as the volume and frequency of the conduct that would be identified in the Special Fraud Alert.

Dated: December 17, 2013.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2013–30429 Filed 12–26–13; 8:45 am]

BILLING CODE 4152–01–P

[1] The OIG *Semiannual Report to Congress* can be accessed through the OIG Web site at *http://oig.hhs.gov/publications/semiannual.asp.*

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–B–7748]

Proposed Flood Elevation Determinations for Pierce County, Washington, and Incorporated Areas

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its proposed rule concerning proposed flood elevation determinations for Pierce County, Washington, and Incorporated Areas.

DATES: The proposed rule published December 6, 2007, at 72 FR 68784, corrected April 16, 2012, at 77 FR 22551, is withdrawn effective December 27, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FEMA–B–7748, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: On December 6, 2007, FEMA published a proposed rulemaking at 72 FR 68784, proposing flood elevation determinations along one or more flooding sources in Pierce County, Washington. On April 16, 2012, FEMA published a proposed rulemaking at 77 FR 22551, proposing corrected flood elevation determinations along one or more flooding sources in Pierce County, Washington. Because FEMA has or will be issuing a Revised Preliminary Flood Insurance Rate Map, and if necessary a Flood Insurance Study report, featuring updated flood hazard information, the proposed rulemaking is being withdrawn. A Notice of Proposed Flood Hazard Determinations will be published in the **Federal Register** and in

the affected community's local newspaper.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Dated: November 22, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–30952 Filed 12–26–13; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 12–375; DA 13–2379]

Rates for Interstate Inmate Calling Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: In this document, the Wireline Competition Bureau grants in part the Motion for Extension of Time to File Comments and Reply Comments filed on December 6, 2013 by the Ohio Department of Rehabilitation and Correction in WC Docket No. 12–375. Specifically, the Bureau agreed that a modest extension of time will facilitate a more complete record in this proceeding.

DATES: Comments are due on or before December 20, 2013; reply comments are due on or before January 13, 2014.

ADDRESSES: You may submit comments, identified by WC Docket No. 12–375, by any of the following methods:

- *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *Mail:* Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lynne Engledow, Wireline Competition Bureau, Pricing Policy Division, (202) 418–1520 or *lynne.engledow@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, in WC Docket No. 12–375, DA 13–2379, adopted and released December 12, 2013. The complete text of this document is available for public inspection during regular business hours in the FCC Reference Information Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554. It is also available on the Commission's Web site at *http://www.fcc.gov.*

1. On September 26, 2013, the Federal Communications Commission (Commission) released the Inmate Calling Report and Order and Further Notice of Proposed Rulemaking (R&O and FNPRM). *See* 78 FR 68005, November 13, 2013. In that item, the Commission adopted reforms of interstate inmate calling service rates, requiring that all providers' rates and charges be cost-based. In the FNPRM portion of the item, the Commission sought comment on a number of outstanding issues. The FNPRM set dates for comments and reply comments as December 13 and December 30, 2013 respectively.

2. The Ohio DRC requests that parties be allowed an extension of time to file comments to those questions raised in the FNPRM portion of the item: January 13, 2014 for initial comments and until February 12, 2014 for reply comments. The Ohio DRC asserts that an additional grant of time would allow for "a more complete factual and legal record in this proceeding." Three parties filed comments in support of the Ohio DRC motion, and none opposed it.

3. Section 1.46 of the Commission's rules provides that "[i]t is the policy of the Commission that extensions of time shall not be routinely granted." Upon review, however, we agree with the commenters that a modest time extension will more fully allow parties to provide us with more fulsome comments that will facilitate the compilation of a complete record in this proceeding, without causing undue delay to the Commission's consideration of these issues.

4. Accordingly, *it is ordered,* pursuant to sections 4(i), 4(j), and 303(r) of the Communications Act, as amended, 47 U.S.C. 154(i), 154(j), and 303(r); and §§ 0.91, 0.291, 1.45, and 1.415 of the Commission's rules, 47 CFR 0.91, 0.291, 1.45, and 1.415 that the Motion for Extension of Time to File Comments and Reply Comments filed by the Ohio Department of Rehabilitation and Correction on December 6, 2013 *is granted in part* to the extent described herein and *is otherwise denied,* and the deadline for filing comments to the FNPRM *is* December 20, 2013 and reply comments *is* January 13, 2014.

Federal Communications Commission.

Lynne H. Engledow,

Assistant Division Chief, Wireline Competition Bureau.

[FR Doc. 2013–30826 Filed 12–26–13; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 78, No. 249
Friday, December 27, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Pacific Southwest Recreation Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Pacific Southwest Recreation Resource Advisory Committee (Recreation RAC) will meet in San Bernardino, California. The Recreation RAC is authorized under the Federal Lands Recreation Enhancement Act (REA) (Pub, L. 108–447) and operates in compliance with the Federal Advisory Committee Act (FACA) (Pub. L. 92–463). Additional information concerning the Recreation RAC can be found by visiting the Recreation RAC's Web site at: *http://www.fs.usda.gov/main/r5/recreation/racs.*

DATES: The meeting will be held on the following dates:

- Wednesday, January 15, 2014–10:00 a.m. to 5:00 p.m.
- Thursday, January 16, 2014–9:00 a.m. to 3:00 p.m. (meeting could end earlier)

ADDRESSES: The meeting will be held at the San Bernardino National Forest Supervisor's Office, 602 S. Tippecanoe Avenue, San Bernardino, California. Written comments may be submitted as described under Supplementary Information. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Region 5 Pacific Southwest Regional Office. Please call ahead to Ramiro Villalvazo, at 707–562–8856 to facilitate entry into the building. Attendees may participate via conference call. For anyone who would like to attend via conference call, please contact Ramiro Villalvazo at *rvillalvazo@fs.fed.us* or visit the Web site listed above.

FOR FURTHER INFORMATION CONTACT: Ramiro Villalvazo, Designated Federal Official, Region 5 Pacific Southwest Regional Office, by phone at 707–562–8856, or by email at *rvillalvazo@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The purpose of the meeting is to:

1. provide proposed fee changes for standard amenity recreation fee areas on the Angeles, Cleveland, Los Padres and San Bernardino National Forests,
2. review and make recommendations on the change in fee structure for Camp Discovery Group Campground, and
3. provide a fee increase at one site in Sycamore Grove Campground on the Mendocino National Forest.

The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by January 8, 2014 to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Recreation RAC may file written statements with the Recreation RAC staff by January 8, 2014. Written comments and time requests for oral comments must be sent to Ramiro Villalvazo, 1323 Club Drive, Vallejo, California 94592, or by email to *rvillalvazo@fs.fed.us*, or via facsimile to 707–562–9047. A summary of the meeting will be posted on the Web site listed above within 21 days after the meeting.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled For Further Information Contact. All reasonable accommodation requests are managed on a case by case basis.

Dated: December 19, 2013.

David Scholes,

Designated Federal Official.

[FR Doc. 2013–31005 Filed 12–26–13; 8:45 am]

BILLING CODE 3410–11–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

TIME AND DATE: January 30, 2014, 6:30 p.m.–9:00 p.m. PST.

PLACE: Brodniak Auditorium, Anacortes High School; 1600 20th St. Anacortes, WA 98221.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Chemical Safety and Hazard Investigation Board (CSB) will convene a public meeting on January 30, 2014, starting at 6:30 p.m. PST at the Brodniak Auditorium, Anacortes High School, 1600 20th St., Anacortes, WA 98221.

At the public meeting, the Board will consider and vote on the final investigation report into the April 2, 2010, explosion and fire that fatally injured seven employees. The CSB's investigation found that at the time of the incident a bank of heat exchangers was being brought online in the refinery's naphtha hydrotreater unit when another heat exchanger in a parallel bank catastrophically failed, spewing highly flammable hydrogen and naphtha which ignited. Seven Tesoro workers who were nearby, assisting with the heat exchanger startup, were fatally burned. The accident at Tesoro was the most deadly U.S. refinery incident since the 2005 explosion at BP Texas City that killed 15 workers and injured 180 others.

At the meeting, CSB staff will present to the Board the results of the investigation findings and safety recommendations.

Following the staff presentation on proposed findings and safety recommendations, the Board will hear comments from the public.

Following the conclusion of the public comment period, the Board will consider whether to approve the final report and recommendations. All staff presentations are preliminary and are intended solely to allow the Board to consider in a public forum the issues and factors involved in this case. No factual analyses, conclusions, or findings presented by staff should be considered final.

Only after the Board has considered the staff presentations, listened to public comments, and adopted a final investigation report and recommendations will there be an

approved final record of the CSB investigation of this incident.

Additional Information

The meeting is free and open to the public. If you require a translator or interpreter, please notify the individual listed below as the "Contact Person for Further Information," at least five business days prior to the meeting.

The CSB is an independent federal agency charged with investigating accidents and hazards that result, or may result, in the catastrophic release of extremely hazardous substances. The agency's Board Members are appointed by the President and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents and hazards, including physical causes such as equipment failure as well as inadequacies in regulations, industry standards, and safety management systems.

Public Comment

Members of the public are invited to make brief statements to the Board at the conclusion of the staff presentation. The time provided for public statements will depend upon the number of people who wish to speak. Speakers should assume that their presentations will be limited to five minutes or less, and may submit written statements for the record.

Contact Person for Further Information

Hillary J. Cohen, Communications Manager, *hillary.cohen@csb.gov* or (202) 446–8094. General information about the CSB can be found on the agency Web site at: *www.csb.gov*.

Dated: December 23, 2013.

Rafael Moure-Eraso,

Chairperson.

[FR Doc. 2013–31111 Filed 12–24–13; 11:15 am]

BILLING CODE 6350–01–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

TIME AND DATE: January 15, 2014, 6:30 p.m.–8:30 p.m. PST.

PLACE: City Council Chambers, Civic Center Campus, 440 Civic Center Plaza, Richmond, CA 94804.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED The Chemical Safety and Hazard Investigation Board (CSB) will convene a public meeting on January 15, 2014, starting at 6:30 p.m. at the City Council Chambers, Civic Center Campus, 440 Civic Center Plaza, Richmond, CA 94804. At the public meeting, the Board will consider and vote on the draft regulatory report of the August 6, 2012, fire at the Chevron refinery that endangered 19 workers and sent more than 15,000 residents to the hospital for medical attention.

At the meeting, CSB staff will present to the Board the results of the second of three reports in the CSB's investigation of this incident. Subject to a vote by the board at the January 15 public meeting, the draft regulatory report would recommend that California "Develop and implement a step-by-step plan to establish a more rigorous safety management regulatory framework for petroleum refineries in the state of California based on the principles of the 'safety case' framework in use in regulatory regimes such as those in the UK, Australia, and Norway." The recommendation urges specific steps to accomplish this, including ensuring that workers are formally involved in the development of a safety case report for each covered facility. The report also urges California to work with industry in gathering refinery safety indicator data to be shared with the public.

As detailed in the CSB draft report, a safety case regime which would require companies to demonstrate to refinery industry regulators—through a written "safety case report"—how major hazards are to be controlled and risks reduced to "as low as reasonably practicable," or ALARP. The CSB report notes that the safety case is more than a written document; rather, it represents a fundamental change by shifting the responsibility for continuous reductions in major accident risks from regulators to the company.

To ensure that a facility's safety goals and programs are accomplished, a safety case report generated by the company is rigorously reviewed, audited, and enforced by highly trained regulatory inspectors, whose technical training and experience are on par with the personnel employed by the companies they oversee, the draft report says.

The CSB's first interim report—which was voted on and approved by the board at a public meeting in Richmond, CA, on April 19, 2013—found that Chevron repeatedly failed over a ten-year period to apply inherently safer design principles and upgrade piping in its crude oil processing unit, which was extremely corroded and ultimately ruptured on August 6, 2012. The CSB's investigation identified missed opportunities on the part of Chevron to apply inherently safer piping design through the use of more corrosion-resistant metal alloys. The first interim report also found a failure by Chevron to identify and evaluate damage mechanism hazards, which if acted upon, would likely have identified the possibility of a catastrophic sulfidation corrosion-related piping failure. There are currently no federal or state regulatory requirements to apply these important preventative measures. The investigation team concluded that enhanced regulatory oversight with greater worker involvement and public participation are needed to improve petroleum refinery safety.

Following the staff presentation on proposed findings and safety recommendations, the Board will hear comments from the public.

Following the conclusion of the public comment period, the Board will consider whether to approve the final report and recommendations. All staff presentations are preliminary and are intended solely to allow the Board to consider in a public forum the issues and factors involved in this case. No factual analyses, conclusions, or findings presented by staff should be considered final.

Only after the Board has considered the staff presentations, listened to public comments, and adopted a final investigation report and recommendations will there be an approved final record of the CSB investigation of this incident.

Additional Information

The meeting is free and open to the public. If you require a translator or interpreter, please notify the individual listed below as the "Contact Person for. Further Information," at least five business days prior to the meeting.

The CSB is an independent federal agency charged with investigating accidents and hazards that result, or may result, in the catastrophic release of extremely hazardous substances. The agency's Board Members are appointed by the President and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents and hazards, including physical causes such as equipment failure as well as inadequacies in regulations, industry standards, and safety management systems.

Public Comment

Members of the public are invited to make brief statements to the Board at the conclusion of the staff presentation. The time provided for public statements will depend upon the number of people who wish to speak. Speakers should assume that their presentations will be limited to five minutes or less, and may submit written statements for the record.

Contact Person for Further Information

Hillary J. Cohen, Communications Manager, hillary.cohen@csb.gov or (202) 446–8094. General information about the CSB can be found on the agency Web site at: *www.csb.gov.*

Dated: December 23, 2013.

Rafael Moure-Eraso,

Chairperson.

[FR Doc. 2013–31156 Filed 12–24–13; 11:15 am]

BILLING CODE 6350–01–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility to Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and Opportunity for Public Comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 et seq.), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[12/19/2013 through 12/19/2013]

Firm name	Firm address	Date accepted for investigation	Product(s)
The Line Group, Inc.	539 W. Algonquin Road, Arlington Heights, IL 60005.	12/18/2013	The firm manufactures metal stampings and assemblies.
Nordic Tugs Incorporated	11367 Higgins Airport Way, Burlington, WA 98233.	12/19/2013	The firm manufactures recreational trawlers/yachts.
CPAC Equipment, Inc.	2364 Leicester Road, Leicester, NY 14481.		The firm manufactures dry heat sterilizers and dental evacuation equipment.
S3 Manufacturing, Inc.	29690 SE Orient Dr, Gresham, OR 97080.	12/19/2013	The firm manufactures parts for bicycle, motorcycle industry; custom job shop for other aluminum, steel and plastics.
Seating, Inc.	60 North Street, Nunda, NY 14517	12/19/2013	The firm manufactures upholstered seats with metal frames.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Dated: December 19, 2013.

Michael DeVillo,

Eligibility Examiner.

[FR Doc. 2013–31006 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–421–811]

Purified Carboxymethylcellulose From the Netherlands: Final Results of Antidumping Duty Administrative Review and Final No Shipment Determination; 2011–2012

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On August 9, 2013, the Department of Commerce (the Department) published the preliminary results of the administrative review and preliminary no shipment determination of the antidumping duty (AD) order on purified carboxymethylcellulose (CMC) from the Netherlands. For the final results, we continue to find that sales of subject merchandise by Akzo Nobel Functional Chemicals, B.V. (Akzo Nobel) were made at less than normal value, and that CP Kelco, B.V. (CP Kelco) had no shipments of subject merchandise during the POR.

DATES: *Effective Date:* December 27, 2013.

FOR FURTHER INFORMATION CONTACT: John Drury or Angelica Mendoza, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0195, and (202) 482–3019, respectively.

Background

On August 9, 2013, the Department published the preliminary results of the administrative review of the AD order on purified CMC from the Netherlands.[1] We invited interested parties to comment on the *Preliminary Results.* We received no comments. The Department has conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Tolling of Deadlines

As explained in the memorandum from the Assistant Secretary for Enforcement and Compliance, the Department has exercised its discretion to toll deadlines for the duration of the

[1] *See Purified Carboxymethylcellulose From the Netherlands: Preliminary Results of Antidumping Duty Administrative Review and Preliminary No Shipment Determination; 2011–2012,* 78 FR 48649 (August 9, 2013) (*Preliminary Results*).

closure of the Federal Government from October 1, through October 16, 2013.[2] Therefore, all deadlines in this segment of the proceeding have been extended by 16 days. If the new deadline falls on a non-business day, in accordance with the Department's practice, the deadline will become the next business day. The revised deadline for the final results of this review is now December 26, 2013.

Scope of the Order

The product covered by the order is all purified CMC, sometimes also referred to as purified sodium CMC, polyanionic cellulose, or cellulose gum, which is a white to off-white, non-toxic, odorless, biodegradable powder, comprising sodium CMC that has been refined and purified to a minimum assay of 90 percent. Purified CMC does not include unpurified or crude CMC, CMC Fluidized Polymer Suspensions, and CMC that is cross-linked through heat treatment. Purified CMC is CMC that has undergone one or more purification operations, which, at a minimum, reduce the remaining salt and other by-product portion of the product to less than ten percent.

The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States at subheading 3912.31.00. This tariff classification is provided for convenience and Customs purposes; however, the written description of the scope of the order is dispositive.

Determination of No Shipments

As noted in the *Preliminary Results*,[3] we received a no-shipment claim from CP Kelco, and we confirmed this claim with U.S. Customs and Border Protection (CBP). Because we continue to find that the record indicates that CP Kelco did not export subject merchandise to the United States during the POR, we determine that it had no reviewable transactions during the POR.

Our former practice concerning respondents submitting timely no-shipment certifications was to rescind the administrative review with respect to those companies if we were able to confirm the no-shipment certifications through a no-shipment inquiry with CBP.[4] As a result, in such circumstances, we normally instructed CBP to liquidate any entries from the no-shipment company at the deposit rate in effect on the date of entry.

In our May 6, 2003, clarification of the "automatic assessment" regulation, we explained that, where respondents in an administrative review demonstrate that they had no knowledge of sales through resellers to the United States, we would instruct CBP to liquidate such entries at the all-others rate applicable to the proceeding.[5] Because "as entered" liquidation instructions do not alleviate the concerns which the May 2003 clarification was intended to address, we find it appropriate in this case to instruct CBP to liquidate any existing entries of merchandise produced by CP Kelco and exported by other parties at the all-others rate. In addition, we continue to find that it is more consistent with the May 2003 clarification not to rescind the review in part in these circumstances but, rather, to complete the review with respect to CP Kelco and issue appropriate instructions to CBP based on the final results of this administrative review. *See* the "Assessment Rates" section of this notice below.

Final Results of Review

We have made no changes to our calculations announced in the *Preliminary Results*. Therefore, as a result of our review, we determine that the following weighted-average dumping margin exists for the period July 1, 2011, through June 30, 2012:

Producer	weighted-average margin (percentage)
Akzo Nobel Functional Chemicals B.V.	0.64

Assessment

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. In accordance with 19 CFR 351.212(b)(1), the Department normally calculates an assessment rate for each importer of the subject merchandise covered by the review. In this review, we have calculated, whenever possible, an importer-specific assessment rate or value for merchandise subject to this review as described below.

As noted in the *Preliminary Results*, all of Akzo Nobel's U.S. sales of CMC were constructed-export-price sales (*e.g.*, sales through Akzo Nobel's U.S. affiliate to the unaffiliated purchaser in the United States).[6] Accordingly, we divided the total dumping margins for the reviewed sales by the total entered value of those reviewed sales for each importer. We will direct CBP to assess the resulting percentage margin against the entered customs values for the subject merchandise on each importer's respective POR entries.[7]

The calculated *ad valorem* rates will be assessed uniformly on all entries made by the respective importers during the POR. Where the assessment rate is above *de minimis*, we will instruct CBP to assess duties on all entries of subject merchandise by that importer.

As stated above, the Department clarified its "automatic assessment" regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the POR produced by reviewed companies for which these companies did not know their merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[8]

The Department intends to issue assessment instructions directly to CBP 15 days after publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Tariff Act of 1930, as amended: (1) The cash deposit rate for Akzo Nobel will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this or any previous review or in the less-than-fair-value (LTFV) investigation but the manufacturer is, the cash-deposit rate will be the rate established for the most recent period for the manufacturer of

[2] *See* Memorandum for the Record from Paul Piquado, Assistant Secretary for Enforcement and Compliance, "Deadlines Affected by the Shutdown of the Federal Government" dated October 18, 2013.

[3] *See Preliminary Results* at 48650.

[4] *See Antidumping Duties; Countervailing Duties; Final rule*, 62 FR 27296, 27393 (May 19, 1997); *see also Stainless Steel Sheet and Strip in Coils from Taiwan: Final Results of Antidumping Duty Administrative Review*, 75 FR 76700, 76701 (December 9, 2010).

[5] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

[6] *See Preliminary Results* and accompanying Preliminary Decision Memorandum at page 7.

[7] *See* 19 CFR 351.212(b).

[8] For a full discussion of this clarification, *see Assessment Policy Notice*.

the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review or the investigation, the cash-deposit rate will continue to be the all-others rate of 14.57 percent, which is the all-others rate established by the Department in the LTFV investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation, which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: December 18, 2013.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2013–31114 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See Notice of Antidumping Duty Orders: Purified Carboxymethylcellulose from Finland, Mexico, the Netherlands and Sweden*, 70 FR 39734, 39735 (July 11, 2005).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–912]

Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: Zhongce Rubber Group Company Limited ("Zhongce") requested a changed circumstances review of the antidumping duty order on certain new pneumatic off-the-road tires ("OTR tires") from the People's Republic of China ("PRC") pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended ("the Act") and 19 CFR 351.216(b). The Department of Commerce ("Department") is initiating this changed circumstances review and preliminarily determining, pursuant to 19 CFR 351.221(c)(3)(ii) that Zhongce is the successor-in-interest to Hangzhou Zhongce Rubber Co., Ltd. ("Hangzhou").

DATES: *Effective Date:* December 27, 2013.

FOR FURTHER INFORMATION CONTACT: Andrew Medley or Brendan Quinn, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–4987 or 202–482–5848, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 4, 2008, the Department published in the **Federal Register** an antidumping duty order on OTR tires from the PRC.[1] Under the *Order,* in the third administrative review, Hangzhou received its own calculated rate of 112.41 percent.[2]

On November 5, 2013, Zhongce requested that the Department conduct a changed circumstances review of the *Order* to confirm that Zhongce is the successor-in-interest to Hangzhou.[3] In its submission, Zhongce explained that the only change was to the name of the company, and provided evidence supporting its claim.[4]

Scope of the Order

The merchandise covered by this *Order* includes new pneumatic tires designed for off-the-road and off-highway use, subject to certain exceptions.[5] The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States ("HTSUS") subheadings: 4011.20.10.25, 4011.20.10.35, 4011.20.50.30, 4011.20.50.50, 4011.61.00.00, 4011.62.00.00, 4011.63.00.00, 4011.69.00.00, 4011.92.00.00, 4011.93.40.00, 4011.93.80.00, 4011.94.40.00, and 4011.94.80.00. The HTSUS subheadings are provided for convenience and customs purposes only; the written product description of the scope of the order is dispositive.

Initiation and Preliminary Results

Pursuant to section 751(b)(1) of the Act, the Department will conduct a changed circumstances review upon receipt of information concerning, or a request from, an interested party for a review of an antidumping duty order which shows changed circumstances sufficient to warrant a review of the order. As indicated in the "Background" section, we received information indicating that Hangzhou changed its name to Zhongce, effective August 19, 2013. This constitutes changed circumstances warranting a review of the order.[6] Therefore, in accordance with section 751(b)(1) of the Act and 19 CFR 351.216(d) and (e), we are initiating a changed circumstances review based upon the information contained in Zhongce's submission.

Section 351.221(c)(3)(ii) of the Department's regulations permits the Department to combine the notice of initiation of a changed circumstances review and the notice of preliminary results if the Department concludes that expedited action is warranted. In this instance, because the record contains information necessary to make a preliminary finding, we find that expedited action is warranted and have

[1] *See Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Notice of Amended Final Affirmative Determination of Sales at Less Than Fair Value and Antidumping Duty Order*, 73 FR 51624 (September 4, 2008) ("*Order*").

[2] *See Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part; 2010–2011*, 78 FR 22513 (April 16, 2013).

[3] *See* Letter from Zhongce to the Department titled "New Pneumatic Off-The-Road Tires from the PRC: Request for Hangzhou Zhongce Rubber Co., Ltd. for Changed Circumstances Review" (November 5, 2013) ("Zhongce Request for CCR").

[4] *Id.* at 2–3 and Attachments 1, 2, and 3.

[5] For a complete description of the Scope of the Order, *see Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Final Results of Antidumping Duty New Shipper Review; 2011–2012*, 78 FR 33341 (June 4, 2013), and accompanying Issues and Decision Memorandum at "Scope."

[6] *See* 19 CFR 351.216(d).

combined the notice of initiation and the notice of preliminary results.

In this changed circumstances review, pursuant to section 751(b) of the Act, the Department conducted a successor-in-interest analysis. In making a successor-in-interest determination, the Department examines several factors, including, but not limited to, changes in the following: (1) Management; (2) production facilities; (3) supplier relationships; and (4) customer base.[7] While no single factor or combination of factors will necessarily provide a dispositive indication of a successor-in-interest relationship, generally, the Department will consider the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor.[8] Thus, if the record evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the predecessor company, the Department may assign the new company the cash deposit rate of its predecessor.[9]

In accordance with 19 CFR 351.216, we preliminarily determine that Zhongce is the successor-in-interest to Hangzhou. Record evidence, as submitted by Zhongce, indicates that the only change undergone was that of the name, from "Hangzhou Zhongce Rubber Co., Ltd." to "Zhongce Rubber Group Company Limited."[10] Specifically, Zhongce provided a board of directors resolution authorizing the change of company name and specifying that the registered capital and business scope of the company were to remain the same;[11] a notarized notice of change in registration, affixed with the sign and seal of the Hangzhou Municipal Administration for Industry and Commerce, showing the change of names;[12] and a copy of its new business license showing Zhongce's new name.[13] In summary, Zhongce presented evidence to support its claim of successorship and the change in name did not impact any of the criteria that the Department typically looks to when making a changed circumstances determination.

We find that the evidence provided by Zhongce is sufficient to preliminarily determine that the change of its corporate name from Hangzhou to Zhongce did not affect the company's operations in a meaningful way. Therefore, based on the aforementioned reasons, we preliminarily determine that Zhongce is the successor-in-interest to Hangzhou and, thus, should receive the same antidumping duty treatment with respect to OTR tires from the PRC as the former Hangzhou.

Public Comment

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of publication of this notice. In accordance with 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the case briefs, in accordance with 19 CFR 351.309(d).

Consistent with 19 CFR 351.216(e), we will issue the final results of this changed circumstances review no later than 270 days after the date on which this review was initiated, or within 45 days if all parties agree to our preliminary finding. This notice is published in accordance with sections 751(b)(1) and 777(i) of the Act and 19 CFR 351.216(b), 351.221(b) and 351.221(c)(3).

Dated: December 20, 2013.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2013–31117 Filed 12–26–13; 8:45 am]

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[7] *See, e.g., Notice of Final Results of Changed Circumstances Antidumping Duty Administrative Review: Polychloroprene Rubber From Japan*, 67 FR 58 (January 2, 2002).

[8] *See, e.g., Fresh and Chilled Atlantic Salmon From Norway; Final Results of Changed Circumstances Antidumping Duty Administrative Review*, 64 FR 9979, 9980 (March 1, 1999).

[9] *See, e.g., Circular Welded Non-Alloy Steel Pipe From the Republic of Korea; Preliminary Results of Antidumping Duty Changed Circumstances Review*, 63 FR 14679 (March 26, 1998), unchanged in *Circular Welded Non-Alloy Steel Pipe From Korea; Final Results of Antidumping Duty Changed Circumstances Review*, 63 FR 20572 (April 27, 1998), in which the Department found that a company which only changed its name and did not change its operations is a successor-in-interest to the company before it changed its name.

[10] *See* Zhongce Request for CCR.

[11] *Id.* at Attachment 1.

[12] *Id.* at Attachment 2.

[13] *Id.* at Attachment 3.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–941]

Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("Department") is rescinding the administrative review of the antidumping duty order on certain kitchen appliance shelving and racks from the People's Republic of China ("PRC") for the period of review ("POR") September 1, 2012, through August 31, 2013. This rescission is based on the timely withdrawal of the request for review by the only interested party that requested a review.

DATES: *Effective Date:* December 27, 2013.

FOR FURTHER INFORMATION CONTACT: Emeka Chukwudebe, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; (202) 482–0219.

SUPPLEMENTARY INFORMATION:

Background

On September 3, 2013, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on certain kitchen appliance shelving and racks from the PRC.[1] On September 30, 2013, the Department received a timely request from U.S. importer Electrolux North America, Inc., Electrolux Home Products, Inc., and Electrolux Major Appliances (collectively "Electrolux") to conduct an administrative review of Jiangsu Weixi Group Co. ("Weixi").[2] On November 8, 2013, in response to Electrolux's September 30, 2013, request, the Department initiated an administrative review of the antidumping duty order on certain kitchen appliance shelving and racks from the PRC.[3] On December 4, 2013, Electrolux withdrew its request for an administrative review of Weixi.[4]

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 78 FR 54235 (September 3, 2013).

[2] *See* letter from Electrolux to the Department titled, "Kitchen Appliance Shelving and Racks from the People's Republic of China: Withdrawal of Request for Administrative Review" (December 4, 2013) ("Electrolux Withdrawal Request").

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation In Part*, 78 FR 67104 (November 8, 2013); *see also* section 751(a) of the Tariff Act of 1930, as amended ("the Act") and 19 CFR 351.221(c)(l)(i).

[4] *See* Electrolux Withdrawal Request.

administrative review, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review, which in this case is February 6, 2014. On December 4, 2013, Electrolux timely withdrew its request for review within the 90-day time limit. Because no other party requested a review, pursuant to 19 CFR 351.213(d)(1), the Department is rescinding the administrative review of the antidumping duty order on certain kitchen appliance shelving and racks from the PRC covering the period September 1, 2012, through August 31, 2013.

Assessment

The Department will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on all appropriate entries of certain kitchen appliance shelving and racks from the PRC during the POR at rates equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(l)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register.**

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: December 20, 2013.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2013–31116 Filed 12–26–13; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 87–9A001]

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Amended Export Trade Certificate of Review to Independent Film & Television Alliance, Application no. 89–9A001.

SUMMARY: The U.S. Department of Commerce issued an amended Export Trade Certificate of Review to Independent Film and Television Alliance ("IFTA") on December 20, 2013.

FOR FURTHER INFORMATION CONTACT: Joseph E. Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR Part 325 (2013). The U.S. Department of Commerce, International Trade Administration, Trade of Trade and Economic Analysis ("OTEA") is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the issuance in the **Federal Register**. Under Section 305(a) of the Export Trading Company Act (15 U.S.C. 4012(b)(1)) and 15 CFR § 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

IFTA Export Trade Certificate of Review has been amended to:

1. Add the following companies as new Members of IFTA's Certificate: Altitude Film Entertainment Limited (London, United Kingdom), Archstone Distribution, LLC (Los Angeles, CA), Artis Films Romania (Bucharest, Romania), Bos Entertainment, Inc., d/b/a The Exchange (Los Angeles, CA), Callister Technology and Entertainment LLC d/b/a Garden Thieves Pictures (Washington, DC), Corsan NV(Antwerp, Belgium), DARO Film Distribution GmbH (Monte Carlo, Monaco), Embankment Films Limited (London, United Kingdom), EntertainME US LLC (Hollywood, CA), Entertainment One (Toronto, Ontario, Canada), Exclusive Films International, Limited (Beverly Hills, CA), Filmnation Entertainment (Los Angeles, CA), Fortune Star Media Limited (Kowloon, Hong Kong), GFM Films (London, United Kingdom), Global Asylum, The (Burbank, CA), Gold Lion Films (Los Angeles, CA), Hasbro, Inc. (Burbank, CA), HBO Enterprises (New York, NY), Highland Film Group LLC (West Hollywood, CA), Huayi Brothers Media Corporation (Beijing, China), Hyde Park International (Sherman Oaks, CA), KSM GmbH (Wiesbaden, Germany), Lotte Entertainment (Seoul, South Korea), Mega-Vision Pictures Limited (Kowloon, Hong Kong), MICA Entertainment, LLC (Century City, CA), Mission Pictures International, LLC (Van Nuys, CA), Mister Smith Entertainment Limited (London, United Kingdom), MonteCristo International Entertainment, LLC (Los Angeles, CA), Multicom Entertainment Group, Inc. (Los Angeles, CA), Premiere Entertainment Group, LLC (Encino, CA), Protagonist Pictures Limited (London, United Kingdom), Reel One Entertainment, Inc. (Beverly Hills, CA), Regal Media International (Wanchai, Hong Kong), Relativity Media, LLC (Beverly Hills, CA), Shine International (London, United Kingdom), Sierra/Affinity (Los Angeles, CA), Six Sales Entertainment Group S.L. (Madrid, Spain), Studio City Pictures, Inc. (Studio City, CA), Taylor & Dodge, LLC (Los Angeles, CA), uConnect Films Ltd. (London, United Kingdom), and Vision Music, Inc. (Los Angeles, CA).

2. Remove the following companies as Members of ITFA's Certificate: 111 Pictures Ltd., Action Concept Film und Stuntproduction GmbH, Adriana Chiesa Enterprises SRL, Alain Siritzky Productions (ASP), Alpine Pictures, Inc., American World Pictures, Bold Films L.P., Brainstorm Media, Brightlight Pictures Inc., Capitol Films Limited, Cinamour Entertainment, Cinemavault Releasing, Cinesavvy Inc.,

Continental Entertainment Capital, DeAPlaneta, Essential Entertainment, Fidec, Film Department (The), First California Bank, Fremantle Corporation (The), GreeneStreet Films, HandMade Films International, ICB Entertainment Finance, Icon Entertainment International, IFD Film & Arts, Ltd., Imagi Studios, Insight Film Releasing Ltd., International Keystone Entertainment, ITN Distribution, Inc., Keller Entertainment Group, Inc., Liberation Entertainment, Inc., Maverick Global, a division of Maverick Entertainment Group, Inc., Media 8 Entertainment, Media Luna Entertainment, Neoclassics Films Ltd., NonStop Sales AB, North by Northwest Entertainment, Oasis International, Odd Lot International, Omega Entertainment, Ltd., Paramount Vantage International, Park Entertainment Ltd., Passport International Entertainment, LLC, Peace Arch Entertainment, Promark/Zenpix, Quantum Releasing LLC, Regent Worldwide Sales LLC, Safir Films, Ltd., Sobini Films, Stevens Entertainment Group, Summit Entertainment, Tandem Communications, Taurus Entertainment Company, U.S. Bank, UGC International, Union Bank of California, Wachovia Bank, Yari Film Group, and York International.

3. Change the names of the following Members: 2929 International, LLC of Santa Monica, CA is now 2929 International, American Cinema International of Van Nuys, CA is now American Cinema International Inc., UK Film Council of London, United Kingdom is now BFI- British Film Institute, Filmax Pictures of Barcelona, Spain is now Castelao Pictures, CJ Entertainment Inc of Seoul, Korea is now CJ E&M Corporation, Classic Media, Inc. of New York, NY is now Classic Media, LLC, ContentFilm International of London, United Kingdom is now Content Media Corporation International Limited, Crystal Sky Worldwide Sales LLC of Los Angeles, CA is now Crystal Sky LLC, Ealing Studios International of London, United Kingdom is now Ealing Metro International, Echo Bridge Entertainment of Needham, MA is now Echo Bridge Entertainment LLC, Emperor Motion Pictures of Wanchai, Hong Kong is now Emperor Motion Picture Enterprise Limited, Boll AG of Vancouver, British Columbia, Canada is now Event Film Distribution, Fabrication Films of Los Angeles, CA is now Fabrication Films International LLC, Freeway Entertainment Group Ltd of Budapest, Hungary is now Freeway Entertainment Group BV, Fremantlemedia Enterprises of London, United Kingdom is now FremantleMedia Limited, GK Films, LLC of Santa Monica, CA is now GK Films, Telepool GmbH of Munich, Germany is now Global Screen GmbH, Goldcrest Films International Ltd of London, UK is now Goldcrest Films International, Green Communications of Los Angeles, CA is now Green Films, Inc., Hanway Films of London, UK is now Hanway Films Ltd., Intandem Films of London, UK is now Intandem Films Plc, K5 International of Munich, Germany is now K5 Media Group GmbH, MarVista Entertainment of Los Angeles, CA is now Mar Vista Entertainment, LLC, Miramax Films of Santa Monica, CA is now Miramax International, Moonstone Entertainment of Studio City, CA is now Moonstone Entertainment, Inc., the entity d/b/a Mainline Releasing of Santa Monica, CA is now MRG Entertainment, Inc., New Line Cinema of Burbank, CA is now New Line Cinema Corporation, Nu Image of Los Angeles, CA is now Nu Image, Inc., Pueblo Film Group of Zurich, Switzerland is now Pueblo Film Group of Companies, Film Finance Corporation Australia of Woolloomooloo, Australia is now Screen Australia, RHI Entertainment Distribution, LLC of New York, NY is now Sonar International Distribution, Inc., Hollywood Wizard of Brighton, United Kingdom is now Stealth Media Group Limited, UFO International Productions of Sherman Oaks, CA is now UFO International Productions, LLC, and Works International, The of London, United Kingdom is now Works, The.

IFTA's amendment of its Export Trade Certificate of Review results in the following membership list:

2929 International, Santa Monica, CA
Alfred Haber Distribution, Inc., Palisades Park, NJ
Altitude Film Entertainment Limited, London, United Kingdom
American Cinema International Inc., Van Nuys, CA
Archstone Distribution, LLC, Los Angeles, CA
Arclight Films Pty Ltd., Moore Park, Australia
Artis Films Romania, Bucharest, Romania
Artist View Entertainment, Inc., Studio City, CA
Atlas International Film GmbH, Munich, Germany
Atrium Productions KFT, Budapest, Hungary
AV Pictures, Ltd., London, United Kingdom
BFI-British Film Institute, London, United Kingdom
Bleiberg Entertainment, Beverly Hills, CA
Blue Galaxy International, LLC, Sherman Oaks, CA
Bos Entertainment, Inc. (dba The Exchange), Los Angeles, CA
Callister Technology and Entertainment LLC (dba Garden Thieves Pictures), Washington, DC
Castelao Pictures, Barcelona, Spain
Cinema Arts Entertainment, Los Angeles, CA
Cinema Management Group, Beverly Hills, CA
CineTel Films, Inc., Los Angeles, CA
City National Bank, Beverly Hills, CA
CJ E&M Corporation, Seoul, S. Korea
Classic Media, LLC, New York, NY
Comerica Entertainment Group, Los Angeles, CA
Content Media Corporation International Limited, London, United Kingdom
Cori Distribution Group, London, United Kingdom
Corsan NV, Antwerp, Belgium
Crystal Sky LLC, Los Angeles, CA
Curb Entertainment International Corporation, Burbank, CA
Daro Film Distribution GmbH, Monte Carlo, Monaco
Distant Horizon, Stanmore, Middlesex, United Kingdom
Distribution Workshop, Kowloon Tong, Hong Kong
Ealing Metro International, London, United Kingdom
Echo Bridge Entertainment LLC, Needham, MA
Embankment Films Limited, London, United Kingdom
Emperor Motion Picture Enterprise Limited, Wanchai, Hong Kong
EntertainME US LLC, Hollywood, CA
Entertainment One, Toronto, Canada
Epic Pictures Group, Inc., Beverly Hills, CA
EuropaCorp, Saint Denis Cedex, France
Event Film Distribution, British Columbia, Canada
Exclusive Films International, Limited, Beverly Hills, CA
Fabrication Films International LLC, Los Angeles, CA
Film Finances, Inc., Los Angeles, CA
Filmexport Group SRL, Rome, Italy
Filmnation Entertainment, New York, NY
Fintage House, Leiden, Netherlands
Focus Features, New York, NY
Foresight Unlimited, Bel Air, CA
Fortissimo Film Sales, Amsterdam, Netherlands
Fortune Star Media Limited, Kowloon, Hong Kong
Freeway Entertainment Group BV, Budapest, Hungary
FremantleMedia Limited, London, United Kingdom

Gaiam Americas, Inc., New York, NY
Gaumont, Neuilly-sur-Seine, France
GFM Films, London, United Kingdom
GK Films, Santa Monica, CA
Global Asylum (The), Burbank, CA
Global Screen GmbH, Munich, Germany
Gold Lion Films, Los Angeles, CA
Goldcrest Films International, London, United Kingdom
Golden Network Asia Limited, Kwun Tong, Hong Kong
Green Films, Inc., Los Angeles, CA
Hanway Films Ltd., London, United Kingdom
Harmony Gold U.S.A., Inc., Los Angeles, CA
Hasbro, Inc., Burbank, CA
HBO Enterprises, New York, NY
Highland Film Group LLC, West Hollywood, CA
Huayi Brothers Media Corporation, Beijing, China
Hyde Park International, Sherman Oaks, CA
IFM World Releasing, Inc., Glendale, CA
IM Global, Los Angeles, CA
Imageworks Entertainment International, Inc., Woodland Hills, CA
Imagination Worldwide, LLC, Beverly Hills, CA
Independent Film Sales, London, United Kingdom
Intandem Films Plc, London, United Kingdom
K5 Media Group GmbH, Munich, Germany
Kathy Morgan International (KMI), Los Angeles, CA
Kimmel International, Beverly Hills, CA
Koan, Inc., Park City, UT
KSM GmbH, Wiesbaden, Germany
Lakeshore Entertainment Group, LLC, Beverly Hills, CA
Lionsgate, Santa Monica, CA
Little Film Company (The), Studio City, CA
Lotte Entertainment, Seoul, South Korea
Mar Vista Entertainment, LLC, Los Angeles, CA
Media Asia Distribution Ltd., Hong Kong
Mega-Vision Pictures Limited, Kowloon, Hong Kong
MICA Entertainment, LLC, Century City, CA
Miramax International, Santa Monica, CA
Mission Pictures International, LLC, Van Nuys, CA
Mister Smith Entertainment Limited, London, United Kingdom
MonteCristo International Entertainment, LLC, Los Angeles, CA
Moonstone Entertainment, Inc., Studio City, CA
Morgan Creek International, Inc., Los Angeles, CA
Motion Picture Corporation of America, Los Angeles, CA
Moviehouse Entertainment, London, United Kingdom
MRG Entertainment, Inc., Santa Monica, CA
Multicom Entertainment Group, Inc., Los Angeles, CA
Myriad Pictures, Santa Monica, CA
New Films International, Sherman Oaks, CA
New Horizons Picture Corp., Los Angeles, CA
New Line Cinema Corporation, Burbank, CA
New Zealand Film Commission, Wellington, New Zealand
Nordisk Film A/S, Copenhagen, Denmark
Nu Image, Inc., Los Angeles, CA
Pathe Distribution, Paris, France
Premiere Entertainment Group, LLC, Encino, CA
Protagonist Pictures Limited, London, United Kingdom
Pueblo Film Group of Companies, Zurich, Switzerland
QED International, Los Angeles, CA
Reel One Entertainment, Inc., Beverly Hills, CA
Regal Media International, Wanchai, Hong Kong
Relativity Media, LLC, Beverly Hills, CA
Screen Australia, Woolloomooloo, Australia
Screen Capital International Corp., Beverly Hills, CA
Screen Media Ventures, LLC, New York, NY
Shine International, London, United Kingdom
Showcase Entertainment, Inc., Calabasas, CA
Sierra/Affinity, Beverly Hills, CA
Six Sales Entertainment Group S.L., Madrid, Spain
SND, Neuilly sur Seine, France
Sonar International Distribution, Inc., New York, NY
Spotlight Pictures, LLC, Hollywood, CA
Starz Media, Beverly Hills, CA
Stealth Media Group Limited, Brighton, United Kingdom
Studio City Pictures, Inc., Studio City, CA
StudioCanal, Issy Les Moulineaux, France
Svensk Filmindustri, AB, Stockholm, Sweden
Taylor & Dodge, LLC, Los Angeles, CA
TF1 International, Boulogne Billancourt, France
Troma Entertainment, Inc., Long Island City, NY
uConnect Films Ltd., London, United Kingdom
UFO International Productions, LLC, Sherman Oaks, CA
Vision Films, Inc., Sherman Oaks, CA
Vision Music, Inc., Los Angeles, CA
Voltage Pictures, Los Angeles, CA
Weinstein Company (The), New York, NY
Wild Bunch, Paris, France
Works, (The), London, United Kingdom
Worldwide Film Entertainment, LLC, Los Angeles, CA

Dated: December 23, 2013.

Joseph E. Flynn,

Office Director, Office of Trade and Economic Analysis.

[FR Doc. 2013–31141 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–DR– P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 13–00001]

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Export Trade Certificate of Review to Emporia Trading LLC, Application No. 13–00001.

SUMMARY: The U.S. Department of Commerce issued an Export Trade Certificate of Review to Emporia Trading LLC on December 16, 2013.

FOR FURTHER INFORMATION CONTACT: Joseph E. Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR Part 325 (2013). The U.S. Department of Commerce, International Trade Administration, Office of Competition and Economic Analysis ("OCEA") is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the issuance in the **Federal Register**. Under Section 305(a) of the Export Trading Company Act (15 U.S.C. 4012(b)(1)) and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Members (Within the Meaning of 15 CFR 325.2(1))

Robert T "Terry" Smith, Sr. and Robert "Bobby" Smith, Jr.

Description of Certified Conduct

Emporia is certified to engage in the Export Trade Activities and Methods of Operation described below in the following Export Trade and Export Markets.

Export Trade

Products: Manufactured Products [NAICS 31–33]

Services: All services related to the export of Products.

Technology Rights: All intellectual property rights associated with Products or Services, including, but not limited to: Patents, trademarks, services marks, trade names, copyrights, neighboring (related) rights, trade secrets, know-how, and confidential databases and computer programs.

Export Trade Facilitation Services (as They Relate to the Export of Products): Export Trade Facilitation Services, including but not limited to: Consulting and trade strategy, arranging and coordinating delivery of Products to the port of export; arranging for inland and/or ocean transportation; allocating Products to vessel; arranging for storage space at port; arranging for warehousing, stevedoring, wharfage, handling, inspection, fumigation, and freight forwarding; insurance and financing; documentation and services related to compliance with customs' requirements; sales and marketing; export brokerage; foreign marketing and analysis; foreign market development; overseas advertising and promotion; Products-related research and design based upon foreign buyer and consumer preferences; inspection and quality control; shipping and export management; export licensing; provisions of overseas sales and distribution facilities and overseas sales staff; legal; accounting and tax assistance; development and application of management information systems; trade show exhibitions; professional services in the area of government relations and assistance with federal and state export assistance programs (e.g., Export Enhancement and Market Promotion programs, invoicing (billing) foreign buyers; collecting (letters of credit and other financial instruments) payment for Products; and arranging for payment of applicable commissions and fees.

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

Export Trade Activities and Methods of Operations

To engage in Export Trade in the Export Markets, Emporia Trading LLC and its individual members (collectively "Emporia") may:

1. Provide and/or arrange for the provision of Export Trade Facilitation Services;

2. Engage in promotional and marketing activities and collect information on trade opportunities in the Export Markets and distribute such information to clients;

3. Enter into exclusive and/or non-exclusive licensing and/or sales agreements with Suppliers for the export of products and services, and/or technology rights to Export Markets;

4. Enter into exclusive and/or non-exclusive agreements with distributors and/or sales representatives in Export Markets;

5. Allocate export sales or divide Export Markets among Suppliers for the sale and/or licensing of products and services and/or technology rights;

6. Allocate export orders among Suppliers;

7. Establish the price of products and services and/or technology rights for sales and/or licensing in Export Markets; and

8. Negotiate, enter into, and/or manage licensing agreements for the export of technology rights.

9. Emporia may exchange information with individual Suppliers on a one-to-one basis regarding that Supplier's inventories and near-term production schedules in order that the availability of Products for export can be determined and effectively coordinated by Emporia with its distributors in Export Markets.

Definition

"Supplier" means a person who produces, provides, or sells Products, Services, and/or Technology Rights.

Dated: December 23, 2013.

Joseph E. Flynn,

Office Director, Office of Trade and Economic Analysis.

[FR Doc. 2013–31140 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Conference on Weights and Measures 99th Interim Meeting

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The 99th Interim Meeting of the National Conference on Weights and Measures (NCWM) will be held in Albuquerque, New Mexico, January 19 to 22, 2014. This notice contains information about significant items on the NCWM Committee agendas, but does not include all agenda items. As a result, the items are not consecutively numbered.

DATES: The meeting will be held January 19 to 22, 2014.

ADDRESSES: This meeting will be held at the Hotel Albuquerque, 800 Rio Grande Boulevard, NW., Albuquerque, NM 87104.

FOR FURTHER INFORMATION CONTACT: Ms. Carol Hockert, Chief, NIST, Office of Weights and Measures, 100 Bureau Drive, Stop 2600, Gaithersburg, MD 20899–2600. You may also contact Ms. Hockert at (301) 975–5507 or by email at *carol.hockert@nist.gov*. The meetings are open to the public, but a paid registration is required. Please see NCWM Publication 15 "Interim Meeting Agenda" (*www.ncwm.net*) to view the meeting agendas, registration forms, and hotel reservation information.

SUPPLEMENTARY INFORMATION: Publication of this notice on the NCWM's behalf is undertaken as a public service; NIST does not endorse, approve, or recommend any of the proposals or other information contained in this notice or in the publications of the NCWM.

The NCWM is an organization of weights and measures officials of the states, counties, and cities of the United States, federal agencies, and representatives from the private sector. These meetings bring together government officials and representatives of business, industry, trade associations, and consumer organizations on subjects related to the field of weights and measures technology, administration, and enforcement. NIST participates to encourage cooperation between federal agencies and the states in the development of legal metrology requirements. NIST also promotes uniformity among the states in laws, regulations, methods, and testing equipment that comprise the regulatory

control of commercial weighing and measuring devices, packaged goods, and other trade and commerce issues.

The following are brief descriptions of some of the significant agenda items that will be considered along with other issues at the NCWM Interim Meeting. Comments will be taken on these and other issues during several public comment sessions. At this stage, the items are proposals. This meeting also includes work sessions in which the Committees may also accept comments, and where recommendations for NCWM consideration and possible adoption at its 2014 Annual Meeting will be developed. The Committees may withdraw or carryover items that need additional development. The 99th Annual Meeting of the NCWM will be held July 13 to 17, 2014, at the Westin Book Cadillac Detroit, 1114 Washington Boulevard, Detroit, MI 48226.

Some of the items listed below provide notice of projects under development by groups working to develop specifications, tolerances, and other requirements for devices used in the retail sales of engine fuels and the establishment of approximate gallon and liter equivalents to diesel fuel that would be used in marketing both compressed and liquefied natural gas. Also included is a notice about efforts to establish a method of sale for pressurized containers that utilize bag-on-valve technology. These notices are intended to make interested parties aware of these development projects and to make them aware that reports on the status of the project will be given at the Interim Meeting. The notices are also presented to invite the participation of manufacturers, experts, consumers, users, and others who may be interested in these efforts.

The Specifications and Tolerances Committee (S&T Committee) will consider proposed amendments to NIST Handbook 44, "Specifications, Tolerances, and other Technical Requirements for Weighing and Measuring Devices." Those items address weighing and measuring devices used in commercial applications, that is, devices that are used to buy from or sell to the public or used for determining the quantity of product sold among businesses. Issues on the agenda of the NCWM Laws and Regulations Committee (L&R Committee) relate to proposals to amend NIST Handbook 130, "Uniform Laws and Regulations in the area of Legal Metrology and Engine Fuel Quality" and NIST Handbook 133, "Checking the Net Contents of Packaged Goods."

NCWM Specifications and Tolerances Committee

The following items are proposals to amend NIST Handbook 44:

General Code

Item 310–2 G.S.5.6. Recorded Representations.

A variety of commercial weighing and measuring devices are required to provide paper receipts for consumers at the end of a transaction. These receipts provide important information for consumers (e.g., seller identity, date, product identity, and amount delivered, along with the unit price and total price of the transaction). Sometimes receipts include details of transaction that are often not readily apparent to consumers at the time of the transaction (e.g., such as when a point of sale system in a grocery store deducts for the tare weight on a package of apples). These documents help consumers understand a transaction and reconcile the transaction with billing invoices or credit card bills in the future. Detailed receipts are especially important in transactions where the customer is often not present, such as when a delivery of heating fuel is made when the consumer is not at home. Receipts describing transaction details help prevent fraud and provide valuable protections for buyers and sellers alike. This item is a proposal to revise the General Code requirement to allow sellers to offer consumers the choice of receiving receipts via digital communications such as email or online account access.

Scales

Item 320–1 S.2.1.6. Combined Zero-Tare Key.

Some manufacturers of high-precision balances that are typically used by precious metal and gem buyers have built balances that have a single pushbutton that combines two functions: (1) Function used to keep the balance on zero and (2) the function used to deduct for the tare weight of a tray or weighing pan. Regulations adopted by most states prohibit the use of weighing devices with this type of feature in direct buying and selling transactions (i.e., where the customer is present). Consumers in direct sale transactions have a legal right under the laws of most states to view the balance indications and weighing operation to prevent fraud. Most states also require scales and balances to automatically indicate that tare has been deducted. Such features benefit both the consumer and the device user since the indication helps to ensure the accuracy of the transaction. Because many devices with the combined zero-tare key feature have found their way into direct sale applications, some manufacturers are now requesting a change to the requirement based on the assumption that there is no evidence that a combined feature key on some balances has led to an increase in fraud in these types of transactions. This item includes a proposal to amend existing regulations to allow scales and balances to be equipped with a combined "zero/tare" pushbutton if it is designed to operate within narrow limits and there are indications or controls built into the device to provide consumers with information about the zero condition of the scale or balance.

Liquefied Petroleum Gas (LPG) and Anhydrous Ammonia Measuring Devices

Item 332–1 Proposed amendments to device specifications and user requirements. This item includes several proposals that will amend the specifications and other requirements for liquid measuring devices used to sell LPG and Anhydrous Ammonia to require electronic measuring devices to be equipped with the means to retain detailed transaction information in the event of a power failure. Another proposal would require the posting of unit price and product identity adjacent to stationary devices in retail outlets. In addition, the proposed specifications would require that measuring devices used in retail applications to fill motor vehicles have a zero-setback interlock in operation to ensure that the product indications would be returned to zero following each completed transaction (note: zero-setback interlocks have been required to be provided on retail gasoline and diesel dispensers for more than 50 years). Another proposal would add requirements for measuring devices used in wholesale and contractual transactions for unit price and product identity posting as well as special requirements for devices used to sell the same products at different unit prices (e.g., discount unit price for sales where the customer purchases an optional car wash).

Mass Flow Meters

Item 337–1 (and others): Appendix D—Definitions: Diesel Liter and Diesel Gallon Energy Equivalents for Liquefied and Compressed Natural Gas.

In response to a request from a coalition of natural gas providers, the NCWM adopted Compressed Natural Gas (CNG) "equivalents" to a liter and gallon of gasoline in 1994. At that time those equivalents were based on the "approximate" value of energy in a

gallon of gasoline and were recommended by the CNG industry to promote broader acceptance and use of CNG as a vehicle fuel base on value. The "Gasoline Liter/Gallon Equivalents" were intended to provide a means for consumers to make accurate value comparisons between gasoline and CNG and to facilitate fuel economy comparisons. In a number of instances since the adoption of these "equivalents," some state weights and measures officials and several CNG providers have expressed the concern that the energy equivalent values adopted in 1994 do not provide an accurate estimate of the true energy content of natural gas. Another concern with the 1994 "equivalents" is that the equivalents have not been reevaluated to ensure that they accurately correlate with the energy content of today's gasoline and gasoline-oxygenate blends or other alternative fuels such as E85: Consequently, many weights and measures officials are reluctant to consider adding other energy "equivalency" values for additional fuels unless some mechanism is established to ensure that all of these energy equivalency values are routinely updated to reflect the current energy content (i.e., Joules/BTUs) of gasoline and diesel fuels and various blends of these products with alternative fuels. The need for such a mechanism is important considering the many blends of fuels that are currently in the marketplace and others that are anticipated to enter the fuel arena in the future (e.g., 15% or higher ethanol blends with gasoline and biodiesel blends greater than 5%). These new proposals would establish a "diesel liter equivalent (DLE)" and a "diesel gallon equivalent (DGE)" and specify equivalent mass values for these units when they are used in retail vehicle refueling applications. The proponents of these proposals indicate that the purpose of these units is to educate consumers that a DLE or DGE of "compressed" or "liquefied" natural gas contains approximately the same amount of energy they would receive if they purchased a liter or gallon of diesel fuel. Most sellers of these products believe that adoption and use of the DLE or DGE in retail fuel sales would make it easier for consumers to make price, value, and fuel economy comparisons between an energy "equivalent" liter or gallon of compressed natural gas and everyday diesel fuel. See also Items 337–2, 337–3, 337–4, and 337–5 on the Specifications and Tolerances Committee Agenda and Items 232–2 and 232–3 in the Laws and Regulations Committee Agenda regarding proposed methods of sale for the DLE and DGE.

NCWM Laws and Regulations Committee (L & R Committee)

The following items are proposals to amend NIST Handbook 130 or NIST Handbook 133:

NIST Handbook 130—Uniform Regulation for the Method of Sale of Commodities

Item 231–2: Section 10.3. Aerosols and Similar Pressurized Containers.

This item includes a proposal to establish a method of sale for pressurized containers that utilize Bag-on-Valve (BOV) technology that have their net content declarations in terms of fluid volume. Unlike most aerosol containers, packages fitted with BOV technology do not expel a propellant with the product when the valve is activated. Currently, under the Uniform Packaging and Labeling Regulation (UPLR) adopted by many states, products sold in aerosol or similar pressurized containers must be offered for sale by weight. BOV packaging, which has been in the marketplace for many years, is used to sell the same products sold in aerosol containers (e.g., sunscreen, wound wash, shaving cream, and car-care products). Because BOV containers (with their net contents declared in fluid volume) are used to sell the same type of products dispensed from aerosol containers (with their net contents declared by weight), consumers are unable to make value comparisons between similar products. The L&R Committee is aware that most countries in the European Union require aerosol and pressurized containers to display net contents in terms of fluid volume, but other countries permit these types of containers to display net contents declarations in terms of both net weight and volume.

Dated: December 19, 2013.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2013–31092 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Manufacturing Extension Partnership Advisory Board

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of Open Meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the Manufacturing Extension Partnership (MEP) Advisory Board will hold an open meeting on Tuesday, January 28, 2014 from 8:30 a.m. to 5:00 p.m. Eastern Time.

DATES: The meeting will be held Tuesday, January 28, 2014, from 8:30 a.m. to 5:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held at the Hilton Charlotte University Place, 8629 J M Keynes Drive, Charlotte, North Carolina 28262.

Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Karen Lellock, Manufacturing Extension Partnership, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800, telephone number (301) 975–4269, email: *Karen.Lellock@nist.gov.*

SUPPLEMENTARY INFORMATION: The MEP Advisory Board (Board) is authorized under Section 3003(d) of the America COMPETES Act (Pub. L. 110–69); codified at 15 U.S.C. 278k(e), as amended, in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. The Board is composed of 10 members, appointed by the Director of NIST. MEP is a unique program consisting of centers across the United States and Puerto Rico with partnerships at the state, federal, and local levels. The Board provides a forum for input and guidance from Hollings MEP program stakeholders in the formulation and implementation of tools and services focused on supporting and growing the U.S. manufacturing industry, provides advice on MEP programs, plans, and policies, assesses the soundness of MEP plans and strategies, and assesses current performance against MEP program plans.

Background information on the Board is available at *http://www.nist.gov/mep/advisory-board.cfm.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the MEP Advisory Board will hold an open meeting on Tuesday, January 28, 2014 from 8:30 a.m. to 5:00 p.m. Eastern Time. This meeting will focus on (1) MEP administrative updates, and (2) Board input into the NIST MEP strategic planning process. The agenda may change to accommodate other Board business. The final agenda will be posted on the MEP Advisory Board Web site at *http://www.nist.gov/mep/*

advisory-board.cfm. This meeting is being held in conjunction with the MEP Update meeting that will be held January 29–30, 2014 also at the Hilton Charlotte University Place, 8629 J M Keynes Drive, Charlotte, North Carolina 28262.

Admittance Instructions: Anyone wishing to attend this meeting should submit their name, email address and phone number to Karen Lellock (*Karen.lellock@nist.gov* or 301–975–4269) no later than Tuesday, January 21, 2014, 5:00 p.m. Eastern Time.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the MEP Advisory Board's business are invited to request a place on the agenda. Approximately 15 minutes will be reserved for public comments at the beginning of the meeting. Speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received but is likely to be no more than three to five minutes each. The exact time for public comments will be included in the final agenda that will be posted on the MEP Advisory Board Web site at *http://www.nist.gov/mep/advisory-board.cfm.* Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to the MEP Advisory Board, National Institute of Standards and Technology, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800, or via fax at (301) 963–6556, or electronically by email to *karen.lellock@nist.gov.*

Dated: December 20, 2013.

Phillip Singerman,

Associate Director for Innovation & Industry Services.

[FR Doc. 2013–31099 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC969

Draft Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammals—Acoustic Threshold Levels for Onset of Permanent and Temporary Threshold Shifts

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The National Marine Fisheries Service (NMFS) on behalf of NMFS and the National Ocean Service (referred collectively here as the National Oceanic and Atmospheric Administration (NOAA)), announces the availability of draft guidance for assessing the effects of anthropogenic sound on marine mammal species under NOAA's jurisdiction. The guidance provides updated received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity (either temporary or permanent) for all underwater anthropogenic sound sources. NOAA solicits public comment on the draft guidance.

DATES: Comments must be received by January 27, 2014.

ADDRESSES: The draft guidance is available in electronic form via the Internet at *http://www.nmfs.noaa.gov/pr/acoustics/.*

You may submit comments, identified by [NOAA–NMFS–2013–0177], by any of the following methods:

Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov.*

Mail: Send comments to: Chief, Marine Mammal and Sea Turtle Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3226, Attn: Acoustic Guidance.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

NMFS will hold a public meeting and webinar to inform interested parties and solicit comments on the draft guidance document. The meeting will be held on January 14, 2014, from 2 p.m. to 5 p.m. (EST) at the NOAA Silver Spring Metro Center Complex, NOAA Science Center, 1301 East-West Highway, Silver Spring, MD 20910. This meeting is accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Amy Scholik-Schlomer, (301) 427–8449 (voice), (301) 713–0376 (fax), or *Amy.Scholik@noaa.gov* at least five days before the scheduled meeting date. Information on how to register for the online webinar will be posted on via the Internet at *http://www.nmfs.noaa.gov/pr/acoustics/* after January 1, 2014.

FOR FURTHER INFORMATION CONTACT: Amy Scholik-Schlomer, Office of Protected Resources, 301–427–8449, *Amy.Scholik@noaa.gov.*

SUPPLEMENTARY INFORMATION: The National Marine Fisheries Service and the National Ocean Service (referred collectively here as the National Oceanic and Atmospheric Administration (NOAA)), have developed draft guidance for assessing the effects of anthropogenic sound on marine mammal species under NOAA's jurisdiction. Specifically, the guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity (either temporary or permanent) for all underwater anthropogenic sound sources. This is the first time NOAA has presented this information in a single, comprehensive document. This guidance is intended to be used by NOAA analysts and managers and other relevant user groups and stakeholders, including other federal agencies, when seeking to determine whether and how their activities are expected to result in particular types of impacts to marine mammals via acoustic exposure. This document outlines NOAA's updated acoustic threshold levels and describes in detail how the thresholds were developed and how they will be updated in the future.

NOAA has compiled, interpreted, and synthesized the best available science to produce updated acoustic threshold levels for the onset of both temporary

(TTS) and permanent hearing threshold shifts (PTS). These thresholds replace those currently in use by NOAA. Updates include a protocol for estimating PTS and TTS onset levels for impulsive (e.g., airguns, impact pile drivers) and non-impulsive (e.g., sonar, vibratory pile drivers) sound sources, the formation of marine mammal functional hearing groups (low-, mid-, and high-frequency cetaceans and otariid and phocid pinnipeds), and the incorporation of marine mammal auditory weighting functions into the calculation of thresholds. These acoustic threshold levels are presented using the dual metrics of cumulative sound exposure level and peak sound pressure level. This document addresses how to combine multiple datasets, as well as how to determine appropriate surrogates when data are not available. While the updated acoustic thresholds are more complex than those previously used by NOAA, they accurately reflect the current state of scientific knowledge regarding the characteristics of sound that have the potential to impact marine mammal hearing sensitivity. Given the specific nature of these updates, it is not possible to compare directly the updated acoustic threshold levels presented in this document with the thresholds previously used by NOAA.

Although NOAA has updated the acoustic threshold levels from those previously used, and these changes may necessitate new methodologies for calculating impacts, the application of the thresholds in the regulatory context under applicable statutes (Marine Mammal Protection Act, Endangered Species Act, and National Marine Sanctuaries Act) remains consistent with past NOAA practice. It is important to note that these updated acoustic threshold levels do not represent the entirety of an impact assessment, but rather serve as one tool (in addition to behavioral impact thresholds, auditory masking assessments, evaluations to help understand the ultimate effects of any particular type of impact on an individual's fitness, population assessments, etc.), to help evaluate the effects of a proposed action on marine mammals and make findings required by our various statutes.

The document is classified as a Highly Influential Scientific Assessment by the Office of Management and Budget. As such, independent peer review is required prior to broad public dissemination by the Federal Government. NOAA conducted a peer review of the updated acoustic threshold levels. Details of the peer review can be found within this document, and at the following Web site: *http://www.nmfs.noaa.gov/pr/acoustics/*.

A summary of the updated acoustic threshold levels can be found in the main body of the document and additional details are provided in the appendices. Section I provides an introduction to the document and a description of how NOAA addressed uncertainty and data limitations. NOAA's updated acoustic threshold levels for onset of PTS and TTS for marine mammals exposed to underwater sound are presented in Section II. Section III describes how acoustic threshold levels are interpreted under NOAA's statutes. NOAA's plan for periodically updating acoustic threshold levels is presented in Section IV. More details on the marine mammal auditory weighting functions, the development of acoustic threshold levels, the peer review process, and a glossary of acoustic terms can be found in the appendices.

NOAA particularly encourages the public to identify any additional datasets for inclusion in the assessment, and to comment on the appropriateness of the proposed accumulation period for the cumulative sound exposure metric and the proposed low-frequency auditory weighting function for which direct measurements of hearing sensitivity are not available.

Dated: December 19, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2013–30951 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD049

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Skate Oversight Committee and Skate Advisory Panel on January 15, 2014 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, January 15, 2014 at 9:30 a.m.

ADDRESSES: *Meeting address:* The meeting will be held at the Sheraton Harborside, 250 Market Street, Portsmouth, NH 03801; telephone: (603) 431–2300; fax: (603) 433–5649.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Skate Oversight Committee and Advisory Panel will review Plan Development Team work on alternatives under consideration and impacts of these alternatives in Framework Adjustment 2 and select preferred alternatives. They will also have a preliminary discussion of the development of future actions for the Skate FMP that include addressing overfishing occurring on thorny skate as well as a discussion of establishing a control date for the wing fishery. Address other business as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 23, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–31043 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD055

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: The North Pacific Fishery Management Council (NPFMC) will hold a Crab Modeling Workshop.

SUMMARY: The workshop will be held January 14–17 at the Hilton Hotel, 500 West Third Avenue, Katmai/King Salmon, Anchorage, AK.

DATES: The workshop will be held January 14–17, 2014, from 9 a.m. to 5 p.m.

ADDRESSES: The workshop will be held at the Anchorage Hilton Hotel, 500 West Third Avenue, Anchorage, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Avenue, Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Diana Stram, NPFMC; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The agenda includes:

Application of a generic crab modeling framework to two BSAI crab stocks: Bristol Bay red king crab and Norton Sound red king crab.

The Agenda is subject to change, and the latest version will be posted at *http://www.alaskafisheries.noaa.gov/npfmc/*

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: December 23, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–31039 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD051

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a webinar of the Socioeconomic Scientific and Statistical Committee (SESSC).

DATES: The webinar will be held from 1 p.m. until 3 p.m. (EST) on Monday, January 13, 2014.

ADDRESSES: This meeting will be held via webinar; visit *https://www4.gotomeeting.com/register/191998663* to register.

Council address: Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Dr. Assane Diagne, Economist, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *Assane.Diagne@gulfcouncil.org.*

SUPPLEMENTARY INFORMATION: The items for discussion on the meeting agenda are as follows:

1. Economic Evaluation of Alternative Red Snapper Allocations: Updated Analyses
2. Economic Effects of Reallocation in Amendment 28
3. Social Effects of Reallocation in Amendment 28
4. Recommendations to the Council
5. Other Business

For meeting materials call (813) 348–1630.

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Socioeconomic Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 23, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–31038 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC784

Takes of Marine Mammals Incidental to Specified Activities; Rockaway Delivery Lateral Project off New York, January 2013 through January 2014

AGENCY: National Marine Fisheries Service, National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed Incidental Harassment Authorization; request for comments.

SUMMARY: We have received an application from Transcontinental Gas Pipe Line Company, LLC (Transco) for an Incidental Harassment Authorization to take marine mammals, by harassment, incidental to expanding a natural gas pipeline system off the coast of New York from April 2014 through August 2014. Per the Marine Mammal Protection Act, we are requesting comments on our proposal to issue an Incidental Harassment Authorization to Transco to incidentally harass by Level B harassment only, seven species of marine mammals during pile driving and removal operations.

DATES: Comments and information must be received no later than January 27, 2014.

ADDRESSES: Comments on the application should be addressed to P. Michael Payne, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing email comments is *ITP.Magliocca@noaa.gov*. Please include 0648–XC784 in the subject line. We are not responsible for email comments sent to other addresses other than the one provided here. Comments sent via email to *ITP.Magliocca@noaa.gov,* including all attachments, must not exceed a 10-megabyte file size.

All submitted comments are a part of the public record and we will post to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

To obtain an electronic copy of the application, write to the previously mentioned address, telephone the contact listed here (see **FOR FURTHER INFORMATION CONTACT**), or visit the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications*.

The public can view documents cited in this notice by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Michelle Magliocca, National Marine Fisheries Service, Office of Protected Resources, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(D) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) directs the Secretary of Commerce to authorize, upon request, the incidental, but not intentional, taking of small numbers of marine mammals of a species or population stock, by United States citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if, after notice of a proposed authorization to the public for review and public comment: (1) we make certain findings; and (2) the taking is limited to harassment.

We shall grant authorization for the incidental taking of small numbers of marine mammals if we find that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). The authorization must set forth the permissible methods of taking; other means of effecting the least practicable adverse impact on the species or stock and its habitat (i.e., mitigation); and requirements pertaining to the monitoring and reporting of such taking. We have defined "negligible impact" in 50 CFR 216.103 as " an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Section 101(a)(5)(D) of the MMPA establishes a 45-day time limit for our review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the public comment period, we must either issue or deny the authorization and must publish a notice in the **Federal Register** within 30 days of our determination to issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

We received an application from Transco on March 21, 2013, requesting that we issue an Incidental Harassment Authorization (Authorization) for the take, by Level B harassment only, of small numbers of marine mammals incidental to the Rockaway delivery lateral project (Project) off the coast of New York from April 2014 August May 2014. We received a revised application from Transco on May 13, 2013, which reflected updates to the proposed mitigation measures, proposed monitoring measures, and incidental take requests for marine mammals. Upon receipt of additional information, we determined the application complete and adequate on May 21, 2013. Further revisions were made to the request in October 2013 due to a change in the project schedule and the application was considered complete and adequate on November 9, 2013.

Transco proposes to expand its pipeline system to meet immediate and future demand for natural gas in the New York City market area. This project would provide an additional delivery point to National Grid's (an international electricity and gas company) local distribution companies, giving National Grid the flexibility to redirect supplies during peak demand periods. The in-water portion of the project, which would require pile driving, may result in the incidental taking of seven species of marine mammals by behavioral harassment.

Description of the Proposed Specified Activities

The specific Project activity would be to install a sub-sea natural gas pipeline extending from the existing Lower New York Bay Lateral in the Atlantic Ocean to an onshore delivery point on the Rockaway Peninsula. The work would include the following:

- Horizontal directional drilling
  - Beginning onshore and exiting offshore
  - Includes excavation of the horizontal directional drilling exit pit and pile driving activities
- Offshore construction and support vessels
  - Various vessels would be used throughout the in-water work
- Sub-sea dual hot-tap installation of the existing Lower New York Bay Lateral
  - Includes use of diver-controlled hand-jetting to clear sediment around the existing pipeline
- Offshore pipeline construction
  - Includes offshore pipe laying and subsea jet-sled trenching
- Anode bed installation and cable crossing
  - Includes use of divers and hand-jetting to clear sediment around the locations of the anode bed and existing power cable crossing
- Hydrostatic test water withdrawal and discharge
  - Would occur four times during the course of in-water construction.
  - Post-installation and final (as-built) hydrographic survey
  - Includes the use of a multibeam echo sounder and high resolution side scan sonar
  - Subsea trench and HDD exit pit backfill
  - Includes the use of a small-scale crane-supported suction dredge for the trench
  - Includes the use of diver-controlled hand jetting and/or clamshell dredge for the HDD exit pit

- Operation and maintenance

Only the pile driving activities associated with horizontal directional drilling offshore construction are expected to result in the take of marine mammals by Level B harassment. Other aspects of the project are discussed in more detail in Transco's IHA application (*http://www.nmfs.noaa.gov/pr/permits/incidental.htm/#applications*). No vessels would use dynamic positioning (a system to maintain position and heading), and only two vessels—a crew boat and escort boat—would make daily trips to the Project area from shore. Elevated sound levels that would result in harassment are not expected from the clamshell dredge because the dredge would be anchored and dynamic positioning would not be used. Dredging and trenching may result in a temporary, localized increase in turbidity, but are not expected to rise to the level of harassment. A complete description of all in-water Project activities is provided in Transco's application (*http://www.nmfs.noaa.gov/pr/permits/incidental.htm/#applications*).

Vibratory Hammer Installation and Removal

Vibratory hammers are commonly used in steel pile installation and removal when the sediment conditions allow for this method. Transco will likely use the MKT V 52 model of vibratory hammer for the Project. The vibratory hammer is considered a continuous sound source because it continuously drives the pile into the substrate until the desired depth is reached. Transco would use a vibratory hammer to install about 70 piles (5 sets of temporary goal posts and up to 60 temporary fender piles). All piles would be 14- to 16-inch diameter steel pipe piles. Two vibratory hammers would be on site, but only one hammer would be used at a time. Each pile should take about 1 to 2 seconds to install per foot of depth driven, with each pile driven to a depth of about 25 to 30 feet below the seafloor. Therefore, each pile would take up to 60 seconds of continuous pile driving to install. All piles should be installed during a 1-week period, with less than 12 hours of pile driving operation. The goal posts and fenders would remain in the offshore environment for the duration of the horizontal directional drilling portion of construction (3 to 4 months). Extraction of all piles at the end of the construction period should take about as long as installation.

Location of the Specified Activity

The Project would be located mostly in nearshore waters (within approximately 3 miles of the Atlantic Ocean), southeast of the Rockaway Peninsula in Queens County, New York. A linear segment of underwater land measuring approximately 2.15 miles would be required for offshore pipe lay and trenching activities from the interconnect with Transco's pipeline to the proposed horizontal directional drilling exit point in the nearshore area, seaward of Jacob Riis Park (see Figure 1 of Transco's application). The Project area is located within the greater New York Bight region, with construction occurring within approximately 2.86 miles from the Jacob Riis Park shoreline. Vessels associated with the Project would travel between the pipe yard in Elizabeth, New Jersey, to the offshore construction site. The greater Project area, therefore, is described as the waters between the pipe yard and construction site and the waters offshore of Jacob Riis Park where construction would occur. However, pile driving activities would only take place around the horizontal directional drilling exit point in the nearshore area. All work would occur in water depths between 25 and 50 feet.

Duration of the Specified Activity

Transco initially proposed to construct the Rockaway Delivery Lateral during the winter and early spring of 2014 (January through May), with actual pile installation and removal occurring approximately 10 percent of the time. However, the construction window will likely be shifted back; pile driving activities would begin in April and should be completed in August. Total installation time for all piles is expected total less than 1 day of operation and would occur during a 1-week period. Total operating time for the extraction of all piles at the end of the construction period is expected to take a similar amount of time (1 day total over a 1-week period).

Metrics Used in This Document

This section includes a brief explanation of the sound measurements frequently used in the discussions of acoustic effects in this document. Sound pressure is the sound force per unit area, and is usually measured in micropascals (μPa), where 1 pascal (Pa) is the pressure resulting from a force of one newton exerted over an area of one square meter. We express sound pressure level as the ratio of a measured sound pressure and a reference level. The commonly used reference pressure level in underwater acoustics is 1 μPa, and the units for sound pressure levels are dB re: 1 μPa. Sound pressure level (in decibels (dB)) = 20 log (pressure/reference pressure)

Sound pressure level is an instantaneous measurement and can be expressed as the peak, the peak-peak (p-p), or the root mean square. Root mean square, which is the square root of the arithmetic average of the squared instantaneous pressure values, is typically used in discussions of the effects of sounds on vertebrates and all references to sound pressure level in this document refer to the root mean square unless otherwise noted. Sound pressure level does not take the duration of a sound into account.

Predicted Sound Levels From Vibratory Pile Driving

No source levels were available for 14- to 16-inch diameter steel pipe piles at water depths of approximately 33 feet. The most applicable source levels available are for 12-inch diameter steel pipe piles in water depths of approximately 16 feet. In-water measurements for the Mad River Slough Project in Arcata, California, indicate that installation of a 12-inch steel pipe pile in about 16 feet of water measured 10 meters from the source generated 155 dB re 1 uPa RMS. To account for the increased diameter of the piles planned for use during the Project, a change in water depth, and a different location than where the reference levels were recorded, Transco increased the source levels from the Mad River Slough Project by 5 dB. The 5 dB increase was chosen due to an overall lack of current information available for reference levels of steel pipe piles of a similar size being driven with a vibratory hammer in similar water depths. Transco expects that this increase overestimates the actual source level from the vibratory hammer.

Transco applied the practical spreading loss model to determine the approximate distance from the sound source to our acoustic threshold for marine mammal harassment. The practical spreading loss model accounts for a 4.5 dB loss per doubling of distance to determine how sound travels away from a source. The calculated distances to our current acoustic threshold criteria for harassment are shown in Table 1 below. Sound levels from vibratory pile driving would not reach the Level A harassment threshold of 180/190 dB (cetaceans/pinnipeds). However, Transco expects that sound levels within the Level B harassment threshold could occur out to 3 miles from the source (assuming no external

impedances or masking by background noise). Transco and NMFS believe that this estimate represents the worst-case scenario and that the actual distance to the Level B harassment threshold may be shorter.

TABLE 1—CALCULATED DISTANCES TO NMFS' ACOUSTIC THRESHOLD CRITERIA

Activity type	Distance to Level B harassment threshold (120 dB)	Distance to Level A harassment threshold (180/190 dB)
Vibratory pile driving (14- to 16-inch steel pipe piles)	4,600 meters	N/A

Description of Marine Mammals in the Area of the Proposed Specified Activity

Thirteen marine mammal species under our jurisdiction may occur in the proposed Project area, including four mysticetes (baleen whales), six odontocetes (toothed cetaceans), and three pinnipeds (seals). Three of these species are listed as endangered under the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*), including: the humpback (*Megaptera novaeangliae*), fin (*Balaenoptera physalus*), and north Atlantic right (*Eubalaena glacialis*) whales.

However, based on occurrence information, stranding records, and seasonal distribution, it is unlikely that humpback whales, fin whales, minke whales, Atlantic white-sided dolphins, short-finned pilot whales, or long-finned pilot whales would be present in the Project area during the winter in-water construction period. Each of these species is discussed in detail in section 3 of Transco's IHA application (*http://www.nmfs.noaa.gov/pr/permits/incidental.htm/#applications*). In summary, humpback whales are typically found in other regions of the east coast and there have been no reported observations within the vicinity of the Project area in recent years; fin whales prefer deeper offshore waters and there have been no reported observations within the vicinity of the Project area in recent years; minke whales are prevalent in other regions there have been no reported observations within the vicinity of the Project area in recent years; Atlantic white-sided dolphins generally occur in areas east and north of the Project area; and short-finned and long-finned pilot whales prefer deeper pelagic waters. Accordingly, we did not consider these species in greater detail and the proposed authorization only addresses requested take authorizations for seven species.

Table 2 presents information on the abundance, distribution, and conservation status of the marine mammals that may occur in the proposed survey area during January through August.

TABLE 2—ABUNDANCE ESTIMATES, MEAN DENSITY, AND ESA STATUS OF MARINE MAMMALS THAT MAY OCCUR IN THE PROPOSED PROJECT AREA DURING JANUARY THROUGH AUGUST

Common Name	Scientific Name	Stock	Abundance Estimate	ESA[a]	Time of Year Expected in Region
Mysticetes					
North Atlantic right whale.	*Eubalaena glacialis*	N/A	444	EN	Nov–April
Odontocetes					
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy.	89,054		Jan–March
Bottlenose dolphin	*Tursiops truncatus*	Western North Atlantic Northern Migratory.	7,147		July–Sept
Short-beaked common dolphin.	*Delphinus delphis*	Western North Atlantic	52,893		Jan–May
Pinnipeds					
Gray seal	*Halichoerus grypus*	Western North Atlantic	348,900		Sept–May
Harbor seal	*Phoca vitulina*	Western North Atlantic	99,340		Sept–May
Harp seal	*Phoca groenlandica*	Western North Atlantic	8.3 million		Jan–May

[a] ESA status codes: EN—Endangered

Refer to section 3 of Transco's application for detailed information regarding the abundance and distribution, population status, and life history and behavior of these species and their occurrence in the proposed Project area. We have reviewed these data and determined them to be the best available scientific information for the purposes of the proposed incidental harassment authorization. Further information may also be presented in NMFS' Stock Assessment Reports: *http://www.nmfs.noaa.gov/pr/sars/species.htm#largewhales*.

Potential Effects on Marine Mammals

Transco's proposed Project (i.e., pile driving and removal) would introduce elevated levels of sound into the marine environment and have the potential to adversely impact marine mammals. The potential effects of sound from the proposed activities may include one or more of the following: tolerance; masking of natural sounds; behavioral disturbance; non-auditory physical effects; and temporary or permanent hearing impairment (Richardson *et al.*, 1995). However, for reasons discussed later in this document, it is unlikely that there would be any cases of temporary or permanent hearing impairment resulting from these activities. As outlined in previous NMFS documents, the effects of sound on marine mammals

are highly variable, and can be categorized as follows (based on Richardson *et al.*, 1995):

1. The sound may be too weak to be heard at the location of the animal (i.e., lower than the prevailing ambient sound level, the hearing threshold of the animal at relevant frequencies, or both);

2. The sound may be audible but not strong enough to elicit any overt behavioral response;

3. The sound may elicit reactions of varying degrees and variable relevance to the well-being of the marine mammal; these can range from temporary alert responses to active avoidance reactions such as vacating an area until the stimulus ceases, but potentially for longer periods of time;

4. Upon repeated exposure, a marine mammal may exhibit diminishing responsiveness (habituation), or disturbance effects may persist; the latter is most likely with sounds that are highly variable in characteristics and unpredictable in occurrence, and associated with situations that a marine mammal perceives as a threat;

5. Any anthropogenic sound that is strong enough to be heard has the potential to result in masking, or reduce the ability of a marine mammal to hear biological sounds at similar frequencies, including calls from conspecifics and underwater environmental sounds such as surf sound;

6. If mammals remain in an area because it is important for feeding, breeding, or some other biologically important purpose even though there is chronic exposure to sound, it is possible that there could be sound-induced physiological stress; this might in turn have negative effects on the well-being or reproduction of the animals involved; and

7. Very strong sounds have the potential to cause a temporary or permanent reduction in hearing sensitivity, also referred to as threshold shift. In terrestrial mammals, and presumably marine mammals, received sound levels must far exceed the animal's hearing threshold for there to be any temporary threshold shift (TTS). For transient sounds, the sound level necessary to cause TTS is inversely related to the duration of the sound. Received sound levels must be even higher for there to be risk of permanent hearing impairment (PTS). In addition, intense acoustic or explosive events may cause trauma to tissues associated with organs vital for hearing, sound production, respiration and other functions. This trauma may include minor to severe hemorrhage.

Tolerance

Numerous studies have shown that underwater sounds from industrial activities are often readily detectable by marine mammals in the water at distances of many kilometers. However, other studies have shown that marine mammals at distances more than a few kilometers away often show no apparent response to industrial activities of various types (Miller *et al.*, 2005). This is often true even in cases when the sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. Although various baleen whales, toothed whales, and (less frequently) pinnipeds have been shown to react behaviorally to underwater sound from sources such as airgun pulses or vessels under some conditions, at other times, mammals of all three types have shown no overt reactions (e.g., Malme *et al.*, 1986; Richardson *et al.*, 1995; Madsen and Mohl, 2000; Croll *et al.*, 2001; Jacobs and Terhune, 2002; Madsen *et al.*, 2002; Miller *et al.*, 2005). In general, pinnipeds seem to be more tolerant of exposure to some types of underwater sound than are baleen whales. Richardson *et al.* (1995) found that vessel sound does not seem to strongly affect pinnipeds that are already in the water. Richardson *et al.* (1995) went on to explain that seals on haul-outs sometimes respond strongly to the presence of vessels and at other times appear to show considerable tolerance of vessels, and Brueggeman *et al.* (1992) observed ringed seals (*Pusa hispida*) hauled out on ice pans displaying short-term escape reactions when a ship approached within 0.16–0.31 mi (0.25–0.5 km).

Masking

Masking is the obscuring of sounds of interest to an animal by other sounds, typically at similar frequencies. Marine mammals are highly dependent on sound, and their ability to recognize sound signals amid other sound is important in communication and detection of both predators and prey. Background ambient sound may interfere with or mask the ability of an animal to detect a sound signal even when that signal is above its absolute hearing threshold. Even in the absence of anthropogenic sound, the marine environment is often loud. Natural ambient sound includes contributions from wind, waves, precipitation, other animals, and (at frequencies above 30 kHz) thermal sound resulting from molecular agitation (Richardson *et al.*, 1995).

Background sound may also include anthropogenic sound, and masking of natural sounds can result when human activities produce high levels of background sound. Conversely, if the background level of underwater sound is high (e.g., on a day with strong wind and high waves), an anthropogenic sound source would not be detectable as far away as would be possible under quieter conditions and would itself be masked. Ambient sound is highly variable on continental shelves (Thompson, 1965; Myrberg, 1978; Chapman *et al.*, 1998; Desharnais *et al.*, 1999). This results in a high degree of variability in the range at which marine mammals can detect anthropogenic sounds.

Although masking is a phenomenon which may occur naturally, the introduction of loud anthropogenic sounds into the marine environment at frequencies important to marine mammals increases the severity and frequency of occurrence of masking. For example, if a baleen whale is exposed to continuous low-frequency sound from an industrial source, this would reduce the size of the area around that whale within which it can hear the calls of another whale. The components of background noise that are similar in frequency to the signal in question primarily determine the degree of masking of that signal. In general, little is known about the degree to which marine mammals rely upon detection of sounds from conspecifics, predators, prey, or other natural sources. In the absence of specific information about the importance of detecting these natural sounds, it is not possible to predict the impact of masking on marine mammals (Richardson *et al.*, 1995). In general, masking effects are expected to be less severe when sounds are transient than when they are continuous. Masking is typically of greater concern for those marine mammals that utilize low-frequency communications, such as baleen whales and, as such, is not likely to occur for pinnipeds or small odontocetes in the Project area.

Disturbance

Behavioral disturbance is one of the primary potential impacts of anthropogenic sound on marine mammals. Disturbance can result in a variety of effects, such as subtle or dramatic changes in behavior or displacement, but the degree to which disturbance causes such effects may be highly dependent upon the context in which the stimulus occurs. For example, an animal that is feeding may be less prone to disturbance from a given stimulus than one that is not. For

many species and situations, there is no detailed information about reactions to sound.

Behavioral reactions of marine mammals to sound are difficult to predict because they are dependent on numerous factors, including species, maturity, experience, activity, reproductive state, time of day, and weather. If a marine mammal does react to an underwater sound by changing its behavior or moving a small distance, the impacts of that change may not be important to the individual, the stock, or the species as a whole. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on the animals could be important. In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Pinniped responses to underwater sound from some types of industrial activities such as seismic exploration appear to be temporary and localized (Harris *et al.*, 2001; Reiser *et al.*, 2009).

Because the few available studies show wide variation in response to underwater and airborne sound, it is difficult to quantify exactly how pile driving sound would affect marine mammals in the area. The literature shows that elevated underwater sound levels could prompt a range of effects, including no obvious visible response, or behavioral responses that may include annoyance and increased alertness, visual orientation towards the sound, investigation of the sound, change in movement pattern or direction, habituation, alteration of feeding and social interaction, or temporary or permanent avoidance of the area affected by sound. Minor behavioral responses do not necessarily cause long-term effects to the individuals involved. Severe responses include panic, immediate movement away from the sound, and stampeding, which could potentially lead to injury or mortality (Southall *et al.*, 2007).

Southall *et al.* (2007) reviewed literature describing responses of pinnipeds to non-pulsed sound in water and reported that the limited data suggest exposures between approximately 90 and 140 dB generally do not appear to induce strong behavioral responses in pinnipeds, while higher levels of pulsed sound, ranging between 150 and 180 dB, will prompt avoidance of an area. It is important to note that among these studies, there are some apparent differences in responses between field and laboratory conditions. In contrast to the mid-frequency odontocetes, captive pinnipeds responded more strongly at lower levels than did animals in the field. Again, contextual issues are the likely cause of this difference. For airborne sound, Southall *et al.* (2007) note there are extremely limited data suggesting very minor, if any, observable behavioral responses by pinnipeds exposed to airborne pulses of 60 to 80 dB; however, given the paucity of data on the subject, we cannot rule out the possibility that avoidance of sound in the Project area could occur.

In their comprehensive review of available literature, Southall *et al.* (2007) noted that quantitative studies on behavioral reactions of pinnipeds to underwater sound are rare. A subset of only three studies observed the response of pinnipeds to multiple pulses of underwater sound (a category of sound types that includes impact pile driving), and were also deemed by the authors as having results that are both measurable and representative. Blackwell *et al.* (2004) is the only cited study directly related to pile driving. The study observed ringed seals during impact installation of steel pipe pile. Received underwater SPLs were measured at 151 dB at 63 m. The seals exhibited either no response or only brief orientation response (defined as "investigation or visual orientation"). It should be noted that the observations were made after pile driving was already in progress. Therefore, it is possible that the low-level response was due to prior habituation. During a Caltrans installation demonstration project for retrofit work on the East Span of the San Francisco Oakland Bay Bridge, California, sea lions responded to pile driving by swimming rapidly out of the area, regardless of the size of the pile-driving hammer or the presence of sound attenuation devices (74 FR 63724).

Several available studies provide information on the reactions of pinnipeds to non-pulsed underwater sound. Kastelein *et al.* (2006) exposed nine captive harbor seals in an approximately 82 × 98 ft (25 × 30 m) enclosure to non-pulse sounds used in underwater data communication systems (similar to acoustic modems). Test signals were frequency modulated tones, sweeps, and bands of sound with fundamental frequencies between 8 and 16 kHz; 128 to 130 ±3 dB source levels; 1- to 2-s duration (60–80 percent duty cycle); or 100 percent duty cycle. They recorded seal positions and the mean number of individual surfacing behaviors during control periods (no exposure), before exposure, and in 15-min experimental sessions (n = 7 exposures for each sound type). Seals generally swam away from each source at received levels of approximately 107 dB, avoiding it by approximately 16 ft (5 m), although they did not haul out of the water or change surfacing behavior. Seal reactions did not appear to wane over repeated exposure (i.e., there was no obvious habituation), and the colony of seals generally returned to baseline conditions following exposure. The seals were not reinforced with food for remaining in the sound field.

Reactions of harbor seals to the simulated sound of a 2-megawatt wind power generator were measured by Koschinski *et al.* (2003). Harbor seals surfaced significantly further away from the sound source when it was active and did not approach the sound source as closely. The device used in that study produced sounds in the frequency range of 30 to 800 Hz, with peak source levels of 128 dB at 1 m at the 80- and 160-Hz frequencies.

Ship and boat sound do not seem to have strong effects on seals in the water, but the data are limited. When in the water, seals appear to be much less apprehensive about approaching vessels. Some would approach a vessel out of apparent curiosity, including noisy vessels such as those operating seismic airgun arrays (Moulton and Lawson, 2002). Gray seals (*Halichoerus grypus*) have been known to approach and follow fishing vessels in an effort to steal catch or the bait from traps. In contrast, seals hauled out on land often are quite responsive to nearby vessels. Terhune (1985) reported that northwest Atlantic harbor seals were extremely vigilant when hauled out and were wary of approaching (but less so passing) boats. Suryan and Harvey (1999) reported that Pacific harbor seals commonly left the shore when powerboat operators approached to observe the seals. Those seals detected a powerboat at a mean distance of 866 ft (264 m), and seals left the haul-out site when boats approached to within 472 ft (144 m).

The studies that address responses of high-frequency cetaceans (such as the harbor porpoise) to non-pulse sounds include data gathered both in the field and the laboratory and related to several different sound sources (of varying similarity to chirps), including: pingers, AHDs, and various laboratory non-pulse sounds. All of these data were collected from harbor porpoises. Southall *et al.* (2007) concluded that the existing data indicate that harbor porpoises are likely sensitive to a wide range of anthropogenic sounds at low received

levels (around 90 to 120 dB), at least for initial exposures. All recorded exposures above 140 dB induced profound and sustained avoidance behavior in wild harbor porpoises (Southall *et al.*, 2007). Rapid habituation was noted in some but not all studies.

Southall *et al.* (2007) also compiled known studies of behavioral responses of marine mammals to airborne sound, noting that studies of pinniped response to airborne pulsed sounds are exceedingly rare. The authors deemed only one study as having quantifiable results. Blackwell *et al.* (2004) studied the response of ringed seals within 500 m of impact driving of steel pipe pile. Received levels of airborne sound were measured at 93 dB at a distance of 63 m. Seals had either no response or limited response to pile driving. Reactions were described as "indifferent" or "curious."

Marine mammals are expected to traverse through and not remain in the Project area. Therefore, animals are not expected to be exposed to a significant duration of construction sound.

Vessel Operations—Fifteen vessels would be used in association with the Project, including a dive support vessel, various barges, a crew boat, an escort boat, and six tug boats. Only the crew boat and the escort boat would make daily trips between shore and the offshore construction site and most vessels would remain stationary during construction activities. During pipe lay activities, the pipe transport barge would also be transported between the pipe yard and the offshore construction site about once or twice a day. Transco would abide by current vessel activity and speed restrictions in place to protect the north Atlantic right whale. Similar and much larger vessels already use the surrounding area in moderately high numbers; therefore, the vessels to be used in the Project area do not represent a new sound source, only a potential increase in the frequency and duration of these sound source types.

There are very few controlled tests or repeatable observations related to the reactions of marine mammals to vessel noise. However, Richardson *et al.* (1995) reviewed the literature on reactions of marine mammals to vessels, concluding overall that pinnipeds and many odontocetes showed high tolerance to vessel noise. Mysticetes, too, often show tolerance of slow, quieter vessels. Because the Project area is highly industrialized, it seems likely that marine mammals that transit the Project area are already habituated to vessel noise, thus the additional vessels that would occur as a result of construction activities would likely not have an additional effect on these animals. Proposed vessel noise and operations in the Project area are unlikely to rise to the level of harassment.

Physical Disturbance—Vessels and in-water structures have the potential to cause physical disturbance to marine mammals. As previously mentioned, various types of vessels already use the Project area in high numbers. Tug boats and barges are slow moving and follow a predictable course. Marine mammals would be able to easily avoid these vessels while transiting through the Project area and are likely already habituated to the presence of numerous vessels. Therefore, vessel strikes are extremely unlikely and, thus, discountable. Potential encounters would likely be limited to brief, sporadic behavioral disturbance, if any at all. Such disturbances are not likely to result in a risk of Level B harassment of marine mammals transiting the Project area.

Hearing Impairment and Other Physiological Effects

Temporary or permanent hearing impairment is a possibility when marine mammals are exposed to very strong sounds. Non-auditory physiological effects might also occur in marine mammals exposed to strong underwater sound. Possible types of non-auditory physiological effects or injuries that may occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, and other types of organ or tissue damage. It is possible that some marine mammal species (i.e., beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds, particularly at higher frequencies. Non-auditory physiological effects are not anticipated to occur as a result of proposed construction activities. The following subsections discuss the possibilities of temporary threshold shift (TTS) and permanent threshold shift (PTS).

TTS—TTS, reversible hearing loss caused by fatigue of hair cells and supporting structures in the inner ear, is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. TTS can last from minutes or hours to (in cases of strong TTS) days. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the sound ends.

Marine mammal hearing plays a critical role in communication with conspecifics and in interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (i.e., recovery time), and frequency range of TTS and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during a time when communication is critical for successful mother/calf interactions could have more serious impacts if it were in the same frequency band as the necessary vocalizations and of a severity that it impeded communication. The fact that animals exposed to levels and durations of sound that would be expected to result in this physiological response would also be expected to have behavioral responses of a comparatively more severe or sustained nature is also notable and potentially of more importance than the simple existence of a TTS. NMFS considers TTS to be a form of Level B harassment, as it consists of fatigue to auditory structures rather than damage to them. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound.

Human non-impulsive sound exposure guidelines are based on exposures of equal energy (the same sound exposure level [SEL]; SEL is reported here in dB re: 1 μPa^2-s/re: 20 μPa^2-s for in-water and in-air sound, respectively) producing equal amounts of hearing impairment regardless of how the sound energy is distributed in time (NIOSH, 1998). Until recently, previous marine mammal TTS studies have also generally supported this equal energy relationship (Southall *et al.*, 2007). Three newer studies, two by Mooney *et al.* (2009a, b) on a single bottlenose dolphin (*Tursiops truncatus*) either exposed to playbacks of U.S. Navy mid-frequency active sonar or octave-band sound (4–8 kHz) and one by Kastak *et al.* (2007) on a single California sea lion exposed to airborne octave-band sound (centered at 2.5 kHz), concluded that for all sound exposure situations, the equal

energy relationship may not be the best indicator to predict TTS onset levels. Generally, with sound exposures of equal energy, those that were quieter (lower SPL) with longer duration were found to induce TTS onset more than those of louder (higher SPL) and shorter duration. Given the available data, the received level of a single seismic pulse (with no frequency weighting) might need to be approximately 186 dB SEL in order to produce brief, mild TTS.

In free-ranging pinnipeds, TTS thresholds associated with exposure to brief pulses (single or multiple) of underwater sound have not been measured. However, systematic TTS studies on captive pinnipeds have been conducted (e.g., Bowles *et al.*, 1999; Kastak *et al.*, 1999, 2005, 2007; Schusterman *et al.*, 2000; Finneran *et al.*, 2003; Southall *et al.*, 2007). Finneran *et al.* (2003) studied responses of two individual California sea lions. The sea lions were exposed to single pulses of underwater sound, and experienced no detectable TTS at received sound level of 183 dB peak (163 dB SEL). There were three studies conducted on pinniped TTS responses to non-pulsed underwater sound. All of these studies were performed in the same lab and on the same test subjects, and, therefore, the results may not be applicable to all pinnipeds or in field settings. Kastak and Schusterman (1996) studied the response of harbor seals to non-pulsed construction sound, reporting TTS of about 8 dB. The seal was exposed to broadband construction sound for 6 days, averaging 6 to 7 hours of intermittent exposure per day, with SPLs from just approximately 90 to 105 dB.

Kastak *et al.* (1999) reported TTS of approximately 4–5 dB in three species of pinnipeds (harbor seal, California sea lion, and northern elephant seal) after underwater exposure for approximately 20 minutes to sound with frequencies ranging from 100–2,000 Hz at received levels 60–75 dB above hearing threshold. This approach allowed similar effective exposure conditions to each of the subjects, but resulted in variable absolute exposure values depending on subject and test frequency. Recovery to near baseline levels was reported within 24 hours of sound exposure. Kastak *et al.* (2005) followed up on their previous work, exposing the same test subjects to higher levels of sound for longer durations. The animals were exposed to octave-band sound for up to 50 minutes of net exposure. The study reported that the harbor seal experienced TTS of 6 dB after a 25-minute exposure to 2.5 kHz of octave-band sound at 152 dB (183 dB SEL). The California sea lion demonstrated onset of TTS after exposure to 174 dB and 206 dB SEL.

Southall *et al.* (2007) reported one study on TTS in pinnipeds resulting from airborne pulsed sound, while two studies examined TTS in pinnipeds resulting from airborne non-pulsed sound. Bowles *et al.* (unpubl. data) exposed pinnipeds to simulated sonic booms. Harbor seals demonstrated TTS at 143 dB peak and 129 dB SEL. California sea lions and northern elephant seals experienced TTS at higher exposure levels than the harbor seals. Kastak *et al.* (2004) used the same test subjects as in Kastak *et al.* 2005, exposing the animals to non-pulsed sound (2.5 kHz octave-band sound) for 25 minutes. The harbor seal demonstrated 6 dB of TTS after exposure to 99 dB (131 dB SEL). The California sea lion demonstrated onset of TTS at 122 dB and 154 dB SEL. Kastak *et al.* (2007) studied the same California sea lion as in Kastak *et al.* 2004 above, exposing this individual to 192 exposures of 2.5 kHz octave-band sound at levels ranging from 94 to 133 dB for 1.5 to 50 min of net exposure duration. The test subject experienced up to 30 dB of TTS. TTS onset occurred at 159 dB SEL. Recovery times ranged from several minutes to 3 days.

Additional studies highlight the inherent complexity of predicting TTS onset in marine mammals, as well as the importance of considering exposure duration when assessing potential impacts (Mooney *et al.*, 2009a, 2009b; Kastak *et al.*, 2007). Generally, with sound exposures of equal energy, quieter sounds (lower SPL) of longer duration were found to induce TTS onset more than louder sounds (higher SPL) of shorter duration (more similar to subbottom profilers). For intermittent sounds, less threshold shift will occur than from a continuous exposure with the same energy (some recovery will occur between intermittent exposures) (Kryter *et al.*, 1966; Ward, 1997). For sound exposures at or somewhat above the TTS-onset threshold, hearing sensitivity recovers rapidly after exposure to the sound ends. Southall *et al.* (2007) considers a 6 dB TTS (that is, baseline thresholds are elevated by 6 dB) to be a sufficient definition of TTS-onset. NMFS considers TTS as Level B harassment that is mediated by physiological effects on the auditory system; however, NMFS does not consider TTS-onset to be the lowest level at which Level B harassment may occur. Southall *et al.* (2007) summarizes underwater pinniped data from Kastak *et al.* (2005), indicating that a tested harbor seal showed a TTS of around 6 dB when exposed to a nonpulse noise at sound pressure level 152 dB re: 1 µPa for 25 minutes. Some studies suggest that harbor porpoises may be more sensitive to sound than other odontocetes (Lucke *et al.*, 2009; Kastelein *et al.*, 2011). While TTS onset may occur in harbor porpoises at lower received levels (when compared to other odontocetes), NMFS' 160-dB and 120-dB threshold criteria are based on the onset of behavioral harassment, not the onset of TTS. The potential for TTS is considered within NMFS' analysis of potential impacts from Level B harassment.

Although underwater sound levels produced by the proposed project may exceed levels produced in studies that have induced TTS in marine mammals, there is a general lack of controlled, quantifiable field studies related to this phenomenon, and existing studies have had varied results (Southall *et al.*, 2007). Therefore, it is difficult to extrapolate from these data to site-specific conditions for the proposed project. For example, because most of the studies have been conducted in laboratories, rather than in field settings, the data are not conclusive as to whether elevated levels of sound would cause marine mammals to avoid the Region of Activity, thereby reducing the likelihood of TTS, or whether sound would attract marine mammals, increasing the likelihood of TTS. In any case, there are no universally accepted standards for the amount of exposure time likely to induce TTS. While it may be inferred that TTS could theoretically result from the proposed project, it is impossible to quantify the magnitude of exposure, the duration of the effect, or the number of individuals likely to be affected. Exposure is likely to be brief because marine mammals use the Region of Activity for transiting, rather than breeding or hauling out. In summary, it is expected that elevated sound would have only a slight probability of causing TTS in marine mammals.

PTS—When PTS occurs, there is physical damage to the sound receptors in the ear. In some cases, there can be total or partial deafness, whereas in other cases, the animal has an impaired ability to hear sounds in specific frequency ranges. There is no specific evidence that exposure to underwater industrial sounds can cause PTS in any marine mammal (see Southall *et al.*, 2007). However, given the possibility that marine mammals might incur TTS, there has been further speculation about the possibility that some individuals occurring very close to industrial activities might incur PTS. Richardson

et al. (1995) hypothesized that PTS caused by prolonged exposure to continuous anthropogenic sound is unlikely to occur in marine mammals, at least for sounds with source levels up to approximately 200 dB. Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage in terrestrial mammals. Studies of relationships between TTS and PTS thresholds in marine mammals are limited; however, existing data appear to show similarity to those found for humans and other terrestrial mammals, for which there is a large body of data. PTS might occur at a received sound level at least several decibels above that inducing mild TTS.

Southall *et al.* (2007) propose that sound levels inducing 40 dB of TTS may result in onset of PTS in marine mammals. The authors present this threshold with precaution, as there are no specific studies to support it. Because direct studies on marine mammals are lacking, the authors base these recommendations on studies performed on other mammals. Additionally, the authors assume that multiple pulses of underwater sound result in the onset of PTS in pinnipeds when levels reach 218 dB peak or 186 dB SEL. In air, sound levels are assumed to cause PTS in pinnipeds at 149 dB peak or 144 dB SEL (Southall *et al.*, 2007). Sound levels this high are not expected to occur as a result of the proposed Project.

The potential effects to marine mammals described in this section of the document do not take into consideration the proposed monitoring and mitigation measures described later in this document (see the Proposed Mitigation and Proposed Monitoring and Reporting sections). It is highly unlikely that marine mammals would receive sounds strong enough (and over a sufficient duration) to cause PTS (or even TTS) during the proposed activities. When taking the mitigation measures proposed for inclusion in the regulations into consideration, it is highly unlikely that any type of hearing impairment would occur as a result of Transco's proposed activities.

Anticipated Effects on Marine Mammal Habitat

Pile driving activities may have temporary impacts on marine mammal habitat by producing temporary in-water acoustic disturbances. However, elevated in-water sound levels would only occur for less than 2 days of pile driving activity, spread out over an 8-week period. While it is anticipated that the specified activity may result in marine mammals avoiding certain areas due to temporary ensonification, this impact to habitat is temporary and reversible and was considered in further detail earlier in this document as behavioral modification. Furthermore, it is possible that marine mammals within the vicinity of the Project area may not be able to perceive noise from the vibratory pile driver due to the potentially louder background noise, which is likely to be dominated by loud low-frequency commercial vessel noise. There are no known pinniped haul-outs within the vicinity of the Project area and the closest known haul-out is about 10 miles away. There is also no designated critical habitat with the proposed Project area. Increased turbidity and changes in prey distribution may also result from pile driving activities, but are expected to be temporary and return to normal shortly after construction is complete. The proposed Project is not anticipated to have any permanent impact on habitats used by the marine mammals in the proposed Project area, including the food sources they use (i.e., fish and invertebrates).

Anticipated Effects on Fish

Fish are a primary dietary component of the marine mammals mentioned previously in this document. Similar to marine mammals, fish can also be affected by noise both physiologically and behaviorally. However, the amount of information regarding impacts on fish from human-generated acoustic sources is limited.

Behavioral disturbance of fish prey species could occur as a result of vibratory pile driving. Fish may avoid the Project area due to disturbing levels of sound during vibratory hammer operation; however, behavioral changes are expected to be temporary. Injury of fish prey species is not expected to occur during the proposed Project because Project-related noise would not exceed NMFS' threshold criteria for fish injury.

Proposed Mitigation

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, we must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and the availability of such species or stock for taking for certain subsistence uses.

To reduce the potential for disturbance from acoustic stimuli associated with the activities, Transco has proposed to implement the following mitigation measures for marine mammals:

(1) Vibratory pile driving only;

(2) Pile driving during daylight hours only;

(3) Shutdown procedures;

(4) Soft-start (ramp-up) procedures; and

(5) Discharge control.

Separately, Transco acknowledges the vessel activity and speed restrictions that are already in place along the east coast for the north Atlantic right whale. While the Seasonal Management Area is in effect (November-April), vessel operators would comply with the established regulations.

Vibratory Pile Driving Only

Transco proposes to use a vibratory hammer instead of an impact hammer for all pile driving activities in order to reduce in-water sound levels while installing and removing up to 70 temporary steel pipe piles. The sound source level for the vibratory hammer is less than the source level for an impact hammer, and by avoiding use of an impact hammer Transco removes the potential for Level A harassment of marine mammals.

Pile Driving During Daylight Hours Only

Pile driving installation and removal would only be conducted when lighting and weather conditions allow the protected species observers to visually monitor the entire Level B harassment area through the use of binoculars or other devices.

Soft-Start (Ramp-Up) Procedures

Transco would implement soft-start procedures at the beginning of each pile driving session. Contractors would initiate the vibratory hammer for 15 seconds at 40 to 60 percent reduced energy, followed by a 1-minute waiting period. This procedure would be repeated two additional times before reach full energy.

Shutdown Procedures

Protected species observers would monitor the entire Level B harassment area for marine mammals displaying abnormal behavior. Such behavior may include aggressive signals related to noise exposure (e.g., tail/flipper slapping or abrupt directed movement), avoidance of the sound source, or an obvious startle response (e.g., rapid change in swimming speed, erratic surface movements, or sudden diving associated with the onset of a sound source). At NMFS' recommendation, if a protected species observer sees any abnormal behavior, this information

will be related to the construction manager and the vibratory hammer would be shutdown until the animal has moved outside of the Level B harassment area.

Control of Discharge

All in-water construction activities would comply with federal regulations to control the discharge of operational waste such as bilge and ballast waters, trash and debris, and sanitary and domestic waste that could be generated from all vessels associated with the Project. All Project vessels would also comply with the U.S. Coast Guard requirements for the prevention and control of oil and fuel spills (see Transco's application for more detail).

NMFS has carefully evaluated the applicant's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an incidental take authorization for an activity, section 101(a)(5)(D) of the MMPA states that we must set forth "requirements pertaining to the monitoring and reporting of such taking." The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for an authorization must include the suggested means of accomplishing the necessary monitoring and reporting that would result in increased knowledge of the species and our expectations of the level of taking or impacts on populations of marine mammals present in the proposed action area.

Visual Monitoring

Two NMFS-approved protected species observers would survey the Level B harassment area (~3 miles) for marine mammals 30 minutes before, during, and 30 minutes after all vibratory pile driving activities. The observers would be stationed on an escort boat, located about 1.5 miles from the pile hammer. The escort boat would circle the pile hammer at a 1.5-mile distance so that the entire Level B harassment area could be surveyed. Information recorded during each observation within the Level B harassment area would be used to estimate numbers of animals potentially taken and would include the following:

- Numbers of individuals observed;
- Frequency of observation;
- Location within the Level B harassment area (i.e., distance from the sound source);
- Vibratory pile driving status (i.e., soft-start, active, post pile driving, etc.); and
- Reaction of the animal(s) to pile driving (if any) and observed behavior within the Level B harassment area, including bearing and direction of travel.

If the Level B harassment area is obscured by fog or poor lighting conditions, vibratory pile driving would be delayed until the area is visible. If the Level B harassment area becomes obscured by fog or poor lighting conditions while pile driving activities are occurring, pile driving would be shutdown until the area is visible again.

Proposed Reporting

Transco would provide NMFS with a draft monitoring report within 90 days of the conclusion of monitoring. This report would include the following:

- A summary of the activity and monitoring plan (i.e., dates, times, locations);
- A summary of mitigation implementation;
- Monitoring results and a summary that addresses the goals of the monitoring plan, including the following:
  - Environmental conditions when observations were made;
    - Water conditions (i.e., Beaufort sea-state, tidal state)
    - Weather conditions (i.e., percent cloud cover, visibility, percent glare)
  - Survey-specific data:
    - Date and time survey initiated and terminated;
  - Date, time, number, species, and any other relevant data regarding marine mammals observed (for pre-activity, during activity, and post-activity surveys);
  - Description of the observed behaviors (in both the presence and absence of activities):
    - If possible, the correlation to underwater sound level occurring at the time of any observable behavior
    - Estimated exposure/take numbers during activities
- An assessment of the implementation and effectiveness of prescribed mitigation and monitoring measures.

Transco would submit a final report within 30 days after receiving NMFS comments on the draft report. If NMFS has no comments, the draft report would be considered final.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner not permitted by the authorization (if issued), such as an injury, serious injury, or mortality (e.g., ship-strike, gear interaction, and/or entanglement), Transco shall immediately cease the specified activities and immediately report the incident to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Michelle.Magliocca@noaa.gov*. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Transco shall not resume its activities until we are able to review the circumstances of the prohibited take. We will work with Transco to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Transco may not resume their activities until notified by us via letter, email, or telephone.

In the event that Transco discovers an injured or dead marine mammal, and

the lead visual observer determines that the cause of the injury or death is unknown and the death is relatively recent (i.e., in less than a moderate state of decomposition as we describe in the next paragraph), Transco shall immediately report the incident to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Michelle.Magliocca@noaa.gov*. The report must include the same information identified in the paragraph above this section. Activities may continue while we review the circumstances of the incident. We would work with Transco to determine whether modifications in the activities are appropriate.

In the event that Transco discovers an injured or dead marine mammal, and the lead visual observer determines that the injury or death is not associated with or related to the authorized activities (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Transco would report the incident to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Michelle.Magliocca@noaa.gov*, within 24 hours of the discovery. Transco would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to us.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

We propose to authorize take by Level B harassment for the proposed Project. Acoustic stimuli (i.e., increased underwater sound) generated during vibratory pile driving and removal activities have the potential to result in the behavioral disturbance of marine mammals. There is no evidence that planned activities could result in serious injury or mortality within the specified geographic area for the requested authorization. The required mitigation and monitoring measures would minimize any potential risk for serious injury or mortality and reduce the amount of Level B harassment takes.

Transco estimated potential take by multiplying the area of the zone of influence (the Level B harassment area) by the local animal density. This provides an estimate of the number of animals that might occupy the Level B harassment area at any given moment during vibratory pile driving activities. However, density estimates for marine mammals within the coastal mid-Atlantic are limited, and there are no density estimates for the specific Project area along the southern coast of Long Island. Therefore, estimated takes were calculated based on the best available information for the region, including density estimates developed by the U.S. Navy through their Navy Operating Area Density Estimate (NODE) for the Northeast operating areas (Boston, Narragansett Bay, and Atlantic City) (DON, 2007). These estimates cover all continental shelf waters from the southern point of New Jersey to Nova Scotia, Canada, from the coast out past the continental shelf. The Navy's report presents density estimates either determined by models created with species-specific data or derived from abundance estimates found in NMFS' 2007 Stock Assessment Reports. Of the Navy's density surface models, two were for species which have the potential to be harassed during this Project: The short-beaked common dolphin and the harbor porpoise. Other density estimates were determined based on shipboard and aerial surveys conducted by the Northeast Fisheries Science Center during summer months between 1998 and 2004. Density for all species was calculated based on seasons and spatial strata. Details on these calculations and how they were applied to each species are provided in section 6.3 of Transco's IHA application (*http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications*).

Transco's requested take amounts may over-estimate the actual number of animals that would be harassed for the following reasons:

- Vibratory pile driving would only occur for 4 days over a 5-month period and the estimated exposures likely do not equate to takes of individual animals;
- The density seasons used in the Navy's NODE report include additional months outside of the proposed Project's schedule for in-water construction (which may have higher density estimates); and
- The density estimates assume even distribution throughout strata and are largely derived from adjacent stratum that may not represent density accurately in the Project area.

Table 2 shows Transco's requested take based on estimated density and the methods described earlier and in section 6.3 of Transco's IHA application.

TABLE 2—ESTIMATED DENSITIES AND REQUESTED MARINE MAMMAL TAKE FOR THE PROJECT

Species	Estimated density (per 100 km^2) Winter[1]	Estimated density (per 100 km^2) Spring[1]	Estimated density (per 100 km^2) Summer[1]	Estimated take by Level B harassment Winter	Estimated take by Level B harassment Spring	Estimated take by Level B harassment Summer	Total takes by Level B harassment requested
Gray seal	N/A	N/A	N/A	7	7	0	14
Harbor seal	156.41	156.41	156.41	69	69	69	138
Harp seal	N/A	N/A	N/A	0	4	0	4
North Atlantic right whale	0.03	0.03	0.03	0.02	0.02	0.02	1
Bottlenose dolphin	0.21	8.14	26.91	0	4	12	16
Short-beaked common dolphin	145.35	1.91	3.59	64	1	2	67
Harbor porpoise	6.40	19.90	0.00	3	9	0	12

[1] Source: Navy OPAREA Density Estimates (NODE) for the Northeast OPAREAS: Boston, Narragansett Bay, and Atlantic City (2007).
N/A = Not available.

Negligible Impact and Small Numbers Analyses and Determinations

As a preliminary matter, we typically include our negligible impact and small numbers analyses and determinations under the same section heading of our **Federal Register** notices. Despite co-locating these terms, we acknowledge that negligible impact and small numbers are distinct standards under the MMPA and treat them as such. The analyses presented below do not conflate the two standards; instead, each standard has been considered independently and we have applied the relevant factors to inform our negligible impact and small numbers determinations.

We have defined "negligible impact" in 50 CFR 216.103 as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival." In making a negligible impact determination, we consider the following:

(1) Number of anticipated mortalities (none in this case);

(2) Number and nature of anticipated injuries (none in this case);

(3) Number, nature, intensity, and duration of Level B harassment (all relatively limited); and

(3) The context in which the takes occur (i.e., impacts to areas of significance, impacts to local populations, and cumulative impacts when taking into account successive/contemporaneous actions when added to baseline data);

(4) The status of stock or species of marine mammals (i.e., depleted, not depleted, decreasing, increasing, stable, impact relative to the size of the population);

(5) Impacts on habitat affecting rates of recruitment/survival; and

(6) The effectiveness of monitoring and mitigation measures.

We do not anticipate that any injuries, serious injuries, or mortalities would occur as a result of Transco's proposed Project, and we do not propose to authorize injury, serious injury, or mortality for this Project.

Table 2 in this document outlines the number of requested Level B harassment takes that we anticipate as a result of these activities. Table 3 below shows the proposed take numbers compared to species population sizes. For each species, these take numbers are small (all estimates are less than one percent) relative to the affected stock size and we have provided the regional population estimates for the marine mammal species that may be taken by Level B harassment in Table 3 below.

TABLE 3—PROPOSED MARINE MAMMAL TAKES AND PERCENTAGE OF STOCK POTENTIALLY AFFECTED

Species	Takes by Level B harassment	Abundance of stock	Percentage of stock potentially affected (percent)
Gray seal	14	348,900	0.004
Harbor seal	207	99,340	0.208
Harp seal	4	8,300,000 (minimum)	0.00
North Atlantic right whale	1	444	0.225
Bottlenose dolphin	16	7,147	0.224
Short-beaked common dolphin	67	52,893	0.001
Harbor porpoise	12	89,054	0.013

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (i.e., 24 hour cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.*, 2007). While vibratory pile driving would occur over 2 consecutive days, this is still considered a short overall duration and it would only occur during daylight hours.

Of the seven marine mammal species under our jurisdiction that are known to occur or likely to occur in the Project area, one of these species is listed as endangered under the ESA: North Atlantic right whale. This species is also categorized as depleted under the MMPA. However, Transco is only requesting one take of a north Atlantic right whale by Level B harassment, which is less than one percent of the population. There are no known important feeding areas for north Atlantic right whales and no designated critical habitat within the proposed project area.

Our practice has been to apply the 120 dB re: 1 μPa received level threshold for underwater non-impulse sound levels to estimate take by Level B harassment. Southall *et al.* (2007) provides a severity scale for ranking observed behavioral responses of both free-ranging marine mammals and laboratory subjects to various types of anthropogenic sound (see Table 4 in Southall *et al.* [2007]).

We have preliminarily determined, provided that the aforementioned mitigation and monitoring measures are implemented, that the impact of conducting pile driving activities off Rockaway Peninsula, from January 2014 through December 2014, may result, at worst, in a modification in behavior and/or low-level physiological effects (Level B harassment) of certain species of marine mammals. There are no known important feeding areas or haul-outs within the project area. While these species may make behavioral modifications, including temporarily vacating the area during the operation of the pile hammer to avoid the resultant acoustic disturbance, the availability of similar habitat surrounding the project area and the short and sporadic duration of the specified activities, have led us to preliminary determine that this action will not adversely affect annual rates of recruitment or survival and therefore, would have a negligible impact on the species in the specified geographic region.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, we preliminarily find that Transco's proposed Project would result in the incidental take of small numbers of marine mammals, by Level B harassment only, and that the required measures mitigate impacts to affected species or stocks of marine mammals to the lowest level practicable.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Section 101(a)(5)(D) of the Marine Mammal Protection Act also requires us to determine that the authorization would not have an unmitigable adverse effect on the availability of marine mammal species or stocks for subsistence use. There are no relevant subsistence uses of marine mammals in the Project area that implicate section 101(a)(5)(D) of the Marine Mammal Protection Act.

Endangered Species Act

Of the species of marine mammals that may occur in the proposed survey area, one is listed as endangered under the Endangered Species Act: The north Atlantic right whale. Under section 7 of the Act, the Federal Energy Regulatory Commission (FERC; the federal agency responsible for permitting Transco's construction) has initiated formal consultation with our Northeast Regional Office on this proposed seismic survey. We (i.e., National Marine Fisheries Service, Office of Protected Resources, Permits and Conservation Division), have also initiated formal consultation under section 7 of the Act with the Northeast Regional Office to obtain a Biological Opinion (Opinion) evaluating the effects of issuing an incidental harassment authorization for threatened and endangered marine mammals and, if appropriate, authorizing incidental take. Both agencies would conclude the formal section 7 consultation (with a single Opinion for FERC and NMFS' Office of Protected Resources, Permits and Conservation Division federal actions) prior to making a determination on whether or not to issue the authorization. If we issue the take authorization, FERC and Transco must comply with the mandatory Terms and Conditions of the Opinion's Incidental Take Statement which would incorporate the mitigation and monitoring requirements included in the Incidental Harassment Authorization.

National Environmental Policy Act (NEPA)

We are participating as a cooperating agency on the FERC's Rockaway Delivery Lateral Project Environmental Impact Statement (EIS). FERC published a Notice of Intent in the **Federal Register** on May 6, 2013 (78 FR 26354). The draft EIS was made available to the public on October 11, 2013 (78 FR 62012). We intend to adopt FERC's final EIS, if adequate and appropriate. Currently, we believe that the adoption of FERC's final EIS will allow us to meet our responsibilities under NEPA for the issuance of an Incidental Harassment Authorization to Transco. If FERC's final EIS is deemed inadequate, we would supplement the existing analysis to ensure that we comply with NEPA prior to the issuance of an authorization.

Proposed Authorization

As a result of these preliminary determinations, we propose to authorize the take of marine mammals incidental to Transco's proposed Project from January 2014 through August 2014, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The proposed Incidental Harassment Authorization language is provided below.

Transcontinental Gas Pipe Line Company, LLC (Transco) (2800 Post Oak Boulevard, Houston, TX 77056) is hereby authorized under section 101(a)(5)(D) of the Marine Mammal Protection Act (16 U.S.C. 1371(a)(5)(D)) and 50 CFR 216.107, to harass marine mammals incidental to pile driving and removal during the Rockaway Delivery Lateral Project, subject to the following:

1. This Authorization is valid from January 2014 through December 2014.

2. This Authorization is valid for the Rockaway Delivery Lateral Project off the Rockaway Peninsula, as described in the Incidental Harassment Authorization (IHA) application.

3. Transco is hereby authorized to take, by Level B harassment only, 14 gray seals (*Halichoerus grypus*), 138 harbor seals (*Phoca vitulina*), 4 harp seals (*Phoca groenlandica*), 1 north Atlantic right whale (*Eubalaena glacialis*), 16 bottlenose dolphins (*Tursiops truncatus*), 65 short-beaked common dolphins (*Delphinus delphis*), and 12 harbor porpoises (*Phocoena phocoena*) incidental to pile driving associated with the Rockaway Delivery Lateral Project.

4. The taking of any marine mammal in a manner prohibited under this Authorization must be reported immediately to NMFS' Northeast Region, 55 Great Republic Drive, Gloucester, MA 01930–2276; phone 978–281–9328, and NMFS' Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910; phone 301–427–8401; fax 301–713–0376.

5. The holder or designees must notify NMFS' Region and Headquarters at least 24 hours prior to the seasonal commencement of the specified activity (see contact information in 4 above).

6. Mitigation Requirements

The holder of this Authorization is required to abide by the following mitigation conditions listed in 6(a)-(e). Failure to comply with these conditions may result in the modification, suspension, or revocation of this Authorization.

(a) *Vibratory Pile Driving:* A vibratory hammer shall be used for all pile installation and removal in order to reduce in-water sound levels.

(b) *Day-light Hours Only:* All pile installation and removal shall be conducted when lighting and weather conditions allow for adequate visual monitoring of the entire Level B harassment area through the use of binoculars or other devices.

(c) *Soft-start Procedures:* Soft-start procedures shall be implemented at the beginning of each pile driving session. Contractors shall initiate the vibratory hammer for 15 seconds at 40 to 60 percent reduced energy, followed by a 1-minute waiting period. This procedure shall be repeated two additional times before full energy is reached.

(d) *Shutdown Procedures:* If a protected species observer sees any abnormal marine mammal behavior (e.g., tail/flipper slapping, abrupt directed movement, avoidance of the sound source, rapid change in swimming speed, erratic surface movements, or sudden diving at the onset of the sound source), pile driving activities shall be shutdown until the animal has moved outside of the Level B harassment area.

(e) *Control of Discharge:* All in-water construction activities shall comply with federal regulations to control the discharge of operational waste such as bilge and ballast waters, trash and debris, and sanitary and domestic waste that could be generated from all vessels associated with the Project. All Project vessels shall also comply with the U.S. Coast Guard requirements for the prevention and control of oil and fuel spills.

7. Monitoring Requirements

The holder of this Authorization is required to abide by the following monitoring conditions listed in 7(a)-(b). Failure to comply with these conditions may result in the modification, suspension, or revocation of this Authorization.

(a) *General:* If the Level B harassment area is obscured by fog or poor lighting conditions, vibratory pile driving shall be delayed until the area is visible. If the Level B harassment area becomes obscured by fog or poor lighting conditions while pile driving activities are occurring, pile driving shall be shutdown until the area is visible again.

(b) *Visual Monitoring:* Two NMFS-approved protected species observers shall survey the Level B harassment area (~3 miles) for marine mammals 30 minutes before, during, and 30 minutes after all vibratory pile driving activities. The observers shall be stationed on an escort boat, located about 1.5 miles from the pile hammer. Information recorded during each observation within the Level B harassment area shall be used to estimate numbers of animals potentially taken and shall include the following:

- Numbers of individuals observed;
- Frequency of observation;
- Location within the Level B harassment area (i.e., distance from the sound source);
- Vibratory pile driving status (i.e., soft-start, active, post pile driving, etc.); and
- Reaction of the animal(s) to pile driving (if any) and observed behavior within the Level B harassment area, including bearing and direction of travel.

8. Reporting Requirements

The holder of this Authorization is required to submit a draft monitoring report to the Office of Protected Resources, NMFS, within 90 days of the conclusion of monitoring.

(a) The monitoring report shall contain the following information:

- A summary of the activity and monitoring plan (i.e., dates, times, locations);
- A summary of mitigation implementation;
- Monitoring results and a summary that addresses the goals of the monitoring plan, including the following:
  - Environmental conditions when observations were made:
  - Water conditions (i.e., Beaufort sea-state, tidal state)
  - Weather conditions (i.e., percent cloud cover, visibility, percent glare)
  - Survey-specific data:
  - Date and time survey initiated and terminated
  - Date, time, number, species, and any other relevant data regarding marine mammals observed (for pre-activity, during activity, and post-activity surveys)
  - Description of the observed behaviors (in both the presence and absence of activities):
    - If possible, the correlation to underwater sound level occurring at the time of any observable behavior
- Estimated exposure/take numbers during activities; and
- An assessment of the implementation and effectiveness of prescribed mitigation and monitoring measures.

(b) In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner not permitted by the authorization (if issued), such as an injury, serious injury, or mortality (e.g., ship-strike, gear interaction, and/or entanglement), Transco shall immediately cease the specified activities and immediately report the incident to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Michelle.Magliocca@noaa.gov*. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Transco shall not resume its activities until we are able to review the circumstances of the prohibited take. NMFS will work with Transco to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Transco may not resume their activities until notified by us via letter, email, or telephone.

(c) In the event that Transco discovers an injured or dead marine mammal, and the lead visual observer determines that the cause of the injury or death is unknown and the death is relatively recent (i.e., in less than a moderate state of decomposition as we describe in the next paragraph), Transco shall immediately report the incident to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Michelle.Magliocca@noaa.gov*. The report must include the same information identified in the paragraph above this section. Activities may continue while we review the circumstances of the incident. NMFS will work with Transco to determine whether modifications in the activities are appropriate.

(d) In the event that Transco discovers an injured or dead marine mammal, and the lead visual observer determines that the injury or death is not associated with or related to the authorized activities (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Transco would report the incident to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Michelle.Magliocca@noaa.gov*, within 24 hours of the discovery. Transco would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to us.

9. A copy of this Authorization must be in the possession of the lead contractor on site and protected species observers operating under the authority of this Authorization.

10. This Authorization may be modified, suspended, or withdrawn if the Holder fails to abide by the conditions prescribed herein or if the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Information Solicited

We request interested persons to submit comments and information concerning this proposed project and our preliminary determination of issuing a take authorization (see **ADDRESSES**). Concurrent with the publication of this notice in the **Federal Register**, we will forward copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: December 23, 2013.

Perry Gayaldo,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–31065 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2013–0062]

Grant of Interim Extension of the Term of U.S. Patent No. 5,496,801; Recombinant Human Parathyroid Hormone

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,496,801.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755; or by email to *Mary.Till@uspto.gov*.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On December 6, 2013, NPS Pharmaceuticals, Inc., timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,496,801. The patent claims the human biological product recombinant human parathyroid hormone. The application indicates that Biologics License Application 125511 for the drug product, recombinant human parathyroid hormone, was filed on October 24, 2013, and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period has continued beyond the original expiration date of the patent, December 23, 2013, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 5,496,801 is granted for a period of one year from the original expiration date of the patent.

Dated: December 20, 2013.

Andrew Hirshfeld,

Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

[FR Doc. 2013–31017 Filed 12–26–13; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO–C–2013–0060]

National Medal of Technology and Innovation Call for 2014 Nominations

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice and request for nominations.

SUMMARY: The Department of Commerce (United States Patent and Trademark Office) is accepting nominations for the National Medal of Technology and Innovation (NMTI). Since establishment by Congress in the Stevenson-Wydler Technology Innovation Act of 1980, the President of the United States has awarded the annual National Medal of Technology and Innovation (initially known as the National Medal of Technology) to our nation's leading innovators. If you know of a candidate who has made an outstanding contribution to the nation's economic, environmental or social well-being through the promotion of technology, technological innovation, or the development of technological manpower, you may obtain a nomination form from: *http://www.uspto.gov/about/nmti/index.jsp*.

ADDRESSES: The NMTI nomination form for the year 2014 may be obtained by visiting the USPTO Web site at *http://www.uspto.gov/about/nmti/index.jsp*. Nomination applications should be submitted to John Palafoutas, Program Manager, National Medal of Technology and Innovation Program, by electronic mail to *NMTI@uspto.gov* or by mail to: John Palafoutas, NMTI Program Manager, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313–1450.

DATES: The deadline for submission of a nomination is 5 p.m. ET, April 1, 2014.

FOR FURTHER INFORMATION CONTACT: John Palafoutas, Program Manager, National Medal of Technology and Innovation Program, United States Patent and Trademark Office, 600 Dulany Street, Alexandria, VA 22314; telephone (571) 272–9821 or by electronic mail: *nmti@uspto.gov*.

SUPPLEMENTARY INFORMATION:

Background

As provided by Congress in the Stevenson-Wydler Technology Innovation Act of 1980, the National Medal of Technology was first awarded in 1985. On August 9, 2007, the President signed the America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Act of 2007. The Act amended Section 16 of the Stevenson-Wydler Technology Innovation Act of 1980, changing the name of the Medal to the "National Medal of Technology and Innovation." The NMTI is the highest honor awarded by the President of the United States to America's leading innovators in the field of technology and is given annually to individuals, teams, or companies/non-profits who have made outstanding contributions to the promotion of technology or technological innovation, or to the development of technological manpower, for the improvement of the economic, environmental or social well-being of the United States. The primary purpose of the NMTI is to recognize American innovators whose vision, creativity, and brilliance in moving ideas to market or in developing of the nation's technological manpower has had a profound and significant impact on our economy and way of life. The NMTI highlights the national importance of fostering technological innovation based upon solid science, resulting in commercially successful products and services.

Eligibility and Nomination Criteria

Nomination Guidelines containing information on eligibility and nomination criteria are at *http://www.uspto.gov/about/nmti/guidelines.jsp*.

Dated: December 16, 2013.

Margaret A. Focarino,

Commissioner for Patents, Performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2013–31019 Filed 12–26–13; 8:45 am]

BILLING CODE P

COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for Canada: Certain Entity-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Comparability Determination for Certain Requirements under the Laws of Canada.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a joint request by the Canadian Bankers Association ("CBA"), five individual Canadian banks provisionally-registered with the Commodity Futures Trading Commission ("Commission") as swap dealers ("SDs"), and the Office of the Superintendent of Financial Institutions ("OSFI") that the Commission determine that certain laws and regulations applicable in Canada provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to SDs and major swap participants ("MSPs") registered with the Commission: (i) Chief compliance officer; (ii) risk management; and (iii) swap data recordkeeping (collectively, the "Internal Business Conduct Requirements").

DATES: *Effective Date:* This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202–418–5977, *gbarnett@cftc.gov*, Frank Fisanich, Chief Counsel, 202–418–5949, *ffisanich@cftc.gov*, and Andy Chapin, Associate Director, 202–418–5465, *achapin@cftc.gov*, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" (the "Guidance").[1] In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the "Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Entity-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3]

On May 13. 2013, the CBA, five individual Canadian banks provisionally registered with the Commission as SDs, and OSFI (collectively hereinafter, the "applicant") submitted a request that the Commission determine that laws and regulations applicable in Canada provide a sufficient basis for an affirmative finding of comparability with respect to certain Entity-Level Requirements, including the Internal Business Conduct Requirements.[4] The applicants provided Commission staff with a supplemental submission from the Ontario Securities Commission ("OSC") dated June 7, 2013. The following is the Commission's analysis and determination regarding the Internal Business Conduct Requirements, as detailed below.[5]

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act[6] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[7] In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations, 78 FR 909 (Jan. 7, 2013).

[2] 78 FR 43785 (July 22, 2013).

[3] The Entity-Level Requirements under the Exemptive Order consist of 17 CFR 1.31, 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, 23.606, 23.608, 23.609, and parts 45 and 46 of the Commission's regulations.

[4] For purposes of this notice, the Internal Business Conduct Requirements consist of 17 CFR 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606.

[5] This notice does not address swap data repository reporting ("SDR Reporting"). The Commission may provide a comparability determination with respect to the SDR Reporting requirement in a separate notice.

[6] Public Law 111–203, 124 Stat. 1376 (2010).

[7] 7 U.S.C. 2(i).

Commission.[8] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[9]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime, subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[10]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[11] The Commission's direct access to the books and records required to be maintained by an SD or MSP registered with the Commission is a core requirement of the CEA [12] and the Commission's regulations,[13] and is a condition to registration.[14]

III. Regulation of SDs and MSPs in Canada

On May 13, 2013, the applicant submitted a request that the Commission assess the comparability of Canadian laws and regulations with the requirements of the CEA and the Commission's regulations promulgated thereunder. OSC provided a supplement to the submission on June 7, 2013. On November 8, 2013, OSFI further supplemented the application with corrections and additional materials.

All of the currently registered Canadian SDs are banks regulated under the Canadian Bank Act (the "Bank Act"),[15] relevant regulations thereunder, and guidelines, advisories, and interpretations provided by OSFI. As the governing prudential regulator in Canada, OSFI supervises all Canadian banks on a consolidated basis, including those provisionally registered with the Commission as SDs (the "Canadian Bank SDs"). To implement its "Supervisory Framework," OSFI has published guidelines, advisories, and interpretations which OSFI expects each bank to follow. Each of the five Canadian Bank SDs also has been designated as Domestic Systemically Important Banks ("DSIBs") due to the potential impact that failure could have on the domestic economy based on their size, interconnectedness, substitutability, and complexity. As DSIBs, these banks are expected to have advanced practices in terms of the design and operation of oversight functions and controls, and are subject to continued supervisory intensity, enhanced disclosure requirements, and a capital surcharge.[16]

Canada's provincial securities administrators, coordinated by the Derivatives Committee of the Canadian Securities Administrators ("CSA"), are responsible for regulating the capital markets. Harmonized policy recommendations are made at the CSA level, while regulations are made at the provincial level. Currently, the CSA has issued a Consultation Paper 91–407 on "Derivatives Registration" (comment period closed June 17, 2013).

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the

[8] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site. (*http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm.*)

[9] 78 FR 45342–45.

[10] *See* the Guidance, 78 FR 45342–44.

[11] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as an SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. See id. at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

[12] *See* e.g., sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[13] *See* e.g., §§ 23.203(b) and 23.606.

[14] *See* supra note 10.

[15] Consolidated Acts of Canada, S.C. 1991, c. 46.

[16] Because the applicant's request and the Commissions determinations herein are based on the comparability of Canadian requirements applicable to banks, an SD or MSP that is not a bank, or is otherwise not subject to the requirements applicable to banks upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein.

basis of the foreign regime as a whole.[17] In making its comparability determinations, the Commission may include conditions that take into account timing and other issues related to coordinating the implementation of reform efforts across jurisdictions.[18]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s),
- The scope and objectives of the relevant regulatory requirement(s),
- The comprehensiveness of the foreign regulator's supervisory compliance program, and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[19]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.*, the home jurisdiction's requirements do not have to be identical).[20] This approach recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis the Commission may determine that no comparability determination can be made[21] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is an SD or MSP with respect to its foreign branches, or non-registrant, to the extent applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[22] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swaps market activities may not be clearly defined, or may not expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[23]

Finally, the Commission will generally rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities[24] of SDs and MSPs[25] in the relevant jurisdictions.[26] Further, as stated in the Guidance, the Commission expects that an applicant would notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[27]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted

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[17] 78 FR 45343.

[18] 78 FR 45343.

[19] 78 FR 45343. The Commission's substituted compliance program would generally be available for SDR Reporting, as outlined in the Guidance, only if the Commission has direct access to all of the data elements that are reported to a foreign trade repository pursuant to the substituted compliance program. Thus, direct access to swap data is a threshold matter to be addressed in a comparability evaluation for SDR Reporting. Moreover, the Commission explains in the Guidance that, due to its technical nature, a comparability evaluation for SDR Reporting "will generally entail a detailed comparison and technical analysis." A more particularized analysis will generally be necessary to determine whether data stored in a foreign trade repository provides for effective Commission use, in furtherance of the regulatory purposes of the Dodd-Frank Act. *See* 78 FR 45345.

[20] 78 FR 45343.

[21] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

[22] 78 FR 45343.

[23] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that [SDs] and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[24] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under Part 23 (17 CFR Part 23) are limited in scope to the swaps activities of SDs and MSPs.

[25] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is responsible for determining whether it is subject to the laws and regulations found comparable. Currently there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outside the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[26] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. The Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurate description of foreign laws and regulations may not be valid.

[27] 78 FR 45345.

compliance [28] for the Internal Business Conduct Requirements.[29]

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement [30] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for information sharing and cooperation in the context of supervising [SDs] and MSPs." [31]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[32] provide for notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[33] and include protections related to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Internal Business Conduct Requirements that are the subject of this comparability determination, and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Internal Business Conduct Requirements that the applicant submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable and comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this notice.

As was stated in the Guidance, the Commission recognizes the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Chief Compliance Officer (§ 3.3).

Commission Requirement: Implementing section 4s(k) of the CEA, Commission regulation 3.3 generally sets forth the following requirements for SDs and MSPs:

- An SD or MSP must designate an individual as Chief Compliance Officer ("CCO");
- The CCO must have the responsibility and authority to develop the regulatory compliance policies and procedures of the SD or MSP;
- The CCO must report to the board of directors or the senior officer of the SD or MSP;
- Only the board of directors or a senior officer may remove the CCO;
- The CCO and the board of directors must meet at least once per year;
- The CCO must have the background and skills appropriate for the responsibilities of the position;
- The CCO must not be subject to disqualification from registration under sections 8a(2) or (3) of the CEA;
- Each SD and MSP must include a designation of a CCO in its registration application;

[28] *See* 78 FR 45348–50. The Commission notes that registrants and other market participants are responsible for determining whether substituted compliance is available pursuant to the Guidance based on the comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[29] This notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in Canada to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in Canada.

This notice also does not address capital adequacy because the Commission has not yet finalized rules for SDs and MSPs in this area, nor SDR Reporting. The Commission may provide a comparability determination with respect to these requirements at a later date or in a separate notice.

[30] An MOU is one type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or, for example, as independent bilateral arrangements, statements of intent, declarations, or letters.

[31] 78 FR 45344.

[32] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. 6s(f); 17 CFR 23.203. In the Guidance, the Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; *see also id.* at 45342 n. 461 (affirming the Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto").

[33] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP. *See* 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

- The CCO must administer the regulatory compliance policies of the SD or MSP;
- The CCO must take reasonable steps to ensure compliance with the CEA and Commission regulations, and resolve conflicts of interest;
- The CCO must establish procedures for detecting and remediating non-compliance issues;
- The CCO must annually prepare and sign an "annual compliance report" containing: (i) A description of policies and procedures reasonably designed to ensure compliance; (ii) an assessment of the effectiveness of such policies and procedures; (iii) a description of material non-compliance issues and the action taken; (iv) recommendations of improvements in compliance policies; and (v) a certification by the CCO or CEO that, to the best of such officer's knowledge and belief, the annual report is accurate and complete under penalty of law; and
- The annual compliance report must be furnished to the CFTC within 90 days after the end of the fiscal year of the SD or MSP, simultaneously with its annual financial condition report.

Regulatory Objective: The Commission believes that compliance by SDs and MSPs with the CEA and the Commission's rules greatly contributes to the protection of customers, orderly and fair markets, and the stability and integrity of the market intermediaries registered with the Commission. The Commission expects SDs and MSPs to strictly comply with the CEA and the Commission's rules and to devote sufficient resources to ensuring such compliance. Thus, through its CCO rule, the Commission seeks to ensure firms have designated a qualified individual as CCO that reports directly to the board of directors or the senior officer of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually to the Commission and the board or senior officer on compliance of the firm.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as section 4s(k) of the CEA and Commission regulation 3.3.

OSFI's Legislative Compliance Management Guideline E–13 ("LCM Guideline") requires Canadian banks to establish an enterprise-wide framework of regulatory risk management controls to ensure that regulatory compliance risks are managed effectively. The required LCM framework must meet the requirements of the LCM Guideline, which sets out OSFI's expectations. The Canadian Bank SDs are required to demonstrate that they satisfy those expectations in particular circumstances. Pursuant to the LCM Guideline:

- The compliance oversight function should be designated to a member of senior management as the bank's CCO;
- Such CCO should have sufficient stature, authority, resources, and access to achieve compliance with applicable law;
- Such CCO should have appropriate skills and knowledge to effectively fulfill the requirements of the function;
- The CCO should approve the content and frequency of reports and that such reports should be sufficient to enable the CCO, senior management, and the bank's board to discharge their compliance responsibilities;
- OSFI expects that each bank's LCM framework will include identification, assessment, communication, and maintenance of applicable regulatory requirements, compliance procedures, monitoring procedures, and reporting procedures;
- OSFI expects the CCO to be responsible for the LCM framework and to report issues directly to the board, including any material compliance issues and their remediation; and
- Normal course reports to the board should be made no less than annually, and contain discussion of material weaknesses, non-compliance issues, and remedial action plans.

In addition, the OSFI Corporate Governance Guideline of Federally Regulated Financial Institutions ("OSFI Corporate Governance Guideline") states that the bank's board of directors should be responsible for the selection, performance, management, compensation, and evaluation of a CCO. Pursuant to the OSFI Supervisory Framework, OSFI monitors banks' management of compliance risk and reports on banks' compliance with the Bank Act annually to the Canadian Minister of Finance.

Commission Determination: The Commission finds that the OSFI standards specified above are generally identical in intent to § 3.3 by seeking to ensure firms have designated a qualified individual as the compliance officer that reports directly to a sufficiently senior function of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually on compliance of the firm.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the CCO requirements of the OSFI standards, specified above, are comparable to and as comprehensive as § 3.3, with the exception of § 3.3(f) concerning certifying and furnishing an annual compliance report to the Commission.[34]

Notwithstanding that the Commission has not determined that the requirements of the OSFI standards are comparable to and as comprehensive as § 3.3(f), any SD or MSP to which both § 3.3 and the OSFI standards specified above are applicable would generally be deemed to be in compliance with § 3.3(f) if that SD or MSP complies with the OSFI standards specified above, subject to certifying and furnishing the Commission with the annual report required under the OSFI standards specified above in accordance with § 3.3(f). The Commission notes that it generally expects registrants to submit required reports to the Commission in the English language.

B. Risk Management Duties (§§ 23.600—23.609)

Section 4s(j) of the CEA requires each SD and MSP to establish internal policies and procedures designed to, among other things, address risk management, monitor compliance with position limits, prevent conflicts of interest, and promote diligent supervision, as well as maintain business continuity and disaster recovery programs.[35] The Commission adopted regulations 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606 to implement the statute.[36] The

[34] Because the Commission has not determined that the requirements of the OSFI standards are comparable to and as comprehensive as § 3.3(f), any SD or MSP to which both § 3.3 and the OSFI standards specified above are applicable would generally be deemed to be in compliance with § 3.3 if that SD or MSP complies with the OSFI standards specified above, subject to certifying and furnishing the Commission with the annual report required under the OSFI standards specified above in accordance with § 3.3(f). The Commission notes that it generally expects registrants to submit required reports to the Commission in the English language.

[35] 7 U.S.C. 6s(j).

[36] *See* Final Swap Dealer and MSP Recordkeeping Rule, 77 FR 20128 (April 3, 2012) (relating to risk management program, monitoring of position

Continued

Commission also adopted regulation 23.609, which requires certain risk management procedures for SDs or MSPs that are clearing members of a derivatives clearing organization ("DCO").[37] Collectively, these requirements help to establish a robust and comprehensive internal risk management program for SDs and MSPs with respect to their swaps activities.[38] which is critical to effective systemic risk management for the overall swaps market. In making its comparability determination with regard to these risk management duties, the Commission will consider each regulation individually.[39]

1. Risk Management Program for SDs and MSPs (§ 23.600)

Commission Requirement: Implementing section 4s(j)(2) of the CEA, Commission regulation 23.600 generally requires that:

- Each SD or MSP must establish and enforce a risk management program consisting of a system of written risk management policies and procedures designed to monitor and manage the risks associated with the swap activities of the firm, including without limitation, market, credit, liquidity, foreign currency, legal, operational, and settlement risks, and furnish a copy of such policies and procedures to the CFTC upon application for registration and upon request;
- The SD or MSP must establish a risk management unit independent from the business trading unit;
- The risk management policies and procedures of the SD or MSP must be approved by the firm's governing body;
- Risk tolerance limits and exceptions therefrom must be reviewed and approved quarterly by senior management and annually by the governing body;
- The risk management program must have a system for detecting breaches of risk tolerance limits and alerting supervisors and senior management, as appropriate;
- The risk management program must account for risks posed by affiliates and be integrated at the consolidated entity level;
- The risk management unit must provide senior management and the governing body with quarterly risk exposure reports and upon detection of any material change in the risk exposure of the SD or MSP;
- Risk exposure reports must be furnished to the CFTC within five business days following provision to senior management;
- The risk management program must have a new product policy for assessing the risks of new products prior to engaging in such transactions;
- The risk management program must have policies and procedures providing for trading limits, monitoring of trading, processing of trades, and separation of personnel in the trading unit from personnel in the risk management unit; and
- The risk management program must be reviewed and tested at least annually and upon any material change in the business of the SD or MSP.

Regulatory Objective: Through the required system of risk management, the Commission seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. To this end, the Commission believes the risk management program of an SD or MSP must contain at least the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and are comparable to and as comprehensive as section 4s(j)(2) of the CEA and Commission regulation § 23.600.

The OSFI Corporate Governance Guideline requires that each bank establish a risk appetite framework ("RAF") that:

- Guides the amount of risk the bank is willing to accept in pursuit of its strategic and business objectives.
- Sets basic goals, benchmarks, parameters, and limits, and should consider all applicable types of risks.
- Contains all elements required by an annex to the Corporate Governance Guideline, including a risk appetite statement, specific risk tolerance limits, and processes for implementation of the RAF.

Further, the OSFI Corporate Governance Guideline states that DSIBs should establish a dedicated risk committee to oversee risk management on an enterprise-wide basis, and that the oversight of the risk management activities of the bank are to be independent from operational management, adequately resourced, and have appropriate status and visibility.

The OSFI Derivatives Best Practice Guideline states that each bank should ensure that each derivative product traded is subject to a product authorization signed off by senior management, and sets forth OSFI's expectations with respect to having documented policies and procedures for risk management, creating risk tolerance limits, and measuring, reporting, managing, and controlling the risks associated with the derivatives business, including market, currency, interest rate, equity price, commodity price, credit, settlement, liquidity, operational, and legal risks.

Finally, OSFI represents that its oversight pursuant to the Supervisory Framework will assess the extent to which the risk management function integrates policies, practices, and limits with day-to-day business activities and with the bank's strategic, capital, and liquidity management policies. Under the Supervisory Framework, OSFI also will assess whether the risk management function effectively monitors risk positions against approved limits and ensures that material breaches are addressed on a timely basis. OSFI represents that it will look at various indicators, including the extent to which the bank proactively updates its policies, practices, and

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limits, business continuity and disaster recovery, conflicts of interest policies and procedures, and general information availability, respectively).

[37] *See* Customer Documentation Rule, 77 FR 21278. Also, SDs must comply with Commission regulation 23.608, which prohibits SDs providing clearing services to customers from entering into agreements that would: (i) Disclose the identity of a customer's original executing counterparty; (ii) limit the number of counterparties a customer may trade with; (iii) impose counterparty-based position limits; (iv) impair a customer's access to execution of a trade on terms that have a reasonable relationship to the best terms available; or (v) prevent compliance with specified time frames for acceptance of trades into clearing.

[38] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under Part 23 (17 CFR Part 23) are limited in scope to the swaps activities of SDs and MSPs.

[39] As stated above, this notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in Canada to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in Canada.

limits in response to changes in the industry and in the institution's strategy, business activities and risk tolerances.[40]

Commission Determination: The Commission finds that the OSFI standards specified above are generally identical in intent to § 23.600 by requiring a system of risk management that seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. Specifically, the Commission finds that the OSFI standards specified above would comprehensively require SDs and MSPs to establish risk management programs containing the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the risk management program requirements of the OSFI standards, as specified above, are comparable to and as comprehensive as § 23.600, with the exception of § 23.600(c)(2) concerning the requirement that each SD and MSP produce a quarterly risk exposure report and provide such report to its senior management, governing body, and the Commission.

Notwithstanding that the Commission has not determined that the requirements of the OSFI standards are comparable to and as comprehensive as § 23.600(c)(2), any SD or MSP to which both § 23.600 and the OSFI standards specified above are applicable would generally be deemed to be in compliance with § 23.600(c)(2) if that SD or MSP complies with the OSFI standards specified above, subject to compliance with the requirement that it produce quarterly risk exposure reports and provide such reports to its senior management, governing body, and the Commission in accordance with § 23.600(c)(2). The Commission notes that it generally expects reports furnished to the Commission by registrants to be in the English language.

2. Monitoring of Position Limits (§ 23.601)

Commission Requirement: Implementing section 4s(j)(1) of the CEA, Commission regulation 23.601 requires each SD or MSP to establish and enforce written policies and procedures that are reasonably designed to monitor for, and prevent violations of, applicable position limits established by the Commission, a DCM, or a SEF.[41] The policies and procedures must include an early warning system and provide for escalation of violations to senior management (including the firm's governing body).

Regulatory Objective: Generally, position limits are implemented to ensure market integrity, fairness, orderliness, and accurate pricing in the commodity markets. Commission regulation 23.601 thus seeks to ensure that SDs and MSPs have established the necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by the Commission, a DCM, or a SEF. As part of its Risk Management Program, § 23.601 is intended to ensure that established position limits are not breached by the SD or MSP.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as section 4s(j)(1) of the CEA and Commission regulation § 23.601.

OSFI states that the monitoring of position limits is an aspect of the risk management and compliance framework for each bank. Specifically:

- OSFI's LCM Guideline requires Canadian banks to establish an enterprise-wide framework of regulatory risk management controls to ensure that regulatory compliance risks are managed effectively. The required LCM framework sets out OSFI's expectations and banks are required to demonstrate that they satisfy those expectations in particular circumstances; and
- OSFI expects that each bank's LCM framework will include identification, assessment, communication, and maintenance of applicable regulatory requirements, compliance procedures, monitoring procedures, and reporting procedures.[42]
- The applicants represent to the Commission that the OSFI requirement to monitor the effectiveness of procedures to ensure compliance with regulatory obligations includes applicable regulatory obligations of an SD or MSP under the CEA, Commission regulations, and position limits set by the Commission, a DCM, or a SEF. OSFI expects banks to comply with all applicable regulatory requirements, which includes legislation, regulations, and regulatory directives applicable to the activities of the bank or its subsidiaries worldwide.

Commission Determination: The Commission finds that the OSFI standards specified above are generally identical in intent to § 23.601 by requiring SDs and MSPs to establish necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by applicable laws and regulations, including those of the Commission, a DCM, or a SEF. Specifically, the Commission finds that the OSFI standards specified above, while not specific to the issue of position limit compliance, nevertheless comprehensively require SDs and MSPs to monitor for regulatory compliance generally, including monitoring for compliance with position limits set pursuant to applicable law (including the CEA and Commission regulations) and the responsibility of senior management (including the board of directors) for such compliance.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the compliance monitoring requirements of the OSFI standards, as specified above, are comparable to and as comprehensive as § 23.601. For the avoidance of doubt, the Commission notes that this determination may not be relied on to relieve an SD or MSP from its obligation to strictly comply with any applicable

[40] In addition to the foregoing, the applicant notes that the Canadian Bank SDs may be subject to heightened standards for their derivatives business in the near future under regulatory recommendations that would require registrants to establish, maintain and apply systems, policies and procedures that establish robust compliance and risk management systems specifically for their derivatives business. *See* CSA Consultation Paper 91–407.

[41] The setting of position limits by the Commission, a DCM, or a SEF is subject to requirements under the CEA and Commission regulations other than § 23.601. The setting of position limits and compliance with such limits is not subject to the Commission's substituted compliance regime.

[42] In addition to the foregoing, the applicant also submitted various guidelines and required best practices concerning the setting of internal risk tolerance limits and monitoring for compliance with such internal limits. Although the Commission recognizes these as prudent risk management practices, the Commission does not believe that these provisions are relevant for a comparability determination with respect to § 23.601 because § 23.601 requires monitoring for compliance with external position limits set by the Commission, a DCM, or a SEF.

position limit established by the Commission, a DCM, or a SEF.

3. Diligent Supervision (§ 23.602)

Commission Requirement: Commission regulation 23.602 implements section 4s(h)(1)(B) of the CEA and requires each SD and MSP to establish a system to diligently supervise all activities relating to its business performed by its partners, members, officers, employees, and agents. The system must be reasonably designed to achieve compliance with the CEA and CFTC regulations. Commission regulation 23.602 requires that the supervisory system must specifically designate qualified persons with authority to carry out the supervisory responsibilities of the SD or MSP for all activities relating to its business as an SD or MSP.

Regulatory Objective: The Commission's diligent supervision rule seeks to ensure that SDs and MSPs strictly comply with the CEA and the Commission's rules. To this end, through § 23.602, the Commission seeks to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as section 4s(h)(1)(B) of the CEA and Commission regulation 23.602.

- Section 157 of the Bank Act imposes a duty on the board of directors of a bank to manage or supervise the management of the business and affairs of the bank.
- OSFI's Supervisory Framework states that the board and senior management are designated as ultimately accountable for the safety and soundness of the bank.
- OSFI's Corporate Governance Guideline states that banks should appoint a senior officer, identified as the Chief Risk Officer ("CRO"), who has responsibility for the oversight of all relevant risks across the firm. The CRO must be identified in the bank's license application along with a description of the resources and authority allocated to discharge his duties. Like the CCO, the CRO should have sufficient stature and authority within the organization, be independent from operational management, have unfettered access and, for functional purposes, a direct reporting line to the board of directors or risk committee.

In addition, the applicant states that diligent supervision is an aspect of the risk management and compliance framework for each bank, which includes requirements for controls and monitoring. Specifically:

- OSFI's LCM Guideline requires Canadian banks to establish an enterprise-wide framework of regulatory risk management controls to ensure that regulatory compliance risks are managed effectively. The required LCM framework sets out OSFI's expectations and banks are required to demonstrate that they satisfy those expectations in particular circumstances; and
- OSFI expects that each bank's LCM framework will include identification, assessment, communication, and maintenance of applicable regulatory requirements, compliance procedures, monitoring procedures, and reporting procedures.
- The applicants represent to the Commission that the OSFI requirement to monitor the effectiveness of procedures to ensure compliance with regulatory obligations includes applicable regulatory obligations of an SD or MSP under the CEA and Commission regulations. OSFI expects banks to comply with all applicable regulatory requirements, which includes legislation, regulations, and regulatory directives applicable to the activities of the bank or its subsidiaries worldwide.

Commission Determination: The Commission finds that the provisions of the Bank Act and the OSFI standards specified above are generally identical in intent to § 23.602 because such standards seek to ensure that SDs and MSPs strictly comply with applicable law, which would include the CEA and the Commission's regulations. Through the provisions of the Bank Act and the OSFI standards specified above, Canadian laws and regulations seek to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with applicable law, which would include the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the internal supervision requirements of the Bank Act and the OSFI standards, as specified above, are comparable to and as comprehensive as § 23.602.

4. Business Continuity and Disaster Recovery (§ 23.603)

Commission Requirement: To ensure the proper functioning of the swaps markets and the prevention of systemic risk more generally, Commission regulation 23.603 requires each SD and MSP, as part of its risk management program, to establish a business continuity and disaster recovery plan that includes procedures for, and the maintenance of, back-up facilities, systems, infrastructure, personnel, and other resources to achieve the timely recovery of data and documentation and to resume operations generally within the next business day after the disruption.

Regulatory Objective: Commission regulation 23.603 is intended to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, this requirement seeks to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan within one business day, if necessary.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as Commission regulation 23.603.

The applicant has represented that business continuity and disaster recovery are aspects of the risk management framework for each bank. Specifically:

- OSFI's Derivatives Best Practice Guideline requires banks to regularly assess contingency plans to deal with operations and systems risks.
- OSFI's Outsourcing of Business Activities, Functions and Processes Guideline requires banks that outsource functions to ensure that adequate continuity and disaster recovery are in place.
- OSFI's Supervisory Framework subjects each bank to a "Business Continuity & Disaster Recovery Preparedness Cross Sector Review" that is divided into three broad sections: Structure, Operational Management, and Controls & Oversight. Pursuant to such review, OSFI ensures: the existence of a plan for both business continuity and disaster recovery; that such plans have essential components related to identification of documents, data, staff, supervisory personnel, back-up locations, third party disruptions,

etc.; that plans are distributed to all employees; that appropriate emergency contacts are identified; that plans are reviewed at least annually; that plans are subject to comprehensive testing and audit; and that records related to developing and maintaining the plans are maintained in accordance with banking supervisory guidelines and are accessible to OSFI.

Commission Determination: The Commission finds that the OSFI standards specified above are generally identical in intent to § 23.603 because such standards seek to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, the Commission finds that the OSFI standards specified above seek to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan in a timely manner.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the business continuity and disaster recovery requirements of the OSFI standards, as specified above, are comparable to and as comprehensive as § 23.603.

5. Conflicts of Interest (§ 23.605)

Commission Requirement: Section 4s(j)(5) of the CEA and Commission regulation 23.605(c) generally require each SD or MSP to establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any commodity or swap are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision.

In addition, section 4s(j)(5) of the CEA and Commission regulation 23.605(d)(1) generally prohibits an SD or MSP from directly or indirectly interfering with or attempting to influence the decision of any clearing unit of any affiliated clearing member of a DCO to provide clearing services and activities to a particular customer, including:

- Whether to offer clearing services to a particular customer;
- Whether to accept a particular customer for clearing derivatives;
- Whether to submit a customer's transaction to a particular DCO;
- Whether to set or adjust risk tolerance levels for a particular customer; or
- Whether to set a customer's fees based on criteria other than those generally available and applicable to other customers.

Commission regulation 23.605(d)(2) generally requires each SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of any affiliated clearing member of a DCO to reasonably ensure compliance with the Act and the prohibitions set forth in § 23.605(d)(1) outlined above.

The Commission observes that § 23.605(d) works in tandem with Commission regulation 1.71, which requires FCMs that are clearing members of a DCO and affiliated with an SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of the FCM to reasonably ensure compliance with the Act and the prohibitions set forth in § 1.71(d)(1), which are the same as the prohibitions set forth in § 23.605(d)(1) outlined above.

Finally, § 23.605(e) requires that each SD or MSP have policies and procedures that mandate the disclosure to counterparties of material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a swap execution facility or DCM or to clear a derivative through a DCO.

Regulatory Objective: Commission regulation 23.605(c) seeks to ensure that research provided to the general public by an SD or MSP is unbiased and free from the influence of the interests of an SD or MSP arising from the SD's or MSP's trading business.

In addition, the § 23.605(d) (working in tandem with § 1.71) seeks to ensure open access to the clearing of swaps by requiring that access to and the provision of clearing services provided by an affiliate of an SD or MSP are not influenced by the interests of an SD's or MSP's trading business.

Finally, § 23.605(e) seeks to ensure equal access to trading venues and clearinghouses, as well as orderly and fair markets, by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as Commission regulation 23.605(c).

The Bank Act subsection 157(2)(c), as well as the Competition Act, requires that directors of a bank establish procedures to resolve conflicts of interest, including techniques for the identification and remediation of potential conflict situations, tied selling, exclusive dealing, and refusal to deal, and for restricting the use of confidential information.

The Bank Act subsection 157(2)(b) requires the directors of a bank to have a review committee to ensure compliance with the self-dealing provisions of the Bank Act, while 157(2)(d) requires that banks designate a committee of the board of directors to monitor the conflict of interest procedures.

The Bank Act subsection 459.1(1) prohibits a bank from imposing undue pressure on, or coercing a person to obtain a product or service from a particular person, including the bank and any of its affiliates, as a condition for obtaining another product or service from the bank.

The Bank Act subsection 459.1(4.1) requires a bank to disclose coercive tied selling arrangements.

OSFI's Supervisory Framework requires monitoring of conflicts of interest through a bank's risk management program.

The applicants have represented to the Commission that OSFI, in the process of its oversight and enforcement of the foregoing Canadian standards, would require any SD or MSP subject to such standards to resolve or mitigate conflicts of interests in the provision of clearing services by a clearing member of a DCO that is an affiliate of the SD or MSP, or the decision of a counterparty to execute a derivative on a SEF or DCM, or clear a derivative through a DCO, through appropriate information firewalls and disclosures.

Commission Determination: The Commission finds that the Bank Act standards specified above with respect to conflicts of interest that may arise in producing or distributing research are generally identical in intent to § 23.605(c) because such standards seek to ensure that research provided to the general public by an SD is unbiased and free from the influence of the interests of an SD arising from the SD's trading business.

With respect to conflicts of interest that may arise in the provision of clearing services by an affiliate of an SD or MSP, the Commission further finds that although the general conflicts of interest prevention requirements under the Bank Act standards specified above

do not require with specificity that access to and the provision of clearing services provided by an affiliate of an SD or MSP not be improperly influenced by the interests of an SD's or MSP's trading business, such general requirements would require prevention and remediation of such improper influence when recognized or discovered. Thus such standards would ensure open access to clearing.

Finally, although not as specific as the requirements of § 23.605(e) (Undue influence on counterparties), the Commission finds that the general disclosure requirements of the Bank Act standards specified above would ensure equal access to trading venues and clearinghouses by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the requirements found in the Bank Act standards specified above in relation to conflicts of interest are comparable to and as comprehensive as § 23.605.

6. Availability of Information for Disclosure and Inspection (§ 23.606)

Commission Requirement: Commission regulation 23.606 implements sections 4s(j)(3) and (4) of the CEA, and requires each SD and MSP to disclose to the Commission, and an SD's or MSP's U.S. prudential regulator (if any) comprehensive information about its swap activities, and to establish and maintain reliable internal data capture, processing, storage, and other operational systems sufficient to capture, process, record, store, and produce all information necessary to satisfy its duties under the CEA and Commission regulations. Such systems must be designed to provide such information to the Commission and an SD's or MSP's U.S. prudential regulator within the time frames set forth in the CEA and Commission regulations and upon request.

Regulatory Objective: Commission regulation 23.606 seeks to ensure that each SD and MSP captures and maintains comprehensive information about their swap activities, and is able to retrieve and disclose such information to the Commission and its U.S. prudential regulator, if any, as necessary for compliance with the CEA and the Commission's regulations and for purposes of Commission oversight, as well as oversight by the SD's or MSP's U.S. prudential regulator, if any.

The Commission observes that it would be impossible to meet the regulatory objective of § 23.606 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.606 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as Commission regulation 23.606.

OSFI relies on general reporting obligations of Canadian banks and OSFI's monitoring function under the OSFI Supervisory Framework with respect to availability of information for disclosure and inspection. Specifically, banks are expected to have appropriate policies and procedures in place to ensure that all regulatory filings are received by OSFI within specified timeframes and are error free. Banks are subject to penalties for late or erroneous filings pursuant to OSFI's Late and Erroneous Filing Penalty Framework.

With respect to data capture and retention, as part of the bank licensing process, OSFI must approve a bank's operational risk management policies, including policies related to information technology, information management and security, and records retention.

As part of the OSFI Supervisory Framework, OSFI generally requires banks to establish and maintain an enterprise-wide LCM framework. OSFI expects the LCM framework to include "Adequate Documentation" as one of its key controls. As set forth in the OSFI Derivatives Best Practice Guideline, each bank should have mechanisms in place to assure the confirmation, maintenance and safeguarding of derivatives contract documentation. In particular, it states:

> [t]he design of information systems will vary according to the risks demanded by the scope and complexity of an institution's involvement in derivatives. The degree of accuracy and timeliness of information processing should be sufficient to meet an institution's risk exposure monitoring needs. Appropriate information processing and reporting capabilities should be put in place and fully operational.

Commission Determination: The Commission finds that the OSFI standards specified above are generally identical in intent to § 23.606 because such standards seek to ensure that each SD and MSP captures and stores comprehensive information about their swap activities, and are able to retrieve and disclose such information as necessary for compliance with applicable law and for purposes of regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the OSFI standards with respect to the availability of information for inspection and disclosure, as specified above, are comparable to, and as comprehensive as, § 23.606, with the exception of § 23.606(a)(2) concerning the requirement that an SD or MSP make information required by § 23.606(a)(1) available promptly upon request to Commission staff and the staff of an applicable U.S. prudential regulator. The applicant has not submitted any provision of law or regulations applicable in Canada upon which the Commission could make a finding that SDs and MSPs would be required to retrieve and disclose comprehensive information about their swap activities to the Commission or any U.S. prudential regulator as necessary for compliance with the CEA and Commission regulations, and for purposes of Commission oversight and the oversight of any U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of the OSFI standards are comparable to and as comprehensive as § 23.606(a)(2), any SD or MSP to which both § 23.606 and the OSFI standards specified above are applicable would generally be deemed to be in compliance with § 23.606(a)(2) if that SD or MSP complies with the OSFI standards specified above, subject to compliance with the requirement that it produce information to Commission staff and the staff of an applicable U.S. prudential regulator in accordance with § 23.606(a)(2).

7. Clearing Member Risk Management (§ 23.609)

Commission Requirement: Commission regulation 23.609 generally requires each SD or MSP that is a clearing member of a DCO to:

- Establish risk-based limits based on position size, order size, margin requirements, or similar factors;
- Screen orders for compliance with the risk-based limits;

- Monitor for adherence to the risk-based limits intra-day and overnight;
- Conduct stress tests under extreme but plausible conditions of all positions at least once per week;
- Evaluate its ability to meet initial margin requirements at least once per week;
- Evaluate its ability to meet variation margin requirements in cash at least once per week;
- Evaluate its ability to liquidate positions it clears in an orderly manner, and estimate the cost of liquidation; and
- Test all lines of credit at least once per year.

Regulatory Objective: Through Commission regulation 23.609, the Commission seeks to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds. Effective risk management by SDs and MSPs that are clearing members is essential to achieving these objectives. A failure of risk management can cause a clearing member to become insolvent and default to a DCO. Such default can disrupt the markets and the clearing system and harm customers.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as Commission regulation 23.609.

OSFI stated that, to the extent that any bank is a clearing member, risk management specifically for clearing members is an aspect of the risk management framework.

OSFI Derivatives Best Practice Guideline states that banks should have knowledgeable individuals or units responsible for risk monitoring and control functions, including the responsibility for actively monitoring transactions and positions for adherence to internal policy limits. Moreover, stress tests should be performed regularly and should account for abnormally large market swings and periods of prolonged inactivity, while considering the effect of price changes on the "mid-market value" of the portfolio.

More generally, the OSFI Corporate Governance Guideline requires that each bank establish a risk appetite framework ("RAF") that:

- Guides the amount of risk the bank is willing to accept in pursuit of its strategic and business objectives.
- Sets basic goals, benchmarks, parameters, and limits, and should consider all applicable types of risks.
- Contains all elements required by an annex to the Corporate Governance Guideline, including a risk appetite statement, specific risk tolerance limits, and processes for implementation of the RAF.

Further, the OSFI Corporate Governance Guideline states that DSIBs should establish a dedicated risk committee to oversee risk management on an enterprise-wide basis, and that the oversight of the risk management activities of the bank are to be independent from operational management, adequately resourced, and have appropriate status and visibility.

The OSFI Derivatives Best Practice Guideline states that each bank should ensure that each derivative product traded is subject to a product authorization signed off by senior management, and sets forth OSFI's expectations with respect to having documented policies and procedures for risk management, creating risk tolerance limits, and measuring, reporting, managing, and controlling the risks associated with the derivatives business, including market, currency, interest rate, equity price, commodity price, credit, settlement, liquidity, operational, and legal risks.

OSFI represents that its oversight pursuant to the Supervisory Framework will assess the extent to which the risk management function integrates policies, practices, and limits with day-to-day business activities and with the bank's strategic, capital, and liquidity management policies. Under the Supervisory Framework, OSFI also will assess whether the risk management function effectively monitors risk positions against approved limits and ensures that material breaches are addressed on a timely basis. OSFI represents that it will look at various indicators, including the extent to which the bank proactively updates its policies, practices, and limits in response to changes in the industry and in the institution's strategy, business activities and risk tolerances.[43]

Specifically, OSFI has represented to the Commission that, in the process of its oversight and enforcement of the foregoing Canadian law and regulations, any SD or MSP subject to such standards that is a clearing member of a DCO would be required to comply with clearing member risk management requirements comparable to Commission regulation 23.609.

Commission Determination: The Commission finds that the OSFI standards specified above are generally identical in intent to § 23.609 because such standards seek to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds.

The Commission notes that the OSFI standards specified above are not as specific as § 23.609 with respect to ensuring that SDs and MSPs that are clearing members of a DCO establish detailed procedures and limits for clearing member risk management purposes. Nevertheless, the Commission finds that the general requirements under the OSFI standards specified above, implemented in the context of clearing member risk management and pursuant to the representations of OSFI, meet the Commission's regulatory objective specified above.

Based on the foregoing and the representations above, the Commission hereby determines that the clearing member risk management requirements of the Canadian law and regulations specified above are comparable to and as comprehensive as § 23.609.

C. Swap Data Recordkeeping (§§ 23.201 and 23.203)

Commission Requirement: Sections 4s(f)(1)(B) and 4s(g)(1) of the CEA, and Commission regulation 23.201 generally require SDs and MSPs to retain records of each transaction, each position held, general business records (including records related to complaints and sales and marketing materials), records related to governance, financial records, records of data reported to SDRs, and records of real-time reporting data along with a record of the date and time the SD or MSP made such reports. Transaction records must be kept in a form and manner identifiable and searchable by transaction and counterparty.

Commission regulation 23.203, requires SDs and MSPs to maintain records of a swap transaction until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction, and for a period of five years after such date. Records must be "readily accessible" for the first 2 years of the 5 year retention period (consistent with § 1.31).

The Commission notes that the comparability determination below with respect to §§ 23.201 and 23.203 encompasses both swap data recordkeeping generally and swap data recordkeeping relating to complaints

[43] In addition to the foregoing, the applicant notes that the Canadian Bank SDs may be subject to heightened standards for their derivatives business in the near future under regulatory recommendations that would require registrants to establish, maintain and apply systems, policies and procedures that establish robust compliance and risk management systems specifically for their derivatives business. *See* CSA Consultation Paper 91–407.

and marketing and sales materials in accordance with § 23.201(b)(3) and (4).[44]

Regulatory Objective: Through the Commission's regulations requiring SDs and MSPs to keep comprehensive records of their swap transactions and related data, the Commission seeks to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

The Commission's regulations require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

By requiring comprehensive records of swap data, the Commission seeks to ensure that SDs and MSPs employ effective risk management, and strictly comply with Commission regulations. Further, such records facilitate effective regulatory oversight.

The Commission observes that it would be impossible to meet the regulatory objective of §§ 23.201 and 23.203 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.203 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Canadian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Canada are in full force and effect in Canada, and comparable to and as comprehensive as sections 4s(f)(1)(B) and 4s(g)(1) of the CEA and §§ 23.201 and 23.203.

OSFI's Supervisory Framework requires banks to establish and maintain an enterprise-wide LCM framework of regulatory risk management controls, and these controls include oversight functions that are independent of the activities they oversee. OSFI expects the LCM framework to include "Adequate Documentation" as one of its key controls.

As set forth in the OSFI Derivatives Best Practice Guideline, each bank should have mechanisms in place to assure the confirmation, maintenance, and safeguarding of derivatives contract documentation. In particular, it states:

> [t]he design of information systems will vary according to the risks demanded by the scope and complexity of an institution's involvement in derivatives. The degree of accuracy and timeliness of information processing should be sufficient to meet an institution's risk exposure monitoring needs. Appropriate information processing and reporting capabilities should be put in place and fully operational.

Finally, Sections 238, 239 and 597 of the Bank Act generally require banks carrying on business in Canada to maintain records in Canada and to ensure that OSFI can access in Canada any records necessary to enable OSFI to fulfill its supervisory mandate.

Commission Determination: The Commission finds that the Bank Act and OSFI standards specified above are generally identical in intent to §§ 23.201 and 23.203 because such standards seek to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

In addition, the Commission finds that the Bank Act and OSFI standards specified above require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

Finally, the Commission finds that the Bank Act and OSFI standards specified above, by requiring comprehensive records of swap data, seek to ensure that SDs and MSPs employ effective risk management, seek to ensure that SDs and MSPs strictly comply with applicable regulatory requirements (including the CEA and Commission regulations), and that such records facilitate effective regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements of the Bank Act and the OSFI standards with respect to swap data recordkeeping, as specified above, are comparable to, and as comprehensive as, §§ 23.201 and 23.203, with the exception of § 23.203(b)(2) concerning the requirement that an SD or MSPs make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator. The applicant has not submitted any provision of law or regulations applicable in Canada upon which the Commission could make a finding that SDs and MSPs would be required to make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of the Bank Act and the OSFI standards are comparable to and as comprehensive as § 23.203(b)(2), any SD or MSP to which both § 23.203 and the Bank Act and OSFI standards specified above are applicable would generally be deemed to be in compliance with § 23.203(b)(2) if that SD or MSP complies with the Bank Act and OSFI standards specified above, subject to compliance with the requirement that it make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator in accordance with § 23.203(b)(2).

Issued in Washington, DC on December 20, 2013, by the Commission.

Christopher J. Kirkpatrick,

Deputy Secretary of the Commission.

Appendices to Comparability Determination for Canada: Certain Entity-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Joint Statement of Chairman Gary Gensler and Commissioners Bart Chilton and Mark Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-

[44] *See* the Guidance for a discussion of the availability of substituted compliance with respect to swap data recordkeeping, 78 FR 45332–33.

level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with . both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Statement of Dissent by Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) Are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States . . ."[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad category-by-category basis, should form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: The differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the full Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical

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[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.

[3] CEA section 2(i); 7 U.S.C. 2(i).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] http://www.cftc.gov/PressRoom/PressReleases/pr6678–13.

[6] http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf. The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

[10] http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomalia-29.

[11] http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.

questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) The Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process; (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30979 Filed 12–26–13; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for Hong Kong: Certain Entity-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Comparability Determination for Certain Requirements under the laws of Hong Kong.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a request by the Hong Kong Monetary Authority ("HKMA") that the Commission determine that laws and regulations applicable in Hong Kong provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to swap dealers ("SDs") and major swap participants ("MSPs") registered with the Commission: (i) Chief compliance officer; (ii) risk management; and (iii) swap data recordkeeping (collectively, the "Internal Business Conduct Requirements").

DATES: *Effective Date:* This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202–418–5977, *gbarnett@cftc.gov*, Frank Fisanich, Chief Counsel, 202–418–5949, *ffisanich@cftc.gov*, and August A. Imholtz III, Special Counsel, 202–418–5140, *aimholtz@cftc.gov*, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" (the "Guidance").[1] In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the "Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Entity-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3]

On July 12, 2013, the HKMA (the "applicant") submitted a request that the Commission determine that laws and regulations applicable in Hong Kong provide a sufficient basis for an affirmative finding of comparability with respect to certain Entity-Level Requirements, including the Internal Business Conduct Requirements.[4] The applicant provided Commission staff with updated submissions on August 8 and 19, 2013. On November 11, November 28, and December 6, 2013, the applicant further supplemented the application with corrections and additional materials. The following is

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations, 78 FR 909 (Jan. 7, 2013).

[2] 78 FR 43785 (July 22, 2013).

[3] The Entity-Level Requirements under the Exemptive Order consist of 17 CFR 1.31, 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, 23.606, 23.608, 23.609, and parts 45 and 46 of the Commission's regulations.

[4] For purposes of this notice, the Internal Business Conduct Requirements consist of 17 CFR 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606.

the Commission's analysis and determination regarding the Internal Business Conduct Requirements, as detailed below.[5]

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act[6] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[7] In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the Commission.[8] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[9]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime, subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[10]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[11] The Commission's direct access to the books and records required to be maintained by an SD or MSP registered with the Commission is a core requirement of the CEA[12] and the Commission's regulations,[13] and is a condition to registration.[14]

III. Regulation of SDs and MSPs in Hong Kong

The HKMA administers the Hong Kong Banking Ordinance and is the government authority in Hong Kong responsible for maintaining monetary and banking stability.[15] Its main functions are:

- Maintaining currency stability within the framework of the Linked Exchange Rate system;
- Promoting the stability and integrity of the financial system, including the banking system;
- Helping to maintain Hong Kong's status as an international financial center, including the maintenance and development of Hong Kong's financial infrastructure; and
- Managing the Exchange Fund.

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[5] This notice does not address swap data repository reporting ("SDR Reporting"). The Commission may provide a comparability determination with respect to the SDR Reporting requirement in a separate notice.

[6] Public Law 111–203, 124 Stat. 1376 (2010).

[7] 7 U.S.C. 2(i).

[8] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site. (*http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm.*)

[9] 78 FR 45342–45.

[10] See the Guidance, 78 FR 45342–44.

[11] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as a SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. See id. at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

[12] See e.g., sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[13] See e.g., §§ 23.203(b) and 23.606.

[14] See supra note 9.

[15] Because the applicant's request and the Commission's determinations herein are based on the comparability of the requirements applicable to Authorized Institutions ("AI") regulated by the HKMA, an SD or MSP that is not an AI, or is otherwise not subject to the requirements applicable to AIs upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein.

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the basis of the foreign regime as a whole.[16] In making its comparability determinations, the Commission may include conditions that take into account timing and other issues related to coordinating the implementation of reform efforts across jurisdictions.[17]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s),
- The scope and objectives of the relevant regulatory requirement(s),
- The comprehensiveness of the foreign regulator's supervisory compliance program, and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[18]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.*, the home jurisdiction's requirements do not have to be identical).[19] This approach recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis the Commission may determine that no comparability determination can be made[20] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is an SD or MSP with respect to its foreign branches, or non-registrant, to the extent applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[21] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swaps market activities may not be clearly defined, or may not expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[22]

Finally, the Commission will generally rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities[23] of SDs and MSPs[24] in the relevant jurisdictions.[25] Further, as stated in the Guidance, the Commission expects that an applicant

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[16] 78 FR 45343.

[17] 78 FR 45343.

[18] 78 FR 45343.

[19] 78 FR 45343. The Commission's substituted compliance program would generally be available for SDR Reporting, as outlined in the Guidance, only if the Commission has direct access to all of the data elements that are reported to a foreign trade repository pursuant to the substituted compliance program. Thus, direct access to swap data is a threshold matter to be addressed in a comparability evaluation for SDR Reporting. Moreover, the Commission explains in the Guidance that, due to its technical nature, a comparability evaluation for SDR Reporting "will generally entail a detailed comparison and technical analysis." A more particularized analysis will generally be necessary to determine whether data stored in a foreign trade repository provides for effective Commission use, in furtherance of the regulatory purposes of the Dodd-Frank Act. *See* 78 FR 45345.

[20] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

[21] 78 FR 45343.

[22] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that [SDs] and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[23] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under Part 23 (17 CFR Part 23) are limited in scope to the swaps activities of SDs and MSPs.

[24] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is responsible for determining whether it is subject to the laws and regulations found comparable. Currently, there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outside the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[25] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. The Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurate description of foreign laws and regulations may not be valid.

would notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[26]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted compliance[27] for the Internal Business Conduct Requirements.[28]

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement[29] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for information sharing and cooperation in the context of supervising [SDs] and MSPs."[30]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[31] provide for notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[32] and include protections related to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Internal Business Conduct Requirements that are the subject of this comparability determination, and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Internal Business Conduct Requirements that the requestor submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable and comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this notice.

As was stated in the Guidance, the Commission recognizes the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Chief Compliance Officer (§ 3.3)

Commission Requirement: Implementing section 4s(k) of the CEA, Commission regulation 3.3 generally sets forth the following requirements for SDs and MSPs:

- An SD or MSP must designate an individual as Chief Compliance Officer ("CCO");
- The CCO must have the responsibility and authority to develop the regulatory compliance policies and procedures of the SD or MSP;

[26] 78 FR 45345.

[27] *See* 78 FR 45348–50. The Commission notes that registrants and other market participants are responsible for determining whether substituted compliance is available pursuant to the Guidance based on the comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[28] This notice does not address § 23.608 (Restrictions on counterparty clearing relationships) nor § 23.609 (Clearing member risk management). The Commission declines to take up the request for a comparability determination with respect to these regulations due to the Commission's view that there are not laws or regulations applicable in Hong Kong to compare with the prohibitions and requirements of §§ 23.608 or 23.609. The Commission may provide a comparability determination with respect to these regulations at a later date in consequence of further developments in the law and regulations applicable in Hong Kong.

This notice also does not address capital adequacy because the Commission has not yet finalized rules for SDs and MSPs in this area, nor SDR Reporting. The Commission may provide a comparability determination with respect to these requirements at a later date or in a separate notice.

[29] An MOU is one type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or, for example, as independent bilateral arrangements, statements of intent, declarations, or letters.

[30] 78 FR 45344.

[31] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. 6s(f); 17 CFR 23.203. In the Guidance, the Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; *see also id.* at 45342 n. 461 (affirming the Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto").

[32] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP. *See* 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

- The CCO must report to the board of directors or the senior officer of the SD or MSP;
- Only the board of directors or a senior officer may remove the CCO;
- The CCO and the board of directors must meet at least once per year;
- The CCO must have the background and skills appropriate for the responsibilities of the position;
- The CCO must not be subject to disqualification from registration under sections 8a(2) or (3) of the CEA;
- Each SD and MSP must include a designation of a CCO in its registration application;
- The CCO must administer the regulatory compliance policies of the SD or MSP;
- The CCO must take reasonable steps to ensure compliance with the CEA and Commission regulations, and resolve conflicts of interest;
- The CCO must establish procedures for detecting and remediating non-compliance issues;
- The CCO must annually prepare and sign an "annual compliance report" containing: (i) A description of policies and procedures reasonably designed to ensure compliance; (ii) an assessment of the effectiveness of such policies and procedures; (iii) a description of material non-compliance issues and the action taken; (iv) recommendations of improvements in compliance policies; and (v) a certification by the CCO or CEO that, to the best of such officer's knowledge and belief, the annual report is accurate and complete under penalty of law; and
- The annual compliance report must be furnished to the CFTC within 90 days after the end of the fiscal year of the SD or MSP, simultaneously with its annual financial condition report.

Regulatory Objective: The Commission believes that compliance by SDs and MSPs with the CEA and the Commission's rules greatly contributes to the protection of customers, orderly and fair markets, and the stability and integrity of the market intermediaries registered with the Commission. The Commission expects SDs and MSPs to strictly comply with the CEA and the Commission's rules and to devote sufficient resources to ensuring such compliance. Thus, through its CCO rule, the Commission seeks to ensure firms have designated a qualified individual as CCO that reports directly to the board of directors or the senior officer of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually to the Commission and the board or senior officer on compliance of the firm.

Comparable Hong Kong Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as section 4s(k) of the CEA and Commission regulation 3.3.

- Hong Kong Banking Ordinance, Section 72B requires all AIs (i.e., banks, restricted license banks and deposit-taking companies), including a bank that is registered as an SD, to appoint a manager principally responsible for the compliance function.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that the primary role of the compliance function is to ensure that the AI is in compliance with the statutory provisions, regulatory requirements, and codes of conduct applicable to its banking or other regulated activities. To this end, the compliance function must ensure that the compliance policies and procedures developed by it or other departments are adequate and effective.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that the compliance function should have appropriate standing and authority within an AI, with a direct reporting line to a designated committee (e.g., Audit Committee) or senior management. AIs are required to have a compliance function that is responsible for ensuring the firm's compliance with statutory and regulatory requirements. The compliance function must have sufficient authority and independence to function effectively. It should also be able to carry out its duties on its own initiative in all business and operating units of the AI in which compliance risk exists, with unfettered access to any records or files necessary to enable it to conduct its work.
- Under the HKMA Supervisory Policy Manual, Module CG–1, the board of directors is responsible for the appointment and removal of senior management, including the compliance manager. The board must meet regularly with senior management and internal control functions (including those responsible for internal audit, risk management and compliance) to review the policies and controls in order to identify areas that need improvement and address significant risks and issues.
- The HKMA Supervisory Policy Manual, Module CG–1 provides that senior managers, such as the compliance manager, are required to have appropriate background and skills to enable them to manage and supervise the AI's internal control and risk management functions, including compliance. Further, the manual also provides guidance for assessing whether senior management, including the CCO, is "fit and proper." One of the considerations is whether the person has a record of non-compliance with various non-statutory codes or has been reprimanded, censured, disciplined or publicly criticized by professional or regulatory bodies.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that the compliance function must monitor and test compliance. The compliance function also must establish a compliance program that sets out its planned activities.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that the compliance function must report regularly to senior management on compliance matters. Additionally, the chief executive of an AI must endorse the Certificate of Compliance submitted to the HKMA quarterly to confirm compliance with the specified statutory requirements under the Hong Kong Banking Ordinance.

Commission Determination: The Commission finds that the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual specified above are generally identical in intent to § 3.3 by seeking to ensure firms have designated a qualified individual as the compliance officer that reports directly to a sufficiently senior function of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, remediate noncompliance issues, and report regularly on compliance of the firm.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual that govern the compliance manager and compliance function within an AI are comparable to and as comprehensive as § 3.3, with the exception of § 3.3(f) concerning certifying and furnishing an annual compliance report to the Commission.

Notwithstanding that the Commission has not determined that the requirements of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual are comparable to and as comprehensive as § 3.3(f), any SD or

MSP to which both § 3.3 and the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual specified above are applicable would generally be deemed to be in compliance with § 3.3(f) if that SD or MSP complies with the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual specified above, subject to certifying and furnishing the Commission with the compliance reports required under the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual specified above in accordance with § 3.3(f). The Commission notes that it generally expects registrants to submit required reports to the Commission in the English language.

B. Risk Management Duties (§§ 23.600—23.609)

Section 4s(j) of the CEA requires each SD and MSP to establish internal policies and procedures designed to, among other things, address risk management, monitor compliance with position limits, prevent conflicts of interest, and promote diligent supervision, as well as maintain business continuity and disaster recovery programs.[33] The Commission adopted regulations 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606 to implement the statute.[34] The Commission also adopted regulation 23.609, which requires certain risk management procedures for SDs or MSPs that are clearing members of a derivatives clearing organization ("DCO").[35] Collectively, these requirements help to establish a robust and comprehensive internal risk management program for SDs and MSPs with respect to their swaps activities,[36] which is critical to effective systemic risk management for the overall swaps market. In making its comparability determination with regard to these risk management duties, the Commission will consider each regulation individually.[37]

1. Risk Management Program for SDs and MSPs (§ 23.600)

Commission Requirement: Implementing section 4s(j)(2) of the CEA, Commission regulation 23.600 generally requires that:

- Each SD or MSP must establish and enforce a risk management program consisting of a system of written risk management policies and procedures designed to monitor and manage the risks associated with the swap activities of the firm, including without limitation, market, credit, liquidity, foreign currency, legal, operational, and settlement risks, and furnish a copy of such policies and procedures to the CFTC upon application for registration and upon request;
- The SD or MSP must establish a risk management unit independent from the business trading unit;
- The risk management policies and procedures of the SD or MSP must be approved by the firm's governing body;
- Risk tolerance limits and exceptions therefrom must be reviewed and approved quarterly by senior management and annually by the governing body;
- The risk management program must have a system for detecting breaches of risk tolerance limits and alerting supervisors and senior management, as appropriate;
- The risk management program must account for risks posed by affiliates and be integrated at the consolidated entity level;
- The risk management unit must provide senior management and the governing body with quarterly risk exposure reports and upon detection of any material change in the risk exposure of the SD or MSP;
- Risk exposure reports must be furnished to the CFTC within five business days following provision to senior management;
- The risk management program must have a new product policy for assessing the risks of new products prior to engaging in such transactions;
- The risk management program must have policies and procedures providing for trading limits, monitoring of trading, processing of trades, and separation of personnel in the trading unit from personnel in the risk management unit; and
- The risk management program must be reviewed and tested at least annually and upon any material change in the business of the SD or MSP.

Regulatory Objective: Through the required system of risk management, the Commission seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. To this end, the Commission believes the risk management program of an SD or MSP must contain at least the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Comparable Hong Kong Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as section 4s(j)(2) of the CEA and Commission regulation 23.600.

HKMA represents to the Commission that it generally requires AIs to have adequate risk management policies, procedures, systems and controls to identify, assess, measure, monitor, and control eight types of inherent risks arising from their activities (on and off balance sheet, and including swap activities) under SA–1 Risk-based Supervisory Approach.

HKMA also represents to the Commission that the risk management requirements in its guidelines apply to swap activities conducted by AIs.

HKMA further represents to the Commission that it has dedicated guidelines on major types of risk (e.g., management of credit (including

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[33] 7 U.S.C. 6s(j).

[34] *See* Final Swap Dealer and MSP Recordkeeping Rule, 77 FR 20128 (April 3, 2012) (relating to risk management program, monitoring of position limits, business continuity and disaster recovery, conflicts of interest policies and procedures, and general information availability, respectively).

[35] *See* Customer Documentation Rule, 77 FR 21278. Also, SDs must comply with Commission regulation 23.608, which prohibits SDs providing clearing services to customers from entering into agreements that would: (i) Disclose the identity of a customer's original executing counterparty; (ii) limit the number of counterparties a customer may trade with; (iii) impose counterparty-based position limits; (iv) impair a customer's access to execution of a trade on terms that have a reasonable relationship to the best terms available; or (v) prevent compliance with specified time frames for acceptance of trades into clearing.

[36] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[37] As stated above, this notice does not address § 23.608 (Restrictions on counterparty clearing relationships) nor § 23.609 (Clearing member risk management). The Commission declines to take up the request for a comparability determination with respect to these regulations due to the Commission's view that there are not laws or regulations applicable in Hong Kong to compare with the prohibitions and requirements of §§ 23.608 or 23.609. The Commission may provide a comparability determination with respect to these regulations at a later date in consequence of further developments in the law and regulations applicable in Hong Kong.

counterparty credit), market, liquidity and operational risks, etc.). Specifically:

- The HKMA Supervisory Policy Manual, Module IC–1 provides that the board is responsible for articulating risk management strategies. Senior management must develop, and the board must approve, a risk management framework based on risk management strategies that is consistent with the AI's business goals and risk appetite. Senior management must: formulate detailed policies, procedures and limits for managing different aspects of risk arising from the AI's business activities; design and implement a risk management framework; and ensure that the relevant control systems within the framework function as intended. The risk management policies and procedures must be approved by the board or its designated committee(s). The board also must exercise oversight over the effectiveness of the risk management framework.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that AIs should have a dedicated risk management function. The risk management function must be independent from the risk-taking and operational units which it reviews. The risk management function must have unfettered access to information from the risk-taking and operational units.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that a set of limits should be put in place to control an AI's exposure to various quantifiable risks associated with its business activities and to control different sources of risk concentration. These limits should be documented and approved by the board or its designated committee(s). Limit utilization should be closely monitored, and excesses or exceptions should be reported promptly to senior management for necessary action.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that risk management must be conducted on a group-wide basis by managing the relevant risks of the parent bank and its group entities as a whole.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that a sound risk management system should include adequate risk measurement, monitoring and reporting systems to support all business activities and related risks. The risk management information system should be capable of reporting excesses in limits and policy exceptions, and alerting management of risk exposures approaching pre-set limits. The risk management information system also should be able to produce information at appropriate intervals, including at more frequent intervals in times of stress as required by management.
- The HKMA collects internal risk exposure reports from the AIs. AIs are required to submit quarterly capital adequacy ratio returns to the HKMA that address market risk. HKMA also conducts regular surveys on AIs' derivative exposures.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that AIs should have in place an internally approved and well-documented "new product approval policy" which addresses not only the development and approval of entirely new products and services but also significant changes in the features of existing products and services.

Commission Determination: The Commission finds that the provisions of the HKMA Supervisory Policy Manual specified above are generally identical in intent to § 23.600 by requiring a system of risk management that seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. Specifically, the Commission finds that the provisions of the HKMA Supervisory Policy Manual specified above comprehensively require SDs and MSPs to establish risk management programs containing the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the risk management program requirements of the HKMA Supervisory Policy Manual, as specified above, are comparable to and as comprehensive as § 23.600, with the exception of § 23.600(c)(2) concerning the requirement that each SD and MSP produce a quarterly risk exposure report and provide such report to its senior management, governing body, and the Commission.

Notwithstanding that the Commission has not determined that the requirements of the provisions of the HKMA Supervisory Policy Manual are comparable to and as comprehensive as § 23.600(c)(2), any SD or MSP to which both § 23.600 and the provisions of the HKMA Supervisory Policy Manual specified above are applicable would generally be deemed to be in compliance with § 23.600(c)(2) if that SD or MSP complies with the provisions of the HKMA Supervisory Policy Manual specified above, subject to compliance with the requirement that it produce quarterly risk exposure reports and provide such reports to its senior management, governing body, and the Commission in accordance with § 23.600(c)(2). The Commission notes that it generally expects reports furnished to the Commission by registrants to be in the English language.

2. Monitoring of Position Limits (§ 23.601)

Commission Requirement: Implementing section 4s(j)(1) of the CEA, Commission regulation 23.601 requires each SD or MSP to establish and enforce written policies and procedures that are reasonably designed to monitor for, and prevent violations of, applicable position limits established by the Commission, a designated contract market ("DCM"), or a swap execution facility ("SEF").[38] The policies and procedures must include an early warning system and provide for escalation of violations to senior management (including the firm's governing body).

Regulatory Objective: Generally, position limits are implemented to ensure market integrity, fairness, orderliness, and accurate pricing in the commodity markets. Commission regulation 23.601 thus seeks to ensure that SDs and MSPs have established the necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by the Commission, a DCM, or a SEF. As part of its Risk Management Program, § 23.601 is intended to ensure that established position limits are not breached by the SD or MSP.

Comparable Hong Kong Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as section 4s(j)(1) of the

[38] The setting of position limits by the Commission, a DCM, or a SEF is subject to requirements under the CEA and Commission regulations other than § 23.601. The setting of position limits and compliance with such limits is not subject to the Commission's substituted compliance regime.

CEA and Commission regulation § 23.601.

The applicant represents to the Commission that AIs have a responsibility to comply with all applicable laws and regulations, whether in Hong Kong or outside of Hong Kong, including applicable position limits established by the Commission, a DCM, or a SEF. Under the HKMA Supervisory Policy Manual, module IC–1, General Risk Management Controls paragraph 5.1.3, an AI's internal control system must cover controls relating to compliance with statutory and regulatory requirements, which would require a system of controls to maintain compliance with applicable position limits established by the Commission, a DCM, or a SEF. AI's must maintain adequate systems of control to maintain a banking license pursuant to the Banking Ordinance, Schedule 7, paragraph 10.[39]

Commission Determination: The Commission finds that the HKMA and Banking Ordinance standards specified above are generally identical in intent to § 23.601 by requiring SDs and MSPs to establish necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by applicable laws and regulations, including those of the Commission, a DCM, or a SEF. Specifically, the Commission finds that the HKMA and Banking Ordinance standards specified above, while not specific to the issue of position limit compliance, nevertheless comprehensively require SDs and MSPs to monitor for regulatory compliance generally, including monitoring for compliance with position limits set pursuant to applicable law (including the CEA and Commission regulations) and escalation of violations to senior management (including the board of directors) responsible for such compliance.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the compliance monitoring requirements of the HKMA and Banking Ordinance standards, as specified above, are comparable to and as comprehensive as § 23.601. For the avoidance of doubt, the Commission notes that this determination may not be relied on to relieve an SD or MSP from its obligation to strictly comply with any applicable position limit established by the Commission, a DCM, or a SEF.

3. Diligent Supervision (§ 23.602)

Commission Requirement: Commission regulation 23.602 implements section 4s(h)(1)(B) of the CEA and requires each SD and MSP to establish a system to diligently supervise all activities relating to its business performed by its partners, members, officers, employees, and agents. The system must be reasonably designed to achieve compliance with the CEA and CFTC regulations. Commission regulation 23.602 requires that the supervisory system must specifically designate qualified persons with authority to carry out the supervisory responsibilities of the SD or MSP for all activities relating to its business as an SD or MSP.

Regulatory Objective: The Commission's diligent supervision rule seeks to ensure that SDs and MSPs strictly comply with the CEA and the Commission's rules. To this end, through § 23.602, the Commission seeks to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Comparable Hong Kong Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as section 4s(h)(1)(B) of the CEA and Commission regulation 23.602.

- The HKMA Supervisory Policy Manual, Module CG–1 provides that the board is ultimately responsible for overseeing senior management to operate within the risk appetite and strategies prescribed by the board, on a prudent basis and in accordance with applicable laws, regulations and supervisory standards.
- The HKMA Supervisory Policy Manual, Module IC–1 provides that an AI's internal control system should, among others, cover controls relating to compliance with statutory and regulatory requirements.
- The Hong Kong Banking Ordinance provides that senior management are responsible for carrying out the supervisory responsibilities of the AIs, and they can be personally liable for breaches of the Banking Ordinance committed by AIs.

Commission Determination: The Commission finds that the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual specified above are generally identical in intent to § 23.602 because such standards seek to ensure that SDs and MSPs strictly comply with applicable law, which would include the CEA and the Commission's regulations. Through the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual specified above, Hong Kong laws and regulations seek to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with applicable law, which would include the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the internal supervision requirements of the provisions of the Hong Kong Banking Ordinance and the HKMA Supervisory Policy Manual, as specified above, are comparable to and as comprehensive as § 23.602.

4. Business Continuity and Disaster Recovery (§ 23.603)

Commission Requirement: To ensure the proper functioning of the swaps markets and the prevention of systemic risk more generally, Commission regulation 23.603 requires each SD and MSP, as part of its risk management program, to establish a business continuity and disaster recovery plan that includes procedures for, and the maintenance of, back-up facilities, systems, infrastructure, personnel, and other resources to achieve the timely recovery of data and documentation and to resume operations generally within the next business day after the disruption.

Regulatory Objective: Commission regulation 23.603 is intended to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, this requirement seeks to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan within one business day, if necessary.

[39] In addition to the foregoing, the applicant also submitted various guidelines and required best practices concerning the setting of internal risk tolerance limits and monitoring for compliance with such internal limits. Although the Commission recognizes these as prudent risk management practices, the Commission does not believe that these provisions are relevant for a comparability determination with respect to § 23.601 because § 23.601 requires monitoring for compliance with external position limits set by the Commission, a DCM, or a SEF.

Comparable Hong Kong Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as Commission regulation 23.603.

- HKMA Supervisory Policy Manual, Module TM–G–2 on Business Continuity Planning requires all AIs to have adequate and regularly tested business continuity plans.

Commission Determination: The Commission finds that the provisions of the HKMA Supervisory Policy Manual specified above are generally identical in intent to § 23.603 because such standards seek to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, the Commission finds that the provisions of the HKMA Supervisory Policy Manual specified above seek to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan in a timely manner.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the business continuity and disaster recovery requirements of the provisions of the HKMA Supervisory Policy Manual, as specified above, are comparable to and as comprehensive as § 23.603.

5. Conflicts of Interest (§ 23.605)

Commission Requirement: Section 4s(j)(5) of the CEA and Commission regulation 23.605(c) generally require each SD or MSP to establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any commodity or swap are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision.

In addition, section 4s(j)(5) of the CEA and Commission regulation 23.605(d)(1) generally prohibits an SD or MSP from directly or indirectly interfering with or attempting to influence the decision of any clearing unit of any affiliated clearing member of a DCO to provide clearing services and activities to a particular customer, including:

- Whether to offer clearing services to a particular customer;
- Whether to accept a particular customer for clearing derivatives;
- Whether to submit a customer's transaction to a particular DCO;
- Whether to set or adjust risk tolerance levels for a particular customer; or
- Whether to set a customer's fees based on criteria other than those generally available and applicable to other customers.

Commission regulation 23.605(d)(2) generally requires each SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of any affiliated clearing member of a DCO to reasonably ensure compliance with the Act and the prohibitions set forth in § 23.605(d)(1) outlined above.

The Commission observes that § 23.605(d) works in tandem with Commission regulation 1.71, which requires FCMs that are clearing members of a DCO and affiliated with an SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of the FCM to reasonably ensure compliance with the Act and the prohibitions set forth in § 1.71(d)(1), which are the same as the prohibitions set forth in § 23.605(d)(1) outlined above.

Finally, § 23.605(e) requires that each SD or MSP have policies and procedures that mandate the disclosure to counterparties of material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a swap execution facility or DCM or to clear a derivative through a DCO.

Regulatory Objective: Commission regulation 23.605(c) seeks to ensure that research provided to the general public by an SD or MSP is unbiased and free from the influence of the interests of an SD or MSP arising from the SD's or MSP's trading business.

In addition, the § 23.605(d) (working in tandem with § 1.71) seeks to ensure open access to the clearing of swaps by requiring that access to and the provision of clearing services provided by an affiliate of an SD or MSP are not influenced by the interests of an SD's or MSP's trading business.

Finally, § 23.605(e) seeks to ensure equal access to trading venues and clearinghouses, as well as orderly and fair markets, by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Comparable Hong Kong Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as Commission regulation 23.605.

The applicant represents to the Commission that AIs that are active in the OTC derivative market are typically also registered with the Hong Kong Securities and Futures Commission ("HKSFC") and hence subject to the HKSFC's Code of Conduct. These AI's registered with the HKSFC include the current SD established in Hong Kong.

Pursuant to Section 16 of the HKSFC's Code of Conduct, registrants must have:

- Mechanisms ensuring that analysts' trading activities or financial interests do not prejudice their investment research and recommendations;
- Mechanisms ensuring that analysts' investment research and recommendations are not prejudiced by the trading activities, financial interests or business relationships of the firms that employ them;
- Reporting lines for analysts and their compensation arrangements that are structured to eliminate or severely limit actual and potential conflicts of interest;
- Written internal procedures or controls to identify and eliminate, avoid, manage, or disclose actual and potential analyst conflicts of interest;
- Procedures to ensure that undue influence of securities issuers, institutional investors, and other outside parties on analysts is eliminated or managed;
- Controls to ensure that disclosures of actual and potential conflicts of interest are complete, timely, clear, concise, specific, and prominent; and
- Policies to ensure that analysts are held to high integrity standards.

The HKMA Supervisory Policy Manual, Module CG–1 requires that the board of directors of an AI establish, implement, and maintain written policies that address the various conflicts of interest that may arise in the AI's business, and that provide for the prevention or management of these conflicts.

In addition, the Banking Ordinance requires an AI to carry on its business with integrity, prudence and the appropriate degree of professional competence. The applicant represents that if an AI permits conflicts of interest (whether general or particular) to continue, it would raise doubts with the HKMA as to whether the AI is carrying on its business with integrity, prudence

and the appropriate degree of professional competence. Carrying on business in such a manner is one of the continuing authorization criteria under the Banking Ordinance. A failure to comply with such criterion is a ground for revocation of that AI's authorization to conduct banking or deposit-taking business in Hong Kong.

Finally, the HKMA has represented to the Commission that, as part of its oversight and enforcement of the foregoing standards for AIs, the HKMA would require any AI (including an AI that is an SD) to adopt measures to prevent or manage any conflicts of interests that may areis or be discovered, including those involving the provision of clearing services by a clearing member of a DCO that is an affiliate of the AI, or the decision of a counterparty to execute a derivative on a SEF or DCM, or clear a derivative through a DCO. The measures include information barriers, segregation of duties, and, as appropriate, disclosures.

Commission Determination: The Commission finds that the HKSFC and Banking Ordinance standards specified above with respect to conflicts of interest that may arise in producing or distributing research are generally identical in intent to § 23.605(c) because such standards seek to ensure that research provided to the general public by an SD is unbiased and free from the influence of the interests of an SD arising from the SD's trading business.

With respect to conflicts of interest that may arise in the provision of clearing services by an affiliate of an SD or MSP, the Commission further finds that although the general conflicts of interest prevention requirements in the Banking Ordinance and the HKMA Supervisory Policy Manual do not require with specificity that access to and the provision of clearing services provided by an affiliate of an SD or MSP not be improperly influenced by the interests of an SD's or MSP's trading business, such general requirements would require prevention and remediation of such improper influence when recognized or discovered. Thus such standards would ensure open access to clearing.

Finally, although not as specific as the requirements of § 23.605(e) (Undue influence on counterparties), the Commission finds that the general disclosure requirements specified above would ensure equal access to trading venues and clearinghouses by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements found in Hong Kong's laws and regulations specified above, in relation to conflicts of interest are comparable to and as comprehensive as § 23.605.

6. Availability of Information for Disclosure and Inspection (§ 23.606)

Commission Requirement: Commission regulation 23.606 implements sections 4s(j)(3) and (4) of the CEA, and requires each SD and MSP to disclose to the Commission, and an SD's or MSP's U.S. prudential regulator (if any) comprehensive information about its swap activities, and to establish and maintain reliable internal data capture, processing, storage, and other operational systems sufficient to capture, process, record, store, and produce all information necessary to satisfy its duties under the CEA and Commission regulations. Such systems must be designed to provide such information to the Commission and an SD's or MSP's U.S. prudential regulator within the time frames set forth in the CEA and Commission regulations and upon request.

Regulatory Objective: Commission regulation 23.606 seeks to ensure that each SD and MSP captures and maintains comprehensive information about their swap activities, and is able to retrieve and disclose such information to the Commission and its U.S. prudential regulator, if any, as necessary for compliance with the CEA and the Commission's regulations and for purposes of Commission oversight, as well as oversight by the SD's or MSP's U.S. prudential regulator, if any.

The Commission observes that it would be impossible to meet the regulatory objective of § 23.606 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.606 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Hong Kong Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as Commission regulation 23.606.

Under Section 56 of the Hong Kong Banking Ordinance, AIs are required to produce records and information whenever requested by the HKMA, including information and records relating to the AI's OTC derivatives or swaps activities. Under the Banking Ordinance, the failure to produce records and information when requested by the HKMA is a criminal offense. The HKMA represents that in order to produce records and information whenever requested by the HKMA, AIs must necessarily have adequate systems and infrastructure to enable them to retrieve such records and information.

Commission Determination: The Commission finds that the Banking Ordinance standards specified above are generally identical in intent to § 23.606 because such standards seek to ensure that AIs capture and store comprehensive information about their swap activities, and are able to retrieve and disclose such information as necessary for compliance with applicable law and for purposes of regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements of the Hong Kong Banking Ordinance with respect to the availability of information for inspection and disclosure, as specified above, are comparable to, and as comprehensive as, § 23.606, with the exception of § 23.606(a)(2) concerning the requirement that an SD or MSP make information required by § 23.606(a)(1) available promptly upon request to Commission staff and the staff of an applicable U.S. prudential regulator. The applicant has not submitted any provision of law or regulations applicable in Hong Kong upon which the Commission could make a finding that SDs and MSPs would be required to retrieve and disclose comprehensive information about their swap activities to the Commission or any U.S. prudential regulator as necessary for compliance with the CEA and Commission regulations, and for purposes of Commission oversight and the oversight of any U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of the Hong Kong Banking Ordinance are comparable to and as comprehensive as § 23.606(a)(2), any SD or MSP to which both § 23.606 and the Banking Ordinance standards specified above are applicable would generally be

deemed to be in compliance with § 23.606(a)(2) if that SD or MSP complies with the Banking Ordinance standards specified above, subject to compliance with the requirement that it produce information to Commission staff and the staff of an applicable U.S. prudential regulator in accordance with § 23.606(a)(2).

C. Swap Data Recordkeeping (§§ 23.201 and 23.203)

Commission Requirement: Sections 4s(f)(1)(B) and 4s(g)(1) of the CEA, and Commission regulation 23.201 generally require SDs and MSPs to retain records of each transaction, each position held, general business records (including records related to complaints and sales and marketing materials), records related to governance, financial records, records of data reported to SDRs, and records of real-time reporting data along with a record of the date and time the SD or MSP made such reports. Transaction records must be kept in a form and manner identifiable and searchable by transaction and counterparty.

Commission regulation 23.203, requires SDs and MSPs to maintain records of a swap transaction until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction, and for a period of five years after such date. Records must be "readily accessible" for the first 2 years of the 5 year retention period (consistent with § 1.31).

The Commission notes that the comparability determination below with respect to §§ 23.201 and 23.203 encompasses both swap data recordkeeping generally and swap data recordkeeping relating to complaints and marketing and sales materials in accordance with § 23.201(b)(3) and (4).[40]

Regulatory Objective: Through the Commission's regulations requiring SDs and MSPs to keep comprehensive records of their swap transactions and related data, the Commission seeks to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

The Commission's regulations require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

By requiring comprehensive records of swap data, the Commission seeks to ensure that SDs and MSPs employ effective risk management, and strictly comply with Commission regulations. Further, such records facilitate effective regulatory oversight.

The Commission observes that it would be impossible to meet the regulatory objective of §§ 23.201 and 23.203 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.203 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Hong Kong Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Hong Kong are in full force and effect in Hong Kong, and comparable to and as comprehensive as sections 4s(f)(1)(B) and 4s(g)(1) of the CEA and §§ 23.201 and 23.203.

Section 20 of Schedule 2 to the Hong Kong Anti-Money Laundering and Counter-Terrorist Financing (Financial Institution) Ordinance (Cap 615) (the "AML–CTF Ordinance") provides that financial institutions must keep all documents, data, and information related to each transaction it carries out. The AML–CTF Ordinance provides that financial institutions must keep all files relating to each customer account and all business correspondence with each customer. The AML–CTF Ordinance provides that transaction records must be kept for six years after the transaction is completed.

The HKMA represents to the Commission that the recordkeeping requirements in the AML–CTF Ordinance apply to all transactions that an AI carries out with each of its customers, including swap and OTC derivative transactions.[41]

Commission Determination: The Commission finds that the Hong Kong standards specified above are generally identical in intent to §§ 23.201 and 23.203 because such standards seek to ensure the effectiveness of the internal controls of SDs and MSPs; and transparency in the swaps market for regulators and market participants.

In addition, the Commission finds that the Hong Kong standards specified above require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

Finally, the Commission finds that the Hong Kong standards specified above, by requiring comprehensive records of swap data, seek to ensure that SDs and MSPs employ effective risk management, seek to ensure that SDs and MSPs strictly comply with applicable regulatory requirements (including the CEA and Commission regulations), and that such records facilitate effective regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the recordkeeping requirements of the Hong Kong AML–CTF Ordinance with respect to swap data recordkeeping, as specified above, are comparable to, and as comprehensive as, §§ 23.201 and 23.203, with the exception of § 23.203(b)(2) concerning the requirement that an SD or MSPs make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator. The applicant has not submitted any provision of law or regulations applicable in Hong Kong upon which the Commission could make a finding that SDs and MSPs would be required to make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of the Hong Kong AML–CTF Ordinance are comparable to and as comprehensive as § 23.203(b)(2), any SD or MSP to which both § 23.203 and the Hong Kong AML–CTF Ordinance are applicable would generally be deemed to be in compliance with § 23.203(b)(2) if that SD or MSP complies with the Hong Kong AML–CTF Ordinance, subject to compliance with the requirement that it make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable

[40] *See* the Guidance for a discussion of the availability of substituted compliance with respect to swap data recordkeeping, 78 FR 45332–33.

[41] The HKMA noted that a record keeping requirement specific to OTC derivative transactions is intended to be included in the forthcoming law implementing the regulatory regime for such transactions. Pursuant to such regulatory regime, the HKMA tentatively expects that records of OTC derivatives transactions (including swaps) will be required to be maintained for the duration of the contract plus six years thereafter. The retention period for voice recordings is to be decided. The HKMA will set out specific recordkeeping requirements in the regulations or guidelines to be issued to supplement the new regulatory regime.

U.S. prudential regulator in accordance with § 23.203(b)(2).

Issued in Washington, DC on December 20, 2013, by the Commission.

Melissa D. Jurgens,

Secretary of the Commission.

Appendices to Comparability Determination for Hong Kong: Certain Entity-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler and Commissioners Chilton and Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Dissenting Statement of Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) Are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States . . ."[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad category-by-category basis, should form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: the differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap

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[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

[3] CEA section 2(i); 7 U.S.C. 2(i).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] *http://www.cftc.gov/PressRoom/PressReleases/pr6678–13.*

[6] *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf.* The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the full Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) The Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process; (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30975 Filed 12–26–13; 8:45 am]
BILLING CODE 6351–01–P

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

[10] *http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomolio-29.*

[11] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omoliostotement071213b.*

COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for Australia: Certain Entity-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Comparability Determination for Certain Requirements under Australian Regulation.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a request by the Australian Bankers Association ("ABA") that the Commission determine that laws and regulations applicable in in the Commonwealth of Australia ("Australia") provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to swap dealers ("SDs") and major swap participants ("MSPs") registered with the Commission: (i) Chief compliance officer; (ii) risk management; and (iii) swap data recordkeeping (collectively, the "Internal Business Conduct Requirements").

DATES: *Effective Date:* This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202–418–5977, *gbarnett@cftc.gov*, Frank Fisanich, Chief Counsel, 202–418–5949, *ffisanich@cftc.gov*, Adam Kezsbom, Special Counsel, 202–418–5372, *akezsbom@cftc.gov*, Israel Goodman, Special Counsel, 202–418–6715, *igoodman@cftc.gov*, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" (the "Guidance").[1] In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations, 78 FR 909 (Jan. 7, 2013).

"Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Entity-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3]

On April 22, 2013, the ABA (the "applicant") submitted a request that the Commission determine that laws and regulations applicable in Australia provide a sufficient basis for an affirmative finding of comparability with respect to certain Entity-Level Requirements, including the Internal Business Conduct Requirements.[4] The applicant provided Commission staff with an updated submission on June 7, 2013. On November 8, 2013, the application was further supplemented with corrections and additional materials. The following is the Commission's analysis and determination regarding the Internal Business Conduct Requirements, as detailed below.[5]

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act[6] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[7]

In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the Commission.[8] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[9]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime, subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[10]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[11] The Commission's direct access to the books and records required to be maintained

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[2] 78 FR 43785 (July 22, 2013).

[3] The Entity-Level Requirements under the Exemptive Order consist of 17 CFR 1.31, 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, 23.606, 23.608, 23.609, and parts 45 and 46 of the Commission's regulations.

[4] For purposes of this notice, the Internal Business Conduct Requirements consist of 17 CFR 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606.

[5] This notice does not address swap data repository reporting ("SDR Reporting"). The Commission may provide a comparability determination with respect to the SDR Reporting requirement in a separate notice.

[6] Public Law 111–203, 124 Stat. 1376 (2010).

[7] 7 U.S.C. 2(i).

[8] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site. (http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm.)

[9] 78 FR 45342–45.

[10] See the Guidance, 78 FR 45342–44.

[11] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as an SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. *See* id. at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

by an SD or MSP registered with the Commission is a core requirement of the CEA [12] and the Commission's regulations,[13] and is a condition to registration.[14]

III. Regulation of SDs and MSPs in Australia

On April 22, 2013, the applicant submitted a request that the Commission assess the comparability of laws and regulations applicable in Australia with the CEA and the Commission's regulations promulgated thereunder. The applicant provided Commission staff with an updated submission on June 7, 2013. On November 8, 2013, the application was further supplemented with corrections and additional materials.

As represented to the Commission by the applicant, currently all five Australian registered SDs are Australian authorized deposit-taking institutions ("ADIs") and holders of an Australian financial services license ("AFSL"). Thus, for the purposes of the Commission's comparability determination, the Commission will consider the laws and regulations applicable to the five SD ADIs with respect to their swap activities. The relevant laws and regulations are administered by two agencies; the Australian Prudential Regulatory Authority ("APRA") and the Australian Securities and Investments Commission ("ASIC").[15]

APRA is the prudential regulator of the Australian financial services industry and oversees the banking industry. It has developed a regulatory framework for Australian ADIs under the Banking Act 1959 (the "Banking Act") that is based on the banking supervision principles published by the Basel Committee on Banking Supervision. This regulatory framework is set out in a number of different prudential standards that govern the activities of ADIs.

ASIC is Australia's corporate, markets, and financial services regulator. ASIC licenses and monitors financial services businesses to ensure they operate efficiently, honestly, and fairly. ASIC administers, among other things, the following legislation and regulations: the Corporations Act 2001 (the "Corporations Act"), the Corporations Regulations 2001, and the Australian Securities and Investments Commission Act 2001 (the "ASIC Act"). Under the Corporations Act, an Australian entity that undertakes specified activities, including dealing or market making in derivatives (including swaps) is required to hold an AFSL. The AFSL regime establishes a number of general licensing obligations that all licensees must comply with. ASIC has also issued regulatory guidance which sets out its expectations of how licensees may comply with their licensing obligations in a range of situations and taking into account the nature, size, and complexity of their financial services business.

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the basis of the foreign regime as a whole.[16] In making its comparability determinations, the Commission may include conditions that take into account timing and other issues related to coordinating the implementation of reform efforts across jurisdictions.[17]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s),
- The scope and objectives of the relevant regulatory requirement(s),
- The comprehensiveness of the foreign regulator's supervisory compliance program, and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[18]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.*, the home jurisdiction's requirements do not have to be identical).[19] This approach recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis the Commission may determine that no comparability determination can be made [20] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is an SD or MSP with respect to its foreign branches, or non-registrant, to the extent applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[21] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swaps market activities may not be clearly defined, or may not

[12] *See* e.g., sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[13] *See* e.g., §§ 23.203(b) and 23.606.

[14] *See* supra note 10.

[15] Because the applicant's request and the Commissions determinations herein are based on the comparability of Australian requirements applicable to ADIs and AFSL holders, an SD or MSP that is not an ADI or AFSL holder, or is otherwise not subject to the requirements applicable to ADIs and AFSL holders upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein.

[16] 78 FR 45343.

[17] 78 FR 45343.

[18] 78 FR 45343.

[19] 78 FR 45343. The Commission's substituted compliance program would generally be available for SDR Reporting, as outlined in the Guidance, only if the Commission has direct access to all of the data elements that are reported to a foreign trade repository pursuant to the substituted compliance program. Thus, direct access to swap data is a threshold matter to be addressed in a comparability evaluation for SDR Reporting. Moreover, the Commission explains in the Guidance that, due to its technical nature, a comparability evaluation for SDR Reporting "will generally entail a detailed comparison and technical analysis." A more particularized analysis will generally be necessary to determine whether data stored in a foreign trade repository provides for effective Commission use, in furtherance of the regulatory purposes of the Dodd-Frank Act. *See* 78 FR 45345.

[20] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

[21] 78 FR 45343.

expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[22]

Finally, the Commission will generally rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities[23] thnsp: of SDs and MSPs[24] in the relevant jurisdictions.[25] Further, as stated in the Guidance, the Commission expects that an applicant would notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[26]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted compliance[27] for the Internal Business Conduct Requirements.[28]

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement[29] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for information sharing and cooperation in the context of supervising [SDs] and MSPs."[30]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[31] provide for notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[32] and include protections related

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[22] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that [SDs] and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[23] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[24] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is responsible for determining whether it is subject to the laws and regulations found comparable. Currently, there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outsida the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[25] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. Tha Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurata description of foreign laws and regulations may not be valid.

[26] 78 FR 45345.

[27] *See* 78 FR 45348–50. The Commission notes that registrants and other market participants ara responsible for determining whether substituted compliance is available pursuant to the Guidance based on tha comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[28] This notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in Australia to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in Australia.

This notice also doas not address capital adequacy because the Commission has not yet finalized rules for SDs and MSPs in this area, nor SDR Reporting. The Commission may provide a comparability determination with respect to these requirements at a later date or in a separate notice.

[29] An MOU is ona type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or, for example, as independent bilateral arrangements, statements of intent, declarations, or letters.

[30] 78 FR 45344.

[31] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. 6s(f); 17 CFR 23.203. In the Guidance, tha Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; see *also id.* at 45342 n. 461 (affirming tha Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with tha CEA and the regulations adopted pursuant thereto").

[32] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP.

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to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Internal Business Conduct Requirements that are the subject of this comparability determination, and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Internal Business Conduct Requirements that the requestor submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable and comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this notice.

As was stated in the Guidance, the Commission recognizes the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Chief Compliance Officer (§ 3.3)

Commission Requirement: Implementing section 4s(k) of the CEA, Commission regulation 3.3 generally sets forth the following requirements for SDs and MSPs:

- An SD or MSP must designate an individual as Chief Compliance Officer ("CCO");
- The CCO must have the responsibility and authority to develop the regulatory compliance policies and procedures of the SD or MSP;
- The CCO must report to the board of directors or the senior officer of the SD or MSP;
- Only the board of directors or a senior officer may remove the CCO;
- The CCO and the board of directors must meet at least once per year;
- The CCO must have the background and skills appropriate for the responsibilities of the position;
- The CCO must not be subject to disqualification from registration under sections 8a(2) or (3) of the CEA;
- Each SD and MSP must include a designation of a CCO in its registration application;
- The CCO must administer the regulatory compliance policies of the SD or MSP;
- The CCO must take reasonable steps to ensure compliance with the CEA and Commission regulations, and resolve conflicts of interest;
- The CCO must establish procedures for detecting and remediating non-compliance issues;
- The CCO must annually prepare and sign an "annual compliance report" containing: (i) A description of policies and procedures reasonably designed to ensure compliance; (ii) an assessment of the effectiveness of such policies and procedures; (iii) a description of material non-compliance issues and the action taken; (iv) recommendations of improvements in compliance policies; and (v) a certification by the CCO or CEO that, to the best of such officer's knowledge and belief, the annual report is accurate and complete under penalty of law; and
- The annual compliance report must be furnished to the CFTC within 90 days after the end of the fiscal year of the SD or MSP, simultaneously with its annual financial condition report.

Regulatory Objective: The Commission believes that compliance by SDs and MSPs with the CEA and the Commission's rules greatly contributes to the protection of customers, orderly and fair markets, and the stability and integrity of the market intermediaries registered with the Commission. The Commission expects SDs and MSPs to strictly comply with the CEA and the Commission's rules and to devote sufficient resources to ensuring such compliance. Thus, through its CCO rule, the Commission seeks to ensure firms have designated a qualified individual as CCO that reports directly to the board of directors or the senior officer of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually to the Commission and the board or senior officer on compliance of the firm.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as section 4s(k) of the CEA and Commission regulation 3.3.

- APRA prudential standard CPS 520—Fit and Proper ("CPS 520") requires the appointment of "responsible persons." CPS 520 states that responsible persons must be fit and proper, and that the ultimate responsibility for ensuring that an institution's responsible persons are fit and proper remains with the board of directors.
- ASIC Regulatory Guide 105 Licensing: Organisational competence requires AFSL licensees to appoint "responsible managers" who have direct responsibility for significant day-to-day decisions about the financial services provided, and for maintaining organizational competence of the entity. Such responsible managers must have the relevant skill and experience and be of good fame and character.
- ASIC Regulatory Guide 104 Licensing: Meeting the general obligations ("RG 104") also requires AFSL holders to allocate to a director or senior manager responsibility for overseeing the AFSL holder's compliance measures, and reporting to the governing body (including having ready access to the governing body).
- When ASIC assesses an application for an AFSL, ASIC requires applicants to describe whether their compliance arrangements are generally consistent with "Australian Standard 3806" ("AS

See 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

3806").[33] AS 3806 provides principles and guidance for designing, developing, implementing, maintaining and improving a flexible, responsive effective and measurable compliance program within an organization. Although this is a non-governmental standard, ASIC refers to AS 3806 in its regulatory guidance for AFSL licensees and asks AFSL holders to refer to the standards when complying with their regulatory obligations.

- AFSL licensees must comply with section 912A of the Corporations Act, which, among other obligations, requires that such entities: Do all things necessary to ensure that the financial services covered by the license are provided efficiently, honestly and fairly; have adequate arrangements in place for managing conflicts of interest that may arise wholly, or partially, in relation to activities undertaken by the licensee or a representative of the licensee in the provision of financial services as part of the financial services business of the licensee or the representative; comply with any conditions on the license; comply with the financial services laws; take reasonable steps to ensure that representatives comply with the financial services laws; maintain the competence to provide the financial services covered by the license; ensure that representatives are adequately trained and competent to provide those financial services; and if those financial services are provided to retail clients, have a dispute resolution system.
- AFSL licensees are also required under section 912D of the Corporations Act to report to ASIC any significant breach (or likely breach) of its regulatory obligations. ASIC Regulatory Guide 78 Breach reporting by AFS licensees expands on this obligation and requires AFSL holders to have a documented process for, amongst other things, rectifying breaches and ensuring that arrangements are in place to prevent the recurrence of the breach.
- ADIs are also required under APRA prudential standard APS 310 Audit and Related Matters ("APS 310") to provide APRA a high-level description of its risk management systems covering all major areas of risk and annually, within three months of its annual balance date, provide APRA with a declaration from its CEO endorsed by the board that attests that: they have established systems to monitor and manage those risk including, where appropriate, by setting and requiring adherence to a series of prudent limits, and by adequate and timely reporting processes; the risk management systems are operating effectively and are adequate with regard to the risks they are designed to control; and the descriptions of risk management systems provided to APRA are accurate and current.[34]

Commission Determination: The Commission finds that the provisions and requirements under the Australian regimes specified above are generally identical in intent to § 3.3 by seeking to ensure firms have designated a qualified individual as the compliance officer that reports directly to a sufficiently senior function of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually on compliance of the firm.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the CCO requirements of the provisions of Australian law and regulations specified above are comparable to and as comprehensive as § 3.3, with the exception of § 3.3(e) concerning preparing and signing an annual compliance report and § 3.3(f) concerning certifying and furnishing an annual compliance report to the Commission.

Notwithstanding that the Commission has not determined that the requirements of Australian law and regulations are comparable to and as comprehensive as §§ 3.3(e) and 3.3(f), any SD or MSP to which both § 3.3 and the Australian law and regulations specified above are applicable would generally be deemed to be in compliance with §§ 3.3(e) and (f) if that SD or MSP complies with the Australian law and regulations specified above, subject to preparing and signing an annual compliance report in accordance with § 3.3(e) and certifying and furnishing the Commission with an annual compliance report in accordance with § 3.3(f). The Commission notes that it generally expects registrants to submit required reports to the Commission in the English language.

B. Risk Management Duties (§§ 23.600—23.609)

Section 4s(j) of the CEA requires each SD and MSP to establish internal policies and procedures designed to, among other things, address risk management, monitor compliance with position limits, prevent conflicts of interest, and promote diligent supervision, as well as maintain business continuity and disaster recovery programs.[35] The Commission adopted regulations 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606 to implement the statute.[36] The Commission also adopted regulation 23.609, which requires certain risk management procedures for SDs or MSPs that are clearing members of a derivatives clearing organization ("DCO").[37] Collectively, these requirements help to establish a robust and comprehensive internal risk management program for SDs and MSPs with respect to their swaps activities,[38] which is critical to effective systemic risk management for the overall swaps market. In making its comparability determination with regard to these risk management duties, the Commission will consider each regulation individually.[39]

[33] AS 3806 is a standard published by "Standards Australia," a non-government standards organization. Australian Standards are not legal documents, but can be referenced in Australian legislation and become mandatory.

[34] Not relevant for the Commission's comparability determination herein, the applicant also referenced APRA draft prudential standard CPS 220 Risk Management ("Draft CPS 220"), which was released by APRA on May 9, 2013. This draft prudential standard, if finalized in a form similar to its draft form, will require each ADI (including SD ADIs) to have a designated compliance function that assists senior management in effectively managing compliance risks. It will also require that the compliance function be adequately staffed by appropriately trained and competent persons who have sufficient authority to perform their role effectively, and have a reporting line independent from business lines. APRA expects to finalize Draft CPS 220 prior to its implementation date of January 1, 2015.

[35] 7 U.S.C. 6s(j).

[36] *See* Final Swap Dealer and MSP Recordkeeping Rule, 77 FR 20128 (April 3, 2012) (relating to risk management program, monitoring of position limits, business continuity and disaster recovery, conflicts of interest policies and procedures, and general information availability, respectively).

[37] *See* Customer Documentation Rule, 77 FR 21278. Also, SDs must comply with Commission regulation 23.608, which prohibits SDs providing clearing services to customers from entering into agreements that would: (i) Disclose the identity of a customer's original executing counterparty; (ii) limit the number of counterparties a customer may trade with; (iii) impose counterparty-based position limits; (iv) impair a customer's access to execution of a trade on terms that have a reasonable relationship to the best terms available; or (v) prevent compliance with specified time frames for acceptance of trades into clearing.

[38] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[39] As stated above, this notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up

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1. Risk Management Program for SDs and MSPs (§ 23.600)

Commission Requirement: Implementing section 4s(j)(2) of the CEA, Commission regulation 23.600 generally requires that:

- Each SD or MSP must establish and enforce a risk management program consisting of a system of written risk management policies and procedures designed to monitor and manage the risks associated with the swap activities of the firm, including without limitation, market, credit, liquidity, foreign currency, legal, operational, and settlement risks, and furnish a copy of such policies and procedures to the CFTC upon application for registration and upon request;
- The SD or MSP must establish a risk management unit independent from the business trading unit;
- The risk management policies and procedures of the SD or MSP must be approved by the firm's governing body;
- Risk tolerance limits and exceptions therefrom must be reviewed and approved quarterly by senior management and annually by the governing body;
- The risk management program must have a system for detecting breaches of risk tolerance limits and alerting supervisors and senior management, as appropriate;
- The risk management program must account for risks posed by affiliates and be integrated at the consolidated entity level;
- The risk management unit must provide senior management and the governing body with quarterly risk exposure reports and upon detection of any material change in the risk exposure of the SD or MSP;
- Risk exposure reports must be furnished to the CFTC within five business days following provision to senior management;
- The risk management program must have a new product policy for assessing the risks of new products prior to engaging in such transactions;
- The risk management program must have policies and procedures providing for trading limits, monitoring of trading, processing of trades, and separation of personnel in the trading unit from personnel in the risk management unit; and
- The risk management program must be reviewed and tested at least annually and upon any material change in the business of the SD or MSP.

Regulatory Objective: Through the required system of risk management, the Commission seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. To this end, the Commission believes the risk management program of an SD or MSP must contain at least the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as section 4s(j)(2) of the CEA and Commission regulation 23.600.[40]

- The regulatory framework for ADIs under the Banking Act is based on the banking supervision principles published by the Basel Committee on Banking Supervision.[41] This prudential framework includes requirements (largely set out in detailed and separate prudential standards) regarding capital adequacy, credit risk, market risk, liquidity, credit quality, large exposures, associations with related entities, outsourcing, business continuity management, audit and related arrangements for prudential reporting, governance, and fit and proper management.
- In particular, APS 310 (discussed above) requires an ADI's board and management to ensure that the ADI meets prudential and statutory requirements and has management practices to limit risks to prudent levels. APS 310 mandates that the ADI's risk management practices must be detailed in descriptions of risk management systems that must be regularly reviewed and updated, at least annually, to take account of changing circumstances.
- APRA Prudential standard APS 116 Capital Adequacy: Market Risk ("APS 116") states that the board, or a board committee, of an ADI must ensure that the ADI has in place adequate systems to identify, measure and manage market risk, including identifying responsibilities, providing adequate separation of duties and avoiding conflicts of interest.
- For certain trading positions, APS 116 states that an ADI must have "clearly defined policies and procedures for the active management of positions such that: positions are managed on a trading desk; position limits are set and monitored for appropriateness; positions are marked-to-market daily and when marking-to-model the parameters are assessed on a daily basis; and positions are reported to senior management as an integral part of the institution's risk management process."
- If an ADI has received approval to apply an "internal model" for market risk, as opposed to the "standard method" of calculating capital requirements, APS 116 requires the ADI to have an independent risk control unit that is responsible for the design and implementation of the ADI's market risk management system. The risk control unit must produce and analyze daily reports on the output of the ADI's risk measurement model, including an evaluation of limit utilization. This risk control unit must be independent from business trading and other risk taking units and must report directly to senior management of the ADI.
- If an ADI has received approval to apply an "internal model" for market risk, APS 116 states that the board or a board committee and senior management of an ADI must be actively involved in the risk control process. Daily reports must be prepared by the independent risk control unit and must be reviewed by a level of management with sufficient seniority and authority to enforce reductions of positions.
- APS 116 states that an ADI must ensure that an independent review of the risk measurement system and

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the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in Australia to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in Australia.

[40] Not relevant for the Commission's comparability determination herein, the applicant also referenced Draft CPS 220. Draft CPS 220 seeks to introduce additional requirements in respect of the risk management framework for ADIs. APRA expects to finalize CPS 220 prior to its implementation date of January 1, 2015. Under Draft CPS 220, an APRA-regulated institution must have policies and procedures that provide the board with a comprehensive institution-wide view of its material risks. Draft CPS 220 also requires the risk management function of an ADI be "operationally independent" and must be headed by a designated Chief Risk Officer ("CRO"). The CRO must be involved in, and have the authority to provide effective challenge to, activities and decisions that may materially affect the institution's risk profile.

[41] The Corporations Act requires AFSL holders to comply with risk management requirements, however, this requirement does not apply where an entity is regulated by APRA. *See* section 912A(1)(h).

overall risk management process is carried out initially (i.e., at the time when model approval is sought) and then regularly as part of the ADI's internal audit process.

Commission Determination: The Commission finds that the provisions of Australian law and regulations specified above are generally identical in intent to § 23.600 by requiring a system of risk management that seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. Specifically, the Commission finds that the Australian provisions specified above comprehensively require SDs and MSPs to establish risk management programs containing the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the risk management program requirements of the provisions of Australian law and regulations specified above, are comparable to and as comprehensive as § 23.600, with the exception of § 23.600(c)(2) concerning the requirement that each SD and MSP produce a quarterly risk exposure report and provide such report to its senior management, governing body, and the Commission.

Notwithstanding that the Commission has not determined that the requirements of Australian law and regulations are comparable to and as comprehensive as § 23.600(c)(2), any SD or MSP to which both § 23.600 and the Australian law and regulations specified above are applicable would generally be deemed to be in compliance with § 23.600(c)(2) if that SD or MSP complies with the Australian law and regulations specified above, subject to compliance with the requirement that it produce quarterly risk exposure reports and provide such reports to its senior management, governing body, and the Commission in accordance with § 23.600(c)(2). The Commission notes that it generally expects reports furnished to the Commission by registrants to be in the English language.

2. Monitoring of Position Limits (§ 23.601)

Commission Requirement: Implementing section 4s(j)(1) of the CEA, Commission regulation 23.601 requires each SD or MSP to establish and enforce written policies and procedures that are reasonably designed to monitor for, and prevent violations of, applicable position limits established by the Commission, a designated contract market ("DCM"), or a swap execution facility ("SEF").[42] The policies and procedures must include an early warning system and provide for escalation of violations to senior management (including the firm's governing body).

Regulatory Objective: Generally, position limits are implemented to ensure market integrity, fairness, orderliness, and accurate pricing in the commodity markets. Commission regulation 23.601 thus seeks to ensure that SDs and MSPs have established the necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by the Commission, a DCM, or a SEF. As part of its Risk Management Program, § 23.601 is intended to ensure that established position limits are not breached by the SD or MSP.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as section 4s(j)(1) of the CEA and Commission regulation 23.601.

- Section 912A(1)(ca) of the Corporations Act, which requires AFSL holders to take reasonable steps to ensure its representatives comply with the financial services laws, which would include regulatory position limits.
- APS 310 (discussed above) requires an ADI's board and management to ensure that the ADI meets prudential and statutory requirements and has management practices to limit risks to prudent levels.

In addition to the foregoing, the applicant also submitted various guidelines and required best practices concerning the setting of internal risk tolerance limits and monitoring for compliance with such internal limits. Although the Commission recognizes these as prudent risk management practices, the Commission does not believe that these provisions are comparable to § 23.601 because § 23.601 requires monitoring for compliance with external position limits set by the Commission, a DCM, or a SEF.

Commission Determination: The Commission finds that the Australian provisions specified above are generally identical in intent to § 23.601 by requiring SDs and MSPs to establish necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by applicable laws and regulations, including those of the Commission, a DCM, or a SEF. Specifically, the Commission finds that the provisions of Australian law and regulations specified above, while not specific to the issue of position limit compliance, nevertheless comprehensively require SDs and MSPs to monitor for regulatory compliance generally, which includes monitoring for compliance with position limits set pursuant to applicable law and the responsibility of senior management (including the board of directors) for such compliance.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the compliance monitoring requirements of Australian law and regulations, as specified above, are comparable to and as comprehensive as § 23.601. For the avoidance of doubt, the Commission notes that this determination may not be relied on to relieve an SD or MSP from its obligation to strictly comply with any applicable position limit established by the Commission, a DCM, or a SEF.

3. Diligent Supervision (§ 23.602)

Commission Requirement: Commission regulation 23.602 implements section 4s(h)(1)(B) of the CEA and requires each SD and MSP to establish a system to diligently supervise all activities relating to its business performed by its partners, members, officers, employees, and agents. The system must be reasonably designed to achieve compliance with the CEA and CFTC regulations. Commission regulation 23.602 requires that the supervisory system must specifically designate qualified persons with authority to carry out the supervisory responsibilities of the SD or MSP for all activities relating to its business as an SD or MSP.

Regulatory Objective: The Commission's diligent supervision rule seeks to ensure that SDs and MSPs

[42] The setting of position limits by the Commission, a DCM, or a SEF is subject to requirements under the CEA and Commission regulations other than § 23.601. The setting of position limits and compliance with such limits is not subject to the Commission's substituted compliance regime.

strictly comply with the CEA and the Commission's rules. To this end, through § 23.602, the Commission seeks to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as section 4s(h)(1)(B) of the CEA and Commission regulation 23.602.

- CPS 520 (discussed above) sets forth the fitness requirements for all APRA regulated institutions. These standards apply to all directors and senior managers of an ADI as well as other "responsible persons." The applicable key requirements of this prudential standard are: an ADI must have a Fit and Proper policy that meets certain standards; the fitness and propriety of a responsible person must generally be assessed prior to initial appointment and then re-assessed annually; and an ADI must take steps to ensure that a person is not appointed to, or does not continue to hold, a responsible person position for which they are not qualified.
- Section 912A(1)(ca) of the Corporations Act requires that an AFSL licensee take reasonable steps to ensure that its representatives comply with the financial services laws.
- RG 104 (discussed above) sets forth guidance for an AFSL licensee with respect to supervision. These regulatory guidelines require that an AFSL licensee have measures for monitoring and supervising their representatives to determine whether they are complying with the financial services laws. They also require that an AFSL licensee take measures to ensure that their representatives who provide financial services have, and maintain the necessary knowledge and skills, to competently provide those services.

Commission Determination: The Commission finds that the provisions of Australian law and regulations specified above are generally identical in intent to § 23.602 because such standards seek to ensure that SDs and MSPs strictly comply with applicable law, which would include the CEA and the Commission's regulations. Through the provisions specified above, Australian law and regulations seek to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with applicable law, which would include the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the internal supervision requirements of the provisions of Australian law and regulations, as specified above, are comparable to and as comprehensive as § 23.602.

4. Business Continuity and Disaster Recovery (§ 23.603)

Commission Requirement: To ensure the proper functioning of the swaps markets and the prevention of systemic risk more generally, Commission regulation 23.603 requires each SD and MSP, as part of its risk management program, to establish a business continuity and disaster recovery plan that includes procedures for, and the maintenance of, back-up facilities, systems, infrastructure, personnel, and other resources to achieve the timely recovery of data and documentation and to resume operations generally within the next business day after the disruption.

Regulatory Objective: Commission regulation 23.603 is intended to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, this requirement seeks to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan within one business day, if necessary.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as Commission regulation 23.603.

APRA prudential standard CPS 232 Business Continuity Management ("CPS 232") requires each ADI to implement a whole-of-business approach to business continuity management. Specifically, CPS 232 states that:

- A regulated institution must identify, assess, and manage potential business continuity risks to ensure that it is able to meet its financial and service obligations to its depositors, policyholders and other creditors;
- The board of a regulated institution must consider business continuity risks and controls as part of its overall risk management systems and approve a Business Continuity Management Policy;
- A regulated institution must develop and maintain a Business Continuity Plan that documents procedures and information which enable the regulated institution to manage business disruptions;
- A regulated institution must review the Business Continuity Plan annually and periodically arrange for its review by the internal audit function or an external expert; and
- A regulated institution must notify APRA in the event of certain disruptions.

Commission Determination: The Commission finds that the provisions of Australian law and regulations specified above are generally identical in intent to § 23.603 because such standards seek to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, the Commission finds that the provisions of Australian law and regulations specified above seek to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan in a timely manner.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the business continuity and disaster recovery requirements of the provisions of Australian law and regulations, as specified above, are comparable to and as comprehensive as § 23.603.

5. Conflicts of Interest (§ 23.605)

Commission Requirement: Section 4s(j)(5) of the CEA and Commission regulation 23.605(c) generally require each SD or MSP to establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any commodity or swap are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision.

In addition, section 4s(j)(5) of the CEA and Commission regulation 23.605(d)(1) generally prohibits an SD or MSP from directly or indirectly interfering with or attempting to influence the decision of any clearing unit of any affiliated clearing member of a DCO to provide

clearing services and activities to a particular customer, including:

- Whether to offer clearing services to a particular customer;
- Whether to accept a particular customer for clearing derivatives;
- Whether to submit a customer's transaction to a particular DCO;
- Whether to set or adjust risk tolerance levels for a particular customer; or
- Whether to set a customer's fees based on criteria other than those generally available and applicable to other customers.

Commission regulation 23.605(d)(2) generally requires each SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of any affiliated clearing member of a DCO to reasonably ensure compliance with the Act and the prohibitions set forth in § 23.605(d)(1) outlined above.

The Commission observes that § 23.605(d) works in tandem with Commission regulation 1.71, which requires FCMs that are clearing members of a DCO and affiliated with an SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of the FCM to reasonably ensure compliance with the Act and the prohibitions set forth in § 1.71(d)(1), which are the same as the prohibitions set forth in § 23.605(d)(1) outlined above.

Finally, § 23.605(e) requires that each SD or MSP have policies and procedures that mandate the disclosure to counterparties of material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a swap execution facility or DCM or to clear a derivative through a DCO.

Regulatory Objective: Commission regulation 23.605(c) seeks to ensure that research provided to the general public by an SD or MSP is unbiased and free from the influence of the interests of an SD or MSP arising from the SD's or MSP's trading business.

In addition, the § 23.605(d) (working in tandem with § 1.71) seeks to ensure open access to the clearing of swaps by requiring that access to and the provision of clearing services provided by an affiliate of an SD or MSP are not influenced by the interests of an SD's or MSP's trading business.

Finally, § 23.605(e) seeks to ensure equal access to trading venues and clearinghouses, as well as orderly and fair markets, by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as Commission regulation 23.605(c).

- Section 912A(1)(aa) of the Corporations Act requires AFSL licensees to have adequate arrangements for the management of conflicts of interest that may arise wholly, or partially, in relation to activities undertaken by a licensee or a representative of the licensee in the provision of financial services.
- ASIC Regulatory Guide 181 Licensing: Managing conflicts of interest and ASIC Regulatory Guide 79 Research report providers: Improving the quality of investment research (specific to research reports provided in Australia), set out ASIC's expectations regarding how financial service licensees are to manage conflicts of interest that arise in relation to the financial services that they provide. The conflicts management obligation requires that all conflicts of interest be adequately managed, recognizing that many conflicts of interest can be managed by a combination of internal controls and disclosures. Where conflicts cannot be adequately managed through internal controls and/or disclosure, the ASIC guidelines require that an AFSL holder must avoid the conflict or refrain from providing the affected financial service.
- Section 941A of the Corporations Act requires AFSL licensees to provide a Financial Services Guide to retail clients if they provide a financial service to the client.
- Section 942B(2)(f) of the Corporations Act states that the Financial Services Guide must provide disclosures about relationships that may influence the provision of the financial service.[43]

The applicant has represented to the Commission that ASIC and APRA, in the process of their oversight and enforcement of the foregoing Australian law and regulations for ADIs and ASFL licensees, would require any SD or MSP subject to such law and regulations to resolve or mitigate conflicts of interests in the provision of clearing services by a clearing member of a DCO that is an affiliate of the SD or MSP, or the decision of a counterparty to execute a derivative on a SEF or DCM, or clear a derivative through a DCO, through appropriate information firewalls and disclosures.

Commission Determination: The Commission finds that the provisions of Australian law and regulations specified above with respect to conflicts of interest that may arise in producing or distributing research are generally identical in intent to § 23.605(c) because such standards seek to ensure that research provided to the general public by an SD is unbiased and free from the influence of the interests of an SD arising from the SD's trading business.

With respect to conflicts of interest that may arise in the provision of clearing services by an affiliate of an SD or MSP, the Commission further finds that although the general conflicts of interest prevention requirements under the Australian law and regulations specified above do not require with specificity that access to and the provision of clearing services provided by an affiliate of an SD or MSP not be improperly influenced by the interests of an SD's or MSP's trading business, such general requirements would require prevention and remediation of such improper influence when recognized or discovered. Thus such standards would ensure open access to clearing.

Finally, although not as specific as the requirements of § 23.605(e) (Undue influence on counterparties), the Commission finds that the general disclosure requirements of the Australian law and regulations specified above would ensure equal access to trading venues and clearinghouses by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the provisions of Australian law and regulations specified above in relation to conflicts of interest are comparable to and as comprehensive as § 23.605.

6. Availability of Information for Disclosure and Inspection (§ 23.606)

Commission Requirement: Commission regulation 23.606 implements sections 4s(j)(3) and (4) of the CEA, and requires each SD and MSP to disclose to the Commission, and an

[43] In addition to the foregoing, the applicant referenced Draft CPS 220. This draft prudential standard, if finalized in a form similar to its draft form, will require each ADI (including SD ADIs) to have policies and procedures for identifying, monitoring, and managing potential and actual conflicts of interest.

SD's or MSP's U.S. prudential regulator (if any) comprehensive information about its swap activities, and to establish and maintain reliable internal data capture, processing, storage, and other operational systems sufficient to capture, process, record, store, and produce all information necessary to satisfy its duties under the CEA and Commission regulations. Such systems must be designed to provide such information to the Commission and an SD's or MSP's U.S. prudential regulator within the time frames set forth in the CEA and Commission regulations and upon request.

Regulatory Objective: Commission regulation 23.606 seeks to ensure that each SD and MSP captures and maintains comprehensive information about their swap activities, and is able to retrieve and disclose such information to the Commission and its U.S. prudential regulator, if any, as necessary for compliance with the CEA and the Commission's regulations and for purposes of Commission oversight, as well as oversight by the SD's or MSP's U.S. prudential regulator, if any.

The Commission observes that it would be impossible to meet the regulatory objective of § 23.606 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.606 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as Commission regulation 23.606.

Section 912C of the Corporations Act and sections 29–33 of the ASIC Act enable ASIC to gather information from AFSL licensees, including:

- A statement containing specified information about the financial services provided by the AFSL holder or its representatives, or the financial services business carried on by the licensee;
- Inspection of books without charge;
- Issuance of a notice to a body corporate to produce books about the affairs of the body corporate;
- Issuance of a notice to a person who carries out a financial services business to produce books relating to, among other things, a dealing in financial products, or the character or financial position of the business;
- Issuance of a notice to produce books relating to the supply of financial services; and
- Issuance of a notice to produce documents in the person's possession that relate to the affairs of the body corporate.

In addition, Section 988A of the Corporations Act requires AFSL license holders to keep financial records that correctly record and explain the transactions and financial position of the financial services business carried out by the licensee.

Part 2.3 of the ASIC Derivative Transaction Rules (Reporting) 2013 places certain requirements on reporting entities (which includes the five SD ADIs as reporting entities from October 1, 2013). Specifically, Rule 2.3.1 requires reporting entities to keep records in relation to OTC derivatives transactions (including swaps) that enable the reporting entity to demonstrate it has complied with the Derivative Transaction Rules, and must keep the records for a period of at least five years from the date the record is made or amended. Reporting entities must also keep a record of all information that it is required to be reported under such rules.

Rule 2.3.2 further requires a reporting entity to, on request by ASIC, provide ASIC within a reasonable time with records or other information relating to compliance with or determining whether there has been compliance with the Rules.

Commission Determination: The Commission finds that the Australian law and regulations specified above are generally identical in intent to § 23.606 because such standards seek to ensure that each SD and MSP captures and stores comprehensive information about their swap activities, and are able to retrieve and disclose such information as necessary for compliance with applicable law and for purposes of regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the Australian law and regulations with respect to the availability of information for inspection and disclosure, as specified above, are comparable to, and as comprehensive as, § 23.606, with the exception of § 23.606(a)(2) concerning the requirement that an SD or MSP make information required by § 23.606(a)(1) available promptly upon request to Commission staff and the staff of an applicable U.S. prudential regulator. The applicant has not submitted any provision of law or regulations applicable in Australia upon which the Commission could make a finding that SDs and MSPs would be required to retrieve and disclose comprehensive information about their swap activities to the Commission or any U.S. prudential regulator as necessary for compliance with the CEA and Commission regulations, and for purposes of Commission oversight and the oversight of any U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of Australian law and regulations are comparable to and as comprehensive as § 23.606(a)(2), any SD or MSP to which both § 23.606 and the Australian law and regulations specified above are applicable would generally be deemed to be in compliance with § 23.606(a)(2) if that SD or MSP complies with the Australian law and regulations specified above, subject to compliance with the requirement that it produce information to Commission staff and the staff of an applicable U.S. prudential regulator in accordance with § 23.606(a)(2).

7. Clearing Member Risk Management (§ 23.609)

Commission Requirement: Commission regulation 23.609 generally requires each SD or MSP that is a clearing member of a DCO to:

- Establish risk-based limits based on position size, order size, margin requirements, or similar factors;
- Screen orders for compliance with the risk-based limits;
- Monitor for adherence to the risk-based limits intra-day and overnight;
- Conduct stress tests under extreme but plausible conditions of all positions at least once per week;
- Evaluate its ability to meet initial margin requirements at least once per week;
- Evaluate its ability to meet variation margin requirements in cash at least once per week;
- Evaluate its ability to liquidate positions it clears in an orderly manner, and estimate the cost of liquidation; and
- Test all lines of credit at least once per year.

Regulatory Objective: Through Commission regulation 23.609, the Commission seeks to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds. Effective risk management by SDs and MSPs that are clearing members is essential to achieving these objectives. A failure of risk management can cause

a clearing member to become insolvent and default to a DCO. Such default can disrupt the markets and the clearing system and harm customers.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as Commission regulation 23.609.

- The regulatory framework for ADIs under the Banking Act is based on the banking supervision principles published by the Basel Committee on Banking Supervision.[44] This prudential framework includes requirements (largely set out in detailed and separate prudential standards) regarding capital adequacy, credit risk, market risk, liquidity, credit quality, large exposures, associations with related entities, outsourcing, business continuity management, audit and related arrangements for prudential reporting, governance, and fit and proper management.
- In particular, APS 310 (discussed above) requires an ADI's board and management to ensure that the ADI meets prudential and statutory requirements and has management practices to limit risks to prudent levels. APS 310 mandates that the ADI's risk management practices must be detailed in descriptions of risk management systems that must be regularly reviewed and updated, at least annually, to take account of changing circumstances.
- APRA Prudential standard APS 116 Capital Adequacy: Market Risk ("APS 116") states that the board, or a board committee, of an ADI must ensure that the ADI has in place adequate systems to identify, measure and manage market risk, including identifying responsibilities, providing adequate separation of duties and avoiding conflicts of interest.
- For certain trading positions, APS 116 states that an ADI must have "clearly defined policies and procedures for the active management of positions such that: Positions are managed on a trading desk; position limits are set and monitored for appropriateness; positions are marked-to-market daily and when marking-to-model the parameters are assessed on a daily basis; and positions are reported to senior management as an integral part of the institution's risk management process.
- If an ADI has received approval to apply an "internal model" for market risk, as opposed to the "standard method" of calculating capital requirements, APS 116 requires the ADI to have an independent risk control unit that is responsible for the design and implementation of the ADI's market risk management system. The risk control unit must produce and analyze daily reports on the output of the ADI's risk measurement model, including an evaluation of limit utilization. This risk control unit must be independent from business trading and other risk taking units and must report directly to senior management of the ADI.
- If an ADI has received approval to apply an "internal model" for market risk, APS 116 states that the board or a board committee and senior management of an ADI must be actively involved in the risk control process. Daily reports must be prepared by the independent risk control unit and must be reviewed by a level of management with sufficient seniority and authority to enforce reductions of positions.
- APS 116 states that an ADI must ensure that an independent review of the risk measurement system and overall risk management process is carried out initially (i.e., at the time when model approval is sought) and then regularly as part of the ADI's internal audit process.

Further, on June 4, 2013, APRA issued a letter to all ADIs, including the Australian SDs outlining the framework for the application of risk management requirements to the Australian banks' membership of CCPs. Such a framework should include, at a minimum: application of appropriate systems and controls to monitor, on a continuing basis, the risk that membership of and conduct of business through a CCP or multiple CCPs may create and to manage such risk. This would include application of limits on potential risk exposures. These clearly articulated conditions together with APRA's prudential standards are designed to achieve a comparable regulatory outcome as Commission regulation 23.609.

Specifically, APRA has represented to the Commission that, in the process of its oversight and enforcement of the foregoing Australian law, regulations, and prudential standards, any SD or MSP subject to such standards that is a clearing member of a DCO would be expected to have established risk-based limits and a compliance and assessment framework for these limits consistent with the Commission's requirements for a clearing member and set out in the SD's or MSP's risk management policy framework. APRA would expect banks in Australia to adhere to their risk limit policies and any targeted review would examine the banks' risk management policy framework that captures these regulatory obligations.

Commission Determination: The Commission finds that the Australian law and regulations specified above are generally identical in intent to § 23.609 because such standards seek to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds.

The Commission notes that the Australian law and regulations specified above are not as specific as § 23.609 with respect to ensuring that SDs and MSPs that are clearing members of a DCO establish detailed procedures and limits for clearing member risk management purposes. Nevertheless, the Commission finds that the general requirements under the Australian law and regulations specified above, implemented in the context of clearing member risk management and pursuant to the representations of ASIC and APRA, meet the Commission's regulatory objective specified above.

Based on the foregoing and the representations above, the Commission hereby determines that the clearing member risk management requirements of the Australian law and regulations specified above are comparable to and as comprehensive as § 23.609.

C. Swap Data Recordkeeping (§§ 23.201 and 23.203)

Commission Requirement: Sections 4s(f)(1)(B) and 4s(g)(1) of the CEA, and Commission regulation 23.201 generally require SDs and MSPs to retain records of each transaction, each position held, general business records (including records related to complaints and sales and marketing materials), records related to governance, financial records, records of data reported to SDRs, and records of real-time reporting data along with a record of the date and time the SD or MSP made such reports. Transaction records must be kept in a form and manner identifiable and searchable by transaction and counterparty.

Commission regulation 23.203, requires SDs and MSPs to maintain records of a swap transaction until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction, and for a period of five years after such date. Records must be "readily accessible" for the first 2 years of the 5 year retention period (consistent with § 1.31).

[44] The Corporations Act requires AFSL holders to comply with risk management requirements, however, this requirement does not apply where an entity is regulated by APRA. *See* section 912A(1)(h).

The Commission notes that the comparability determination below with respect to §§ 23.201 and 23.203 encompasses both swap data recordkeeping generally and swap data recordkeeping relating to complaints and marketing and sales materials in accordance with § 23.201(b)(3) and (4).[45]

Regulatory Objective: Through the Commission's regulations requiring SDs and MSPs to keep comprehensive records of their swap transactions and related data, the Commission seeks to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

The Commission's regulations require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

By requiring comprehensive records of swap data, the Commission seeks to ensure that SDs and MSPs employ effective risk management, and strictly comply with Commission regulations. Further, such records facilitate effective regulatory oversight.

The Commission observes that it would be impossible to meet the regulatory objective of §§ 23.201 and 23.203 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.203 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Australian Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Australia are in full force and effect in Australia, and comparable to and as comprehensive as sections 4s(f)(1)(B) and 4s(g)(1) of the CEA and §§ 23.201 and 23.203.

- Section 286 of the Corporations Act requires firms to keep financial records that correctly record and explain its transactions, financial position and performance for 7 years after the transactions are completed.
- Section 988A of the Corporations Act requires AFSL licensees to keep financial records that correctly record and explain the transactions and financial position of the licensee's financial services business.
- Section 988E of the Corporations Act specifies a list of categories of information to be shown in the records of an AFSL licensee, including records of all money received or paid by the licensee; acquisitions and disposals of financial products, the charges and credits arising from them, and the names of the person acquiring or disposing of each of those products; all income from commissions, interest and other sources and all payments of interest, commissions and other expenses; and records pertaining to the securities or managed investment products that are the property of the licensee or held by the licensee for other persons.
- Corporations regulation 7.8.11 further specifies categories of information to be shown in records, including all financial products dealt with by the AFSL licensee under instructions from another person; and records pertaining to property held by the licensee for another person.
- Corporations regulation 7.8.12 further specifies categories of information to be shown in records, including separate particulars of every transaction by the AFSL licensee, the date of such transactions, and copies of acknowledgments of the receipt of financial products or documents of title to financial products.

Part 2.3 of the ASIC Derivative Transaction Rules (Reporting) 2013 places certain requirements on reporting entities (which includes the five SD ADIs as reporting entities from October, 1 2013). Specifically, Rule 2.3.1 requires reporting entities to keep records in relation to OTC derivatives transactions (including swaps) that enable the reporting entity to demonstrate it has complied with the Derivative Transaction Rules, and must keep the records for a period of at least five years from the date the record is made or amended. Reporting entities must also keep a record of all information that it is required to be reported under such rules.

Rule 2.3.2 further requires a reporting entity to, on request by ASIC, provide ASIC within a reasonable time with records or other information relating to compliance with or determining whether there has been compliance with the Rules.

Commission Determination: The Commission finds that the provisions of Australian law and regulations specified above are generally identical in intent to §§ 23.201 and 23.203 because such provisions seek to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

In addition, the Commission finds that the provisions of Australian law and regulations specified above require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

Finally, the Commission finds that the provisions of Australian law and regulations specified above, by requiring comprehensive records of swap data, seek to ensure that SDs and MSPs employ effective risk management, seek to ensure that SDs and MSPs strictly comply with applicable regulatory requirements (including the CEA and Commission regulations), and that such records facilitate effective regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements of Australian law and regulation with respect to swap data recordkeeping, as specified above, are comparable to, and as comprehensive as, §§ 23.201 and 23.203, with the exception of § 23.203(b)(2) concerning the requirement that an SD or MSP make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator. The applicant has not submitted any provision of Australian law or regulation upon which the Commission could make a finding that SDs and MSPs would be required to make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of Australian law and regulations are comparable to and as comprehensive as § 23.203(b)(2), any SD or MSP to which both § 23.203 and the Australian law and regulations specified above are applicable would generally be deemed to be in compliance with § 23.203(b)(2) if that SD or MSP complies with the Australian law and regulations specified above, subject to compliance with the requirement that it make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator in accordance with § 23.203(b)(2).

[45] *See* the Guidance for a discussion of the availability of substituted compliance with respect to swap data recordkeeping, 78 FR 45332–33.

Issued in Washington, DC on December 20, 2013, by the Commission.

Melissa D. Jurgens,

Secretary of the Commission.

Appendices to Comparability Determination for Australia: Certain Entity-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler and Commissioners Chilton and Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Dissenting Statement of Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) Are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States * * *"[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad category-by-category basis, should form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: the differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap Regulations ("Exemptive Order"),[9] the

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[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

[3] CEA section 2(i); 7 U.S.C. 2(i).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] *http://www.cftc.gov/PressRoom/PressReleases/pr6678–13.*

[6] *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf.* The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the full Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) The Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process; (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30974 Filed 12–26–13; 8:45 am]

BILLING CODE 6351–01–P

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

[10] *http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomalia-29.*

[11] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for the European Union: Certain Transaction-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Comparability Determination for Certain Requirements under the European Market Infrastructure Regulation.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a joint request by the European Commission ("EC") and the European Securities and Markets Authority ("ESMA") that the Commission determine that laws and regulations applicable in the European Union ("EU") provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to swap dealers ("SDs") and major swap participants ("MSPs") registered with the Commission: (i) swap trading relationship documentation; (ii) swap portfolio reconciliation and compression; (iii) trade confirmation; and (iv) daily trading records (collectively, the "Business Conduct Requirements").

DATES: *Effective Date:* This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202–418–5977, *gbarnett@cftc.gov,* Frank Fisanich, Chief Counsel, 202–418–5949, *ffisanich@cftc.gov,* and Ellie Jester, Special Counsel, 202–418–5874, *ajester@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" ("Guidance").[1] In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations,78 FR 909 (Jan. 7, 2013).

Exemptive Order Regarding Compliance with Certain Swap Regulations (the "Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs (and foreign branches of U.S. SDs and MSPs) in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Transaction-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3] However, the Commission provided only transitional relief from the real-time public reporting requirements under part 43 of the Commission's regulations until September 30, 2013, stating that "it would not be in the public interest to further delay reporting under part 43 . . . ."[4] Similarly, the Commission provided transitional relief only until October 10, 2013, from the clearing and swap processing requirements (as described in the Guidance), stating that, "[b]ecause SDs and MSPs have been committed to clearing their [credit default swaps] and interest rate swaps for many years, and indeed have been voluntarily clearing for many years, any further delay of the Commission's clearing requirement is unwarranted."[5] The Commission did not make any comparability determination with respect to clearing and swap processing prior to October 10, 2013, or real-time public reporting prior to September 30, 2013.

On May 7, 2013, the EC and ESMA (collectively, the "applicant") submitted a request that the Commission determine that laws and regulations applicable in the EU provide a sufficient basis for an affirmative finding of comparability with respect to certain Transaction-Level Requirements, including the Business Conduct Requirements.[6] The applicant provided Commission staff with an updated submission on August 6, 2013. On November 11, 2013, the application was further supplemented with corrections and additional materials. The following is the Commission's analysis and determination regarding the Business Conduct Requirements, as detailed below.

In addition to the Business Conduct Requirements described below, the applicant also requested a comparability determination with respect to law and regulations applicable in the EU governing (1) clearing and swap processing;[7] and (2) real-time public reporting. The Commission declines to take up the request for such comparability determination at this time due to the Commission's view that there are not laws or regulations applicable in the EU to compare with the requirements of the Commission's regulations on mandatory clearing and swap processing, and real-time public reporting. The Commission may address these requests in a separate notice at a later date in consequence of further developments in the law and regulations applicable in the EU.

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act[8] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[9]

In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the Commission.[10] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally describes the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission established a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant

[2] 78 FR 43785 (July 22, 2013).

[3] The Transaction-Level Requirements under the Exemptive Order consist of 17 CFR 37.12, 38.11, 23.202, 23.205, 23.400–451, 23.501, 23.502, 23.503, 23.504, 23.505, 23.506, 23.610, and parts 43 and 50 of the Commission's regulations.

[4] *See* id. at 43789.

[5] *See* id. at 43790.

[6] For purposes of this notice, the Business Conduct Requirements consist of 17 CFR 23.202, 23.501, 23.502, 23.503, and 23.504.

[7] According to the most recent Financial Stability Board Progress Report, the EU is scheduled to have a clearing requirement by Q3 2014. That report also states that the EU is scheduled to begin authorizing CCPs in Q4 2013, issue its first clearing determinations in Q1 2014, and adopt central clearing Regulatory Technical Standards (RTS) in Q2 2014 (OTC Derivatives Working Group, "OTC Derivatives Market Reforms: Sixth Progress Report on Implementation," Financial Stability Board, Sept. 2, 2013). Under EMIR, ESMA would determine which swaps would be subject to mandatory clearing according to provisions that are comparable to those set forth in Commission regulation 39.5(b). A clearing requirement would apply to financial entities, as well as to non-financial entities whose swap activity exceeds a certain threshold. ESMA's "Discussion Paper, The Clearing Obligation under EMIR" (July 2013) describes the standardized swaps that could be subject to a clearing requirement. Such swaps include the interest rate and credit default swaps covered by the Commission's clearing requirement (Commission regulation 50.4), other credit default swap indices, non-deliverable forwards that may be included in a Commission clearing requirement, and many other swaps including OTC equity index derivatives cleared only through European central counterparties, some of which are not Commission-registered derivatives clearing organizations.

[8] Public Law 111–203, 124 Stat. 1376 (2016).

[9] 7 U.S.C. 2(i).

[10] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site. (*http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm.*)

factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[11]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[12]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[13] The Commission's direct access to the books and records required to be maintained by an SD or MSP registered with the Commission is a core requirement of the CEA[14] and the Commission's regulations,[15] and is a condition to registration.[16]

III. Regulation of SDs and MSPs in the EU

On May 7, 2013, the EC and ESMA submitted a request that the Commission assess the comparability of laws and regulations applicable in the EU with the requirements of the CEA and the Commission's regulations, and that a determination be made on the extent to which SDs and MSPs in the EU can rely on substituted compliance.[17] The applicant provided Commission staff with an updated submission on August 6, 2013. On November 11, 2013, the application was further supplemented with corrections and additional materials.

As represented to the Commission by the applicant, swap activities in the EU member states is governed primarily by the European Market Infrastructure Regulation ("EMIR").[18]

EMIR and the Regulatory Technical Standards ("RTS") are regulations with immediate, binding, and direct effect in all EU member states (*i.e.*, no transposition into domestic law is required). EMIR entered into force on August 16, 2012.

Commission Delegated Regulation (EU) No 149/2013 of December 19, 2012 supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to regulatory technical standards on indirect clearing arrangements, the clearing obligation, the public register, access to a trading venue, non-financial counterparties, and risk mitigation techniques for OTC derivatives contracts not cleared by a central counterparty ("CCP") ("OTC RTS") entered into force on March 15, 2013.

It is helpful to note certain terminology used in EMIR:

- *Financial counterparties ("FCs")*, Article 2(8) EMIR: all types of counterparties established in the EU—regardless of size or activity—that are financial in nature and authorized as such: credit institutions, insurers/reinsurers, pension funds, and hedge funds.
- *Non-financial counterparties ("NFCs")*, Article 2(9) EMIR: all types of counterparties established in the EU that do not meet the definition of an FC (*e.g.*, corporates, certain SPVs).
- *Non-financial counterparties above the clearing threshold ("NFCs+"), Non-financial counterparties below the clearing threshold ("NFCs-"):*
- The clearing thresholds are calculated at the group level and are as follows:

(a) EUR 1 billion in gross notional value for OTC credit derivative contracts;

(b) EUR 1 billion in gross notional value for OTC equity derivative contracts;

(c) EUR 3 billion in gross notional value for OTC interest rate derivative contracts;

(d) EUR 3 billion in gross notional value for OTC foreign exchange derivative contracts; and

(e) EUR 3 billion in gross notional value for OTC commodity derivative contracts and other OTC derivative contracts not provided for under points (a) to (d).

However, transactions objectively measurable as reducing risks directly relating to the commercial activity or treasury financing activity of the NFC or its group (*i.e.*, hedges) do not count towards the clearing threshold.[19] Under the hedging definition both portfolio and macro hedging are allowed.

Certain requirements of EMIR and the RTS are subject to delayed implementation. EMIR Article 11 and

[11] 78 FR 45342–45345.

[12] *See* the Guidance, 78 FR 45342–44.

[13] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as an SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. *See* id. at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

[14] *See* e.g., sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[15] *See* e.g., §§ 23.203(b) and 23.606.

[16] *See* supra note 13.

[17] On July 11, 2013, the Commission staff issued a no-action letter related to EU rules on risk mitigation. *See* No-Action Relief for Registered Swap Dealers and Major Swap Participants from Certain Requirements under Subpart I of Part 23 of Commission Regulations in Connection with Uncleared Swaps Subject to Risk Mitigation Techniques under EMIR, CFTC Letter No. 13–45 (July, 11, 2013) ("Risk Mitigation Letter"). The Commission staff found that the Commission and the EU have essentially identical rules in important areas of risk mitigation for the largest counterparty swap market participants. Specifically, the Commission staff determined that under EMIR, the EU has adopted risk mitigation rules that are essentially identical to certain provisions of the Commission's business conduct standards for SDs and MSPs. In areas such as confirmation, portfolio reconciliation, portfolio compression, valuation, and dispute resolution, the Commission staff found that the respective regimes are essentially identical. The Commission staff determined that where a swap/OTC derivative is subject to concurrent jurisdiction under US and EU risk mitigation rules, compliance under EMIR will achieve compliance with the relevant Commission rules because they are essentially identical. The Commission's analysis of the subject submission is informed by the staff's finding in connection with the Risk Mitigation Letter but the Commission notes that the standards applied in that context are distinguishable from the "comparable and comprehensive" standards applied in the instant comparability determination.

[18] EMIR: Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories. *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0001:0059:EN:PDF*

[19] *See* EMIR Article 10 and RTS Article 10.

RTS Articles 12 to 17 are subject to a phase-in period:

- *Timely Confirmation:* Staggered phase-in according to product type.
- *Portfolio Reconciliation, Compression, and Dispute Resolution:* Requirements operational for all market participants subject to them (different provisions apply to FC, NFC+ and NFC-) as of September 15, 2013.
- *Daily mark-to-market and mark-to-model:* Applies to FC and NFC+ as of March 15, 2013.

In addition, as represented to the Commission by the applicant, swap activities in the EU are also governed by a number of regulatory requirements other than EMIR.

Markets in Financial Instruments Directive ("MiFID"):[20] MiFID is a directive and in accordance with the Treaty on the Functioning of the European Union, all member states of the EU are legally bound to implement the provisions of MiFID by November 1, 2007, by transposing them into their national laws. MiFID applies in particular to investment firms, which comprise any legal person whose regular occupation or business is the provision of one or more investment services to third parties and/or the performance of one or more investment activities on a professional basis. Investment services and activities means any of the services and activities listed in Section A of Annex I of MiFID relating to any of the instruments listed in Section C of Annex I of MiFID. Section C of Annex 1 refers explicitly to swaps as well as "other derivative financial instruments."

Due to the requirement that each EU member state transpose MiFID into its national law, the comparability determinations in this notice are based on the representations of the applicant to the Commission that (i) each member state of the EU where an SD or MSP would seek to rely on substituted compliance on the basis of the comparability of the MiFID standards has completed the process of transposing MiFID into its national law;[21] (ii) such national laws have transposed MiFID without change in any aspect that is material for a comparability determination contained herein; and (iii) such transposed law is in full force and effect as of the time that any SD or MSP seeks to rely on a relevant comparability determination contained herein. The Commission notes that to the extent that any of the foregoing representations are incorrect, an affected comparability determination will not be valid.[22]

In addition to MiFID, the applicant noted that there are a number of proposed laws and regulations that, when implemented, would affect the regulation of SDs and MSPs in the EU.[23]

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the basis of the foreign regime as a whole.[24] In making its comparability determinations, the Commission may include conditions that take into account timing and other issues related to coordinating the implementation of reform efforts across jurisdictions.[25]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s),
- The scope and objectives of the relevant regulatory requirement(s),
- The comprehensiveness of the foreign regulator's supervisory compliance program, and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[26]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.*, the home jurisdiction's requirements do not have to be identical).[27] This approach recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis, the Commission may determine that no comparability determination can be made[28] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is an SD or MSP with respect to its foreign branches, or non-registrant, to the extent

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[20] Directive 2004/39/EC and the relevant implementing measures (Directive 2006/73/EC and Regulation 1287/2006). *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0039:EN:NOT*

[21] See the Web site of the European Commission for confirmation of the transposition of MiFID into the national law of each member state, available here: *http://ec.europa.eu/internal_market/securities/docs/transposition/table_en.pdf*. Note that the issue of partial implementation in the Netherlands was resolved in 2008, *http://ec.europa.eu/eu_law/eulaw/decisions/dec_08_05_06.htm*.The Commission notes that the EC has certified to the Commission that each member state in which a registered SD or MSP is organized has completed the transposition process (e.g., Ireland, UK, France, Spain, and Germany).

[22] Because the applicant's request and the Commission's determinations herein are based on the comparability of EU requirements applicable to entities subject to EMIR and MiFID, an SD or MSP that is not subject to the requirements of EMIR or MiFID upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein. The applicant has noted for the Commission that the concept of an MSP is not explicitly mirrored in EU legislation and so it cannot be confirmed that MSPs would always be covered by EMIR and MiFID. However, the applicant states that the definition of an "investment firm" under MiFID is considerably wider than that of an SD, and thus MSP's should, in most cases, be caught within the definition of "investment firm."

[23] The applicant provided information regarding MiFID II and the Markets in Financial Instruments Regulation ("MiFIR"), *http://ec.europa.eu/internal_market/securities/isd/mifid/index_en.htm*, stating that these two proposals are part of the legislative package for the review of MiFID, and that the legislative process may be concluded with the adoption of the final political agreement by the end of 2013. The applicant further stated that an additional 18 to 24 months will be needed to adopt implementing measures, with the overall package to be applied by the end of 2015.

[24] 78 FR 45343.

[25] 78 FR 45343.

[26] 78 FR 45343.

[27] 78 FR 45343. The Commission's substituted compliance program would generally be available for swap data repository reporting ("SDR Reporting"), as outlined in the Guidance, only if the Commission has direct access to all of the data elements that are reported to a foreign trade repository pursuant to the substituted compliance program. Thus, direct access to swap data is a threshold matter to be addressed in a comparability evaluation for SDR Reporting. Moreover, the Commission explains in the Guidance that, due to its technical nature, a comparability evaluation for SDR Reporting "will generally entail a detailed comparison and technical analysis." A more particularized analysis will generally be necessary to determine whether data stored in a foreign trade repository provides for effective Commission use, in furtherance of the regulatory purposes of the Dodd-Frank Act. *See* 78 FR 45345.

[28] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[29] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swap market activities may not be clearly defined, or may not expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[30]

Finally, the Commission generally will rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities[31] of SDs and MSPs[32] in the relevant jurisdictions.[33] Further, as stated in the Guidance, the Commission expects that an applicant would notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[34]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted compliance[35] for the Business Conduct Requirements.

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement[36] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for information sharing and cooperation in the context of supervising [SDs] and MSPs."[37]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[38] provide for

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[29] 78 FR 45343.

[30] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that [SDs] and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[31] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under Part 23 (17 CFR Part 23) are limited in scope to the swaps activities of SDs and MSPs.

[32] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is solely responsible for determining whether it is legally required to comply with the laws and regulations found comparable. Currently, there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outside the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[33] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. The Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurate description of foreign laws and regulations may not be valid.

[34] 78 FR 45345.

[35] See 78 FR 45348–50. The Commission notes that registrants and other market participants are responsible for determining whether substituted compliance is available pursuant to the Guidance based on the comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[36] An MOU is one type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or, for example, as independent bilateral arrangements, statements of intent, declarations, or letters.

[37] 78 FR 45344.

[38] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. 6s(f); 17 CFR 23.203. In the Guidance, the Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; *see also id.* at 45342 n. 461 (affirming the Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly

notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[39] and include protections related to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Business Conduct Requirements in the "risk mitigation and transparency" category that are the subject of this comparability determination and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Business Conduct Requirements that the requestor submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable to and as comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this release.

As was stated in the Guidance, the Commission understands the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Portfolio Reconciliation and Compression

CEA section 4s(i) directs the Commission to prescribe regulations for the timely and accurate processing and netting of all swaps entered into by SDs and MSPs. Accordingly, pursuant to CEA section 4s(i), the Commission adopted §§ 23.502 and 23.503, which require SDs and MSPs to perform portfolio reconciliation and compression, respectively, for all swaps.[40]

1. Portfolio Reconciliation (§ 23.502)

Commission Requirement: Regulation 23.502 provides standards for the timely and accurate confirmation, processing, and valuation of uncleared swaps by SDs and MSPs. The regulation requires SDs and MSPs to engage in portfolio reconciliation,[41] which is a post-execution processing and risk management technique that is designed to: (i) identify and resolve discrepancies between the counterparties with regard to the terms of a swap after execution and during the life of the swap; and (ii) identify and resolve discrepancies between the counterparties regarding the valuation of the swap.

Pursuant to Commission regulation 23.502, for swap portfolios with other SDs/MSPs, an SD/MSP must agree in writing on the terms of reconciling the terms and valuations of each uncleared swap in the portfolio (which may be performed bilaterally or by a qualified third party), and must perform the reconciliation no less frequently than:

- Each business day for portfolios of 500 or more swaps;
- Once each week for portfolios of more than 50 but fewer than 500 swaps; and
- Quarterly for portfolios of no more than 50 swaps.

Discrepancies in material terms must be resolved immediately; and SDs and MSPs must have policies and procedures to resolve discrepancies of 10% or greater in valuations as soon as possible but no later than five business days, provided that the SD or MSP has policies and procedures for identifying how it will comply with variation margin requirements pending resolution of a valuation dispute.

For swap portfolios with non-SDs/MSPs, an SD/MSP must establish policies and procedures for engaging in portfolio reconciliation that include:

- Agreement in writing on the terms for reconciling the terms and valuations of each uncleared swap in the portfolio (which may be performed bilaterally or by a qualified third party);
- Portfolio reconciliation frequencies of quarterly for portfolios of more than 100 swaps, and annually for portfolios of 100 or fewer swaps; and
- Discrepancies in material terms and valuations of more than 10% must be subject to procedures for resolving such discrepancies in a timely fashion.

An SD/MSP must report any valuation dispute exceeding $20,000,000 to the Commission and any applicable prudential regulator if not resolved within three business days (with respect to disputes between SDs/fMSPs) or five business days (with any other counterparty).

Regulatory Objective: The Commission's portfolio reconciliation rule is designed to ensure accurate confirmation of a swap's terms and to identify and resolve any discrepancies between counterparties regarding the valuation of the swap. Given that arriving at a daily valuation is one of the building blocks for the margin regulations and is essential for the mitigation of risk posed by swaps, the regulations are aimed at ensuring that valuation disputes are resolved in a timely manner. Disputes related to confirming the terms of a swap, as well as swap valuation disputes impacting margin payments, have long been recognized as a significant problem in the OTC derivatives market, and portfolio reconciliation is widely recognized as an effective means of identifying and resolving these disputes. By identifying and managing mismatches in key economic terms and valuation for individual transactions across an entire portfolio, the regulations are aimed at achieving a process in which overall risk can be

monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto").

[39] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP. *See* 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

[40] 7 U.S.C. 6s(i).

[41] The term "portfolio reconciliation" is defined in § 23.500(i) as any process by which the two parties to one or more swaps: (1) exchange the terms of all swaps in the swap portfolio between the counterparties; (2) exchange each counterparty's valuation of each swap in the swap portfolio between the counterparties as of the close of business on the immediately preceding business day; and (3) resolve any discrepancy in material terms and valuations.

identified and reduced. The frequency of reconciliation of material terms and valuations of each swap required by the regulations will ensure the risk-reducing benefits of reconciliation by presenting a consolidated view of counterparty exposure down to the transaction level. The frequency with which portfolio reconciliation must be performed is a key component of this regulation.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(i) of the CEA and Commission regulation 23.502.

- OTC RTS Art. 13.1: FCs and NFCs must agree with each of their counterparties in writing or other equivalent electronic means on the terms on which portfolios of uncleared OTC derivative contracts shall be reconciled. Such agreement must be reached before entering into the OTC derivative contract.
- OTC RTS Art. 13.2: Portfolio reconciliation must be performed by the counterparties to the OTC derivative contracts with each other, or by a qualified third party duly mandated to this effect by a counterparty.
- The portfolio reconciliation must cover key trade terms that identify each particular OTC derivative contract and must include *at least* the valuation attributed to each contract in accordance with the mark-to-market/mark-to-model obligation.
- In order to identify at an early stage any discrepancy in a material term of the OTC derivative contract, including its valuation, the portfolio reconciliation must be performed within the following timeframes. For portfolios between or among FCs or NFCs+, each business day when the counterparties have 500 or more OTC derivative contracts outstanding with each other; once per week when the counterparties have between 51 and 499 OTC derivative contracts outstanding with each other at any time during the week; and once per quarter when the counterparties have 50 or less OTC derivative contracts outstanding with each other at any time during the quarter. For portfolios where at least one of the counterparties is an NFC-, once per quarter when the counterparties have more than 100 OTC derivative contracts outstanding with each other at any time during the quarter; and once per year when the counterparties have 100 or less OTC derivative contracts outstanding with each other.

Commission Determination: Pursuant to the foregoing standards under EMIR, FCs and NFCs must agree in writing with each of their OTC derivatives counterparties on the terms on which portfolios will be reconciled,[42] which corresponds to the requirement in Commission regulation 23.502(a) and (b) that SDs and MSPs agree in writing with each counterparty (financial and non-financial) on the terms for conducting portfolio reconciliation.

The EMIR standards require portfolio reconciliation covering key trade terms of each OTC derivative contract, including at least the valuation of each contract,[43] which corresponds to the requirements under Commission regulation 23.502 that discrepancies in material terms and valuations be resolved.

Frequency of reconciliation required under the EMIR standards for FCs and NFCs+ is daily when the number of outstanding OTC derivative contracts between counterparties is 500 or more, weekly when the number of outstanding OTC derivative contracts between counterparties is greater than 50 and less than 500, and quarterly when the number of OTC derivative contracts between counterparties is 50 or less,[44] which corresponds with the frequency required of SDs and MSPs outlined above with respect to portfolios with other SDs and MSPs. EMIR requires reconciliation with NFCs- less frequently; quarterly for portfolios of more than 100 transactions and annually otherwise[45]—which corresponds with the requirement of Commission regulation 23.502(b)(3).

The EMIR standards require FCs to report to the relevant competent authority any disputes between counterparties relating to an OTC derivative contract, its valuation or the exchange of collateral for an amount or a value higher than €15 million and outstanding for at least 15 business days,[46] while Commission regulation 23.502(c) has a similar reporting requirement for disputes of at least $20 million outstanding from three to five days, depending on counterparty type. The EMIR standards, similar to § 23.502(a)(5), require FCs and NFCs to have detailed procedures and processes for resolving disputes related to valuation.

Generally identical in intent to § 23.502, the EMIR portfolio reconciliation standards are designed to ensure that valuation disputes are recognized and resolved in a timely manner. This regular reconciliation will assist in identifying and resolving discrepancies, which in turn will aid the entities in their collateralization and risk management.

Based on the foregoing and the representations of the applicant, the Commission finds that the portfolio reconciliation requirements of the EMIR standards submitted by the applicant are comparable to and as comprehensive as the portfolio reconciliation requirements of Commission regulation 23.502.

2. Portfolio Compression (§ 23.503)

Commission Requirement: Portfolio compression is a post-trade processing and netting mechanism whereby substantially similar transactions among two or more counterparties are terminated and replaced with a smaller number of transactions of decreased notional value. Portfolio compression is intended to ensure timely and accurate processing and netting of swaps,[47] and is widely acknowledged as an effective risk mitigation tool.[48]

Pursuant to § 23.503, an SD/MSP must establish policies and procedures for terminating fully offsetting uncleared swaps, when appropriate; for periodically participating in bilateral and multilateral compression exercises for uncleared swaps with other SDs/MSPs, when appropriate; and for engaging in such exercises for uncleared swaps with non-SDs/MSPs upon request.

Regulatory Objective: The purpose of portfolio compression is to reduce the operational risk, cost, and inefficiency of maintaining unnecessary transactions on the counterparties' books.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(i) of the CEA and Commission regulation 23.503:

[42] *See* Article 13 of the EMIR Regulatory Technical Standards. In addition, Article 13(2) permits the reconciliation to be performed by a third-party, which corresponds to Commission regulation 23.502(a)(2) and (b)(2).

[43] *See* Article 13(2) of the EMIR Regulatory Technical Standards.

[44] *See* Article 13(3)(a) of the EMIR Regulatory Technical Standards.

[45] *See* Article 13(3)(b) of the EMIR Regulatory Technical Standards.

[46] *See* Article 15(2) of the EMIR Regulatory Technical Standards.

[47] For example, the reduced transaction count may decrease operational risk as there are fewer trades to maintain, process, and settle.

[48] *See* Confirmation, Portfolio Reconciliation, Portfolio Compression, and Swap Trading Relationship Requirements for Swap Dealers and Major Swap Participants, 77 FR 55904, 55932 (Sept. 11, 2012).

• OTC RTS Art. 14: FCs and NFCs with 500 or more uncleared OTC derivative contracts outstanding with a counterparty must have procedures to regularly, and at least twice a year, analyse the possibility of conducting a portfolio compression exercise in order to reduce their counterparty credit risk and engage in such a portfolio compression exercise; and

• FCs and NFCs must ensure that they are able to provide a reasonable and valid explanation to the relevant competent authority for concluding that a portfolio compression exercise is not appropriate.

Commission Determination: The EMIR standards specified above require FCs and NFCs with 500 or more OTC uncleared derivative contracts outstanding with a counterparty to have procedures to regularly, and at least twice a year, analyze the possibility of conducting a portfolio compression exercise in order to reduce their counterparty credit risk and engage in such a portfolio compression exercise,[49] which corresponds to the requirement under § 23.503 that SDs and MSPs establish procedures for periodically engaging in compression exercises with their counterparties.

Under the EMIR standards, FCs and NFCs also must ensure that they are able to provide a reasonable and valid explanation to the relevant competent authority for concluding that a portfolio compression exercise is not appropriate.[50] This requirement corresponds directly to regulation 23.503 that SDs and MSPs engage in compression exercises with their counterparties "when appropriate," which would necessarily require such registrants to demonstrate to the Commission why a compression opportunity was not appropriate.

Generally identical in intent to § 23.503, the EMIR portfolio compression standards are designed to reduce the operational risk, cost, and inefficiency of maintaining unnecessary transactions on the counterparties' books.

Based on the foregoing and the representations of the applicant, the Commission finds that the EMIR portfolio compression standards submitted by the applicant are comparable to and as comprehensive as the portfolio compression requirements of Commission regulation 23.503.

[49] *See* Article 14 of the EMIR Regulatory Technical Standards.

[50] *See id.*

B. Trade Confirmation (§ 23.501)

Commission Requirement: Section 4s(i) of the CEA[51] requires that each SD and MSP comply with the Commission's regulations prescribing timely and accurate confirmation of swaps.

Subject to an implementation period, § 23.501 requires confirmation of swap transactions (which includes execution, termination, assignment, novation, exchange, transfer, amendment, conveyance, or extinguishing of rights or obligations of a swap) among SDs and MSPs by the end of the first business day following the day of execution.

Subject to an implementation period, with respect to swaps with non-SDs/MSPs, SDs and MSPs are required to establish policies and procedures reasonably designed to ensure confirmation with non-SDs and non-MSPs by the end of the first business day following the day of execution if the counterparty is a financial entity or the end of the second business day if the counterparty is a non-financial entity.

SDs and MSPs are also required to send an acknowledgement of a swap transaction to a counterparty that is not an SD/MSP by the end of the first business day following the day of execution, and are required to provide a draft confirmation to non-SDs/MSPs prior to execution of a swap, if requested.

The day of execution is determined by reference to the business days of the counterparties and whether the swap was executed after 4:00 p.m. in the place of at least one of the counterparties.

Commission regulation 23.501 does not apply to swaps executed on a swap execution facility ("SEF") or designated contract market ("DCM") if the SEF/DCM provides for confirmation of swap transactions at the same time as execution. It also does not apply to swap transactions that are submitted for clearing by a derivatives clearing organization ("DCO") within the time required for confirmation and the DCO provides confirmation at the same time the swap transaction is accepted for clearing.

Regulatory Objective: Timely and accurate confirmation of swaps—together with portfolio reconciliation and compression—are important post-trade processing mechanisms for reducing risks and improving operational efficiency. Through § 23.501, the Commission seeks to ensure that both parties to a trade are informed of and agree upon all terms of a swap transaction[52] in writing in a timely manner following execution, thereby promoting post-trade processing, netting, and valuation of the swap for risk management purposes. The correct calculation of cash flows, margin requirements, discharge of settlement obligations, and accurate measurement of counterparty credit exposure are all dependent on timely and accurate confirmation.[53]

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(i) of the CEA and Commission regulation 23.501.

OTC RTS Art 12.1: Subject to an implementation period, FCs and NFCs+ must have in place procedures to ensure that uncleared OTC derivatives transactions between FCs and NFCs+ are confirmed, where available via electronic means, as soon as possible and at the latest by the end of the next business day following the date of execution.

OTC RTS Art. 12.2: Subject to an implementation period, FCs and NFCs+ must have in place procedures to ensure that non-centrally cleared OTC derivatives transactions with non- FCs/NFCs+ are confirmed, where available via electronic means, as soon as possible and at the latest by the end of the second business day following the date of execution.

OTC RTS Art. 12.3: For transactions concluded after 4:00 p.m. local time, or with a counterparty located in a different time zone which does not allow confirmation by the set deadline, the confirmation must take place as soon as possible and, at the latest, one business day following the deadline set out above.

OTC RTS Art. 12.4: FCs must establish the necessary procedure to report on a monthly basis to the relevant competent authority the number of unconfirmed OTC derivative transactions referred to in OTC RTS Art. 12.1—12.3 that have been outstanding for more than five business days.

[51] 7 U.S.C. 6s(i).

[52] Pursuant to § 23.500(l), "swap transaction" is defined to mean "any event that results in a new swap or in a change to the terms of a swap, including execution, termination, assignment, novation, exchange, transfer, amendment, conveyance, or extinguishing of rights or obligations of a swap."

[53] *See* Confirmation, Portfolio Reconciliation, Portfolio Compression, and Swap Trading Relationship Documentation Requirements for Swap Dealers and Major Swap Participants, 12 CFR Part 23, 77 FR 55904 at 55917 (September 11, 2012) (Final Rule).

Commission Determination: Pursuant to the EMIR standards specified above, and subject to a phase-in period, OTC derivative contracts entered into between FCs or NFCs+ must be confirmed as soon as possible and at the latest by the end of the next business day following the date of execution,[54] which corresponds to Commission regulation 23.501(a)(1) and (3)(i), requiring confirmation with other SDs, MSPs, and financial entities by the end of the first business day following the day of execution.

For OTC derivative contracts with all other NFCs, the EMIR standards require confirmation as soon as possible and, at the latest, by the end of the second business day following the date of execution.[55] This approach corresponds to the Commission regulation 23.501(a)(3)(ii), which requires written policies and procedures reasonably designed to ensure confirmation with non-SDs, non-MSPs, or non-financial entities by the end of the second business day following the day of execution.

As with Commission regulation 23.501(a)(5), which provides for a next business day adjustment for transactions executed after 4:00 p.m. or on a non-business day, the EMIR standards provide that transactions concluded after 4:00 p.m. local time, or with a counterparty located in a different time zone that does not allow confirmation by the set deadline, the confirmation must take place as soon as possible and, at the latest, one business day following the otherwise applicable deadline.

Generally identical in intent to § 23.501, the EMIR trade confirmation requirements are designed to ensure that both parties to a trade are informed of, and agree upon, all terms of a swap transaction in writing in a timely manner following execution, thereby promoting post-trade processing, netting, and valuation of the swap for risk management purposes.

Based on the foregoing and the representations of the applicant, the Commission finds that the trade confirmation requirements of the EMIR standards are comparable to and as comprehensive as the swap transaction confirmation requirements of Commission regulation 23.501.

C. Swap Trading Relationship Documentation (§ 23.504)

Commission Requirement: Section 4s(i) of the CEA requires each SD and MSP to conform to Commission standards for the timely and accurate confirmation, processing, netting, documentation, and valuation of swaps.[56] Pursuant to this requirement, the Commission adopted § 23.504.

Pursuant to § 23.504(a), SDs and MSPs must have policies and procedures reasonably designed to ensure that the SD or MSP enters into swap trading relationship documentation with each counterparty prior to executing any swap with such counterparty. Such requirement does not apply to cleared swaps.

Pursuant to § 23.504(b), SDs and MSPs must, at a minimum, document terms relating to:

- Payment obligations;
- Netting of payments;
- Events of default or other termination events;
- Netting of obligations upon termination;
- Transfer of rights/obligations;
- Governing law;
- Valuation—must be able to value swaps in a predictable and objective manner—complete and independently verifiable methodology for valuation;
- Dispute resolution procedures; and
- Credit support arrangements with initial/variation margin at least as high as set for SD/MSPs or prudential regulator (identifying haircuts and class of eligible assets).

Regulatory Objective: Through Commission regulation 23.504, the Commission seeks to reduce the legal, operational, counterparty credit, and market risk that can arise from undocumented swaps or undocumented terms of swaps. Inadequate documentation of swap transactions is more likely to result in collateral and legal disputes, thereby exposing counterparties to significant counterparty credit risk.

In particular, documenting agreements regarding valuation is critical because, as the Commission has noted, the ability to determine definitively the value of a swap at any given time lies at the center of many of the OTC derivatives market reforms contained in the Dodd-Frank Act and is a cornerstone of risk management. With respect to other SDs/MSPs and financial entities, or upon request of any other counterparty, the regulation requires agreement on the process (including alternatives and dispute resolution procedures) for determining the value of each swap for the duration of such swap for purposes of complying with the Commission's margin and risk management requirements, with such valuations based on objective criteria to the extent practicable.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(i) of the CEA and Commission regulation 23.504.

MiFID requires counterparties to be classified as retail clients, professional clients,[57] and eligible counterparties,[58] and corresponding different conduct of business rules apply.[59] Investment firms have to correctly categorize clients and notify those clients of their classification; furthermore, investment firms should be able to demonstrate the correctness of the classification.

Firms have to conclude agreements with retail and professional clients setting out the respective rights and obligations and any other terms for the provision of the services.[60] Ex-ante information has to be provided to clients on the services provided, the risks, and the safeguarding of their assets.[61] Adequate ex-post reports also have to be provided.[62] Irrespective of the classification of clients, specific record-keeping obligations regulate the recording of client orders and transactions.[63]

With respect to dispute resolution, when concluding OTC derivative contracts with each other, FCs and NFCs must have agreed detailed procedures and processes in relation to: (a) the identification, recording, and monitoring of disputes relating to the recognition or valuation of the contract and to the exchange of collateral between counterparties, and (b) the resolution of disputes in a timely manner with a specific process for handling those disputes that are not resolved within five business days. Those procedures must at least record the length of time for which the dispute remains outstanding, the counterparty, and the amount which is disputed.[64]

Commission Determination: The EMIR standards specified above require OTC derivative contracts entered into between FCs or NFCs to be confirmed in

[54] *See* Article 12 of the EMIR Regulatory Technical Standards.

[55] *See id.*

[56] *See* 7 U.S.C. 6s(i).

[57] Annex II of MiFID.

[58] Article 24 MiFID.

[59] Article 19 MiFID and 28 to 34 of MiFID L2D.

[60] Article 19 (7) MiFID.

[61] Article 19 (3) MiFID and Articles 29–33 MiFID L2D.

[62] Article 19 (8) MiFID and Articles 40–43 of MiFID L2D.

[63] Article 51 MiFID L2D and Articles 7–8 and Annex I, table I of MiFID L2R.

[64] EMIR Art. 11 and OTC RTS Art 15.

writing,[65] which corresponds to the requirements of Commission regulation 23.504(b)(2).

Pursuant to EMIR Article 11, FCs and NFCs+ are required to value outstanding OTC derivatives contracts on a mark-to-market basis daily, or where market conditions determine otherwise, a "reliable and prudent marking to model" may be used.[66] This corresponds with Commission regulation 23.504(b)(4)(i), which requires SDs and MSPs to engage in daily valuation with other SDs and MSPs, and financial entities, but allows such procedures to be included in documentation with NFCs to the extent such counterparties request them.

Under the EMIR standards, when concluding OTC derivative contracts with each other, counterparties must have agreed detailed procedures and processes in relation to the identification, recording, and monitoring of disputes relating to the recognition or valuation of the contracts and to the exchange of collateral between counterparties and in relation to the resolution of disputes in a timely manner, including a specific process for handling disputes that are not resolved within five business days. These aspects of the EMIR standards correspond to the valuation documentation requirements under Commission regulation 23.504(b)(4), which also require use of market transactions for valuations to the extent practicable, or other objective criteria, and an agreement on detailed processes for valuation dispute resolution for purposes of complying with margin requirements.

Generally identical in intent to § 23.504(b)(2) and (4), the EMIR confirmation and valuation documentation requirements are designed to reduce the legal, operational, counterparty credit, and market risk that can arise from undocumented transactions or terms, reducing the risk of collateral and legal disputes, and exposure of counterparties to significant counterparty credit risk.

Based on the foregoing and the representations of the applicant, the Commission finds the confirmation and valuation documentation requirements of the EMIR standards specified above are comparable to and as comprehensive as the swap trading relationship documentation requirements of Commission regulations § 23.504(b)(2) and (4).

For the avoidance of doubt the Commission notes that the foregoing comparability determination only applies with regard to two provisions of § 23.504 (*i.e.*, § 23.504(b)(2) and (4)). No comparability finding is made regarding the other provisions of § 23.504, namely § 23.504(a)(2) and (c)(2), that SDs and MSPs establish policies and procedures, approved in writing by senior management of the SD or MSP, reasonably designed to ensure that they have entered into swap trading relationship documentation with each counterparty prior to or contemporaneously with entering into a swap transaction with such counterparty.[67]

Moreover, the foregoing comparability determination does not extend to the requirement that such documentation include terms addressing payment obligations, netting of payments, events of default or other termination events, calculation and netting of obligations upon termination, transfer of rights and obligations, governing law, dispute resolution, and credit support arrangements, as well as notice of the status of the counterparty under the orderly liquidation procedures of Title II of the Dodd-Frank Act, and the effect of clearing on swaps executed bilaterally.[68] Nor does this determination relieve an SD or MSP from the documentation audit and recordkeeping requirements under § 23.504(c) and (d).

D. Daily Trading Records (§ 23.202)

Commission Requirement: Section 4s(g)(1) of the CEA and Commission regulation 23.202 generally require that SDs and MSPs retain daily trading records for swaps and related cash and forward transactions, including:

- Documents on which transaction information is originally recorded;
- All information necessary to conduct a comprehensive and accurate trade reconstruction;
- Pre-execution trade information including records of all oral and written communications concerning quotes, solicitations, bids, offers, instructions, trading, and prices that lead to the execution of a swap or related cash and forward transactions, whether communicated by phone, fax, instant messaging, chat rooms, email, mobile device, or other digital or electronic media;
- Reliable timing date for the initiation of a trade;
- A record of the time, to the nearest minute using Coordinated Universal Time (UTC), of each quotation provided or received prior to trade execution;
- Execution trade information including the terms of each swap and related cash or forward transaction, terms regarding payment or settlement, initial and variation margin requirements, option premiums, and other cash flows;
- The trade ticket for each swap and related cash or forward transaction;
- The date and time of execution of each swap and related cash or forward transaction to the nearest minute using UTC;
- The identity of the counterparty and the date and title of the agreement to which each swap is subject, including any swap trading relationship documentation and credit support arrangements;
- The product name and identifier, the price at which the swap was executed, and the fees, commissions and other expenses applicable;
- Post-execution trade information including records of confirmation, termination, novation, amendment, assignment, netting, compression, reconciliation, valuation, margining, collateralization, and central clearing;
- The time of confirmation to the nearest minute using UTC;
- Ledgers of payments and interest received, moneys borrowed and loaned, daily swap valuations, and daily calculation of current and potential future exposure for each counterparty;
- Daily calculation of initial and variation margin requirements;
- Daily calculation of the value of collateral, including haircuts;
- Transfers of collateral, including substitutions, and the types of collateral transferred; and
- Credits and debits for each counterparty's account.

Daily trading records must be maintained in a form and manner identifiable and searchable by transaction and counterparty, and records of swaps must be maintained for the duration of the swap plus five years, and voice recordings for one year. Records must be "readily accessible" for the first two years of the five year retention period (consistent with § 1.31).

Regulatory Objective: Through § 23.202, the Commission seeks to ensure that an SD's or MSP's records include all information necessary to conduct a comprehensive and accurate trade reconstruction for each swap, which necessarily requires the records to be identifiable by transaction and

[65] *See* Article 12 of the EMIR Regulatory Technical Standards.

[66] *See* Article 11(2) of EMIR. *See also* Article 16 of the EMIR Regulatory Technical Standards (describing the market conditions that prevent marking-to-market) and Article 17 of the EMIR Regulatory Technical Standards (describing the criteria for using marking-to-model).

[67] *See* Commission regulation 23.504(a)(2), 17 CFR 23.504(c)(2).

[68] *See* § 23.504(b)(1), (3), (5), and (6).

counterparty. Complete and accurate trade reconstruction is critical for both regulatory oversight and investigations of illegal activity pursuant to the Commission's enforcement authority. The Commission believes that a comprehensive and accurate trade reconstruction requires records of pre-execution, execution, and post-execution trade information.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to- and as comprehensive as section 4s(g) of the CEA and Commission regulation 23.202.

MiFID Article 13.6 and MiFID L2D Articles 5.1.f and 51: Firms are required to maintain records of all services and transactions undertaken by the firm that are sufficient to enable regulator authorities to monitor compliance with MiFID and to ascertain whether the firm has complied with all obligations with respect to clients or potential clients.

Firms are required to keep detailed records in relation to every client order and decision to deal, and every client order executed or transmitted.

All required records must be retained in a medium available for future reference by the regulator, and in a form/manner that:

- Allows the regulator to access them readily and reconstitute each key stage of processing each transaction;
- Allows corrections or other amendments, and the contents of the records prior to such corrections or amendments, to be easily ascertained; and
- Ensures that records are not manipulated or altered.

MiFID Article 25(2): Firms must keep at the disposal of the regulator, for at least five years, the relevant data relating to all transactions in financial instruments which they have carried out, whether on their own account or on behalf of a client.

MiFID L2R Articles 9 to 16: Requires transaction reporting in order to provide the competent authorities with the necessary information to conduct proper market surveillance.

Investment firms are required to report details of all executed transactions in any financial instruments admitted to trading on a Regulated Market to the competent authority as quickly as possible and no later than the close of the following working day.

The content of the transaction report is specified in L2 measures (MiFID L2R Article 13).

The reporting obligation lies with investment firms. In a case where all the required information with respect to derivatives transactions has been transmitted to a TR that transmits this information onwards to the competent authority the obligation on the investment firm to report will be waived.

Commission Determination: The Commission finds that compliance with MiFID would enable the relevant competent authority to conduct a comprehensive and accurate trade reconstruction for each swap, which the Commission finds generally meets the regulatory objective of § 23.202. However, the request did not provide any basis on which the Commission could determine that MiFID or EMIR are comparable to and as comprehensive as § 23.202(a)(1) or regulation 23.202(b)(1), which require records of oral communications to be maintained for swap transactions and related cash and forward transactions, respectively, including telephone, voicemail, and mobile device recordings.[69]

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the daily trading records requirements of MiFID are comparable to and as comprehensive as § 23.202, excepting § 23.202(a)(1) and (b)(1). This determination is limited to the content of the recordkeeping requirements of § 23.202 (excepting subsections (a)(1) and (b)(1)) and does not extend to the requirement that the Commission and any U.S. prudential regulator of an SD or MSP have direct access to such records.[70]

[69] In the EU's request for a comparability determination proposed regulations concerning the recording of oral communications were submitted. These requirements are currently under negotiation. The Commission may reconsider the EU's request when and if the proposal is enacted.

[70] Unless the records required by MiFID are available to the Commission and any U.S. prudential regulator under the foreign legal regime, it would be impossible to meet the regulatory objective of § 23.202. As stated in the Guidance, the ability to rely on a substituted compliance regime is dependent on direct access to the books and records of a registrant. This is the case with respect to any Transaction-Level Requirement, and not only the daily trading records required by § 23.202. *See* 78 FR 45344–45.

Issued in Washington, DC, on December 20, 2013, by the Commission.

Christopher J. Kirkpatrick,

Deputy Secretary of the Commission.

Appendices to Comparability Determination for the European Union: Certain Transaction-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Joint Statement of Chairman Gary Gensler and Commissioners Bart Chilton and Mark Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Statement of Dissent by Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States . . ."[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad category-by-category basis, should form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: the differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the *full* Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to

[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

[3] CEA section 2(i); 7 U.S.C. 2(i).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] *http://www.cftc.gov/PressRoom/PressReleases/pr6678–13.*

[6] *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf.* The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations. 78 FR 43785 (Jul. 22, 2013).

[10] *http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomalia-29.*

[11] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) the Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process; (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30981 Filed 12–26–13; 8:45 am]

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COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for Japan: Certain Transaction-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Comparability Determination for Certain Requirements under the Japanese Laws and Regulations.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a request by the Bank of Tokyo-Mitsubishi UFJ, Ltd ("BTMU") that the Commission determine that laws and regulations applicable in the Japan provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to swap dealers ("SDs") and major swap participants ("MSPs") registered with the Commission: (i) Swap trading relationship documentation and (ii) daily trading records (collectively, the "Business Conduct Requirements").

DATES:

Effective Date: This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202–418–5977; gbarnett@cftc.gov, Frank Fisanich, Chief Counsel, 202–418–5949, ffisanich@cftc.gov, and Jason Shafer, Special Counsel, 202–418–5097, jshafer@cftc.gov, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" ("Guidance").[1] In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the "Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs (and foreign branches of U.S. SDs and MSPs) in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Transaction-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3] However, the Commission provided only transitional relief from the real-time public reporting requirements under part 43 of the Commission's regulations until

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations,78 FR 909 (Jan. 7, 2013).

[2] 78 FR 43785 (July 22, 2013).

[3] The Transaction-Level Requirements under the Exemptive Order consist of 17 CFR 37.12, 38.11, 23.202, 23.205, 23.400–451, 23.501, 23.502, 23.503, 23.504, 23.505, 23.506, 23.610, and parts 43 and 50 of the Commission's regulations.

September 30, 2013, stating that "it would not be in the public interest to further delay reporting under part 43 . . . ." [4] Similarly, the Commission provided transitional relief only until October 10, 2013, from the clearing and swap processing requirements (as described in the Guidance), stating that, "[b]ecause SDs and MSPs have been committed to clearing their [credit default swaps] and interest rate swaps for many years, and indeed have been voluntarily clearing for many years, any further delay of the Commission's clearing requirement is unwarranted." [5] The Commission did not make any comparability determination with respect to clearing and swap processing prior to October 10, 2013, or real-time public reporting prior to September 30, 2013.

On September 20, 2013, BTMU submitted a request that the Commission determine that laws and regulations applicable in Japan provide a sufficient basis for an affirmative finding of comparability with respect to certain Transaction-Level Requirements, including the Business Conduct Requirements.[6] (BTMU is referred to herein as the "applicant"). On December 16, 2013, the application was further supplemented with corrections and additional materials. The following is the Commission's analysis and determination regarding the Business Conduct Requirements, as detailed below.

In addition to the Business Conduct Requirements described below, the applicant also requested a comparability determination with respect to law and regulations applicable in Japan governing trade execution, real-time public reporting, clearing, and swap processing.

With respect to trade execution and real-time reporting, the Commission has not made a comparability determination at this time due to the Commission's view that although a legislative framework for such requirements exists in Japan, detailed regulations with which to compare the requirements of the Commission's regulations on trade execution and real-time public reporting under such framework are still under consideration in Japan. The Commission may address these requests in a separate notice at a later date, taking into account further developments in the U.S. and Japan.

With respect to clearing and swap processing, this notice does not address § 50.2 (Treatment of swaps subject to a clearing requirement), § 50.4 (Classes of swaps required to be cleared), § 23.506 (Swap processing and clearing), or § 23.610 (Clearing member acceptance for clearing).

The mandatory clearing requirement in Japan, which is consistent with the G20 commitments [7] and objectives, was implemented in November 2012, ahead of other G20 jurisdictions. Japan's clearing requirement, at its initial stage, is applied to transactions between large domestic financial institutions registered under the Financial Instruments and Exchange Act, No. 25 of 1948 ("FIEA"), who are members of licensed clearing organizations [8], for (i) certain credit default swaps (i.e., those referencing iTraxx Japan—an investment-grade index CDS from 50 Japanese firms); and (ii) certain interest rate swaps (i.e., three month or six month Japanese yen LIBOR interest rate swaps). According to Japanese authorities, the scope of entities and products subject to the clearing requirement in Japan will be expanded over the next two years in a phased manner.

While the Commission considers that the legal framework in respect of clearing and swap processing in Japan is comparable to the U.S framework, it also recognizes that there are differences in the scope of entities and products between its clearing requirement under section 2(h)(1)(A) of the CEA and § 50.2 ("the CEA clearing requirement") and the Japanese FIEA clearing requirement, due to differences in market structures and conditions. Due to such differences, the Commission has not made a comparability determination with respect to §§ 50.2, 50.4, 23.506, or 23.610 at this time. The Commission may address these requests in a separate notice at a later date, taking into account further developments in the U.S. and Japan.

The Commission notes that its Division of Clearing and Risk has granted certain no-action relief from the CEA clearing requirement to qualified clearing participants of JSCC. Pursuant to such no-action relief, clearing participants of JSCC that are subject to Commission regulation 50.2, as well as parents and affiliates of such participants, may continue clearing yen-denominated interest rate swaps at JSCC instead of at a Commission-registered derivatives clearing organization ("DCO"). Further, JSCC is in the process of registering with the Commission as a DCO. Upon JSCC's registration, a Japanese SD could comply with both the CEA and FIEA clearing requirements by clearing relevant swaps at JSCC.

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act [9] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[10]

In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the Commission.[11] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope

[4] *See* id. at 43789.

[5] *See* id. at 43790.

[6] For purposes of this notice, the Business Conduct Requirements consist of 17 CFR 23.202 and 23.504.

[7] In 2009, leaders of the Group of 20 ("G20")—whose membership includes Japan, the United States, and 18 other countries—agreed that: (i) OTC derivatives contracts should be reported to trade repositories; (ii) all standardized OTC derivatives contracts should be cleared through central counterparties and traded on exchanges or electronic trading platforms, where appropriate, by the end of 2012; and (iii) non-centrally cleared contracts should be subject to higher capital requirements.

[8] Japan Securities Clearing Corporation ("JSCC") is currently the only licensed clearing organization under the FIEA in Japan.

[9] Public Law 111–203, 124 Stat. 1376 (2010).

[10] 7 U.S.C. 2(i).

[11] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site. (http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm.)

of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally describes the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission established a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[12]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime, subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[13]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[14] The Commission's direct access to the books and records required to be maintained by SD or MSP registered with the Commission is a core requirement of the CEA[15] and the Commission's regulations,[16] and is a condition to registration.[17]

III. Regulation of SDs and MSPs in Japan

As represented to the Commission by the applicant, swap activities in Japan may be governed by the Banking Act of Japan, No. 59 of 1981 ("Banking Act"), covering banks and bank holding companies, and the FIEA, covering, among others, Financial Instrument Business Operators ("FIBOs") and Registered Financial Institutions ("RFIs"). The Japanese Prime Minister delegated broad authority to implement these laws to the Japanese Financial Services Agency ("JFSA"). Pursuant to this authority, the JFSA has promulgated the Order for Enforcement,[18] Cabinet Office Ordinance,[19] Supervisory Guidelines[20] and Inspection Manuals.[21] The Securities and Exchange Surveillance Commission ("SESC") is within the JFSA and has promulgated, among other things, the Inspection Manual for FIBOs.

These requirements supplement the requirements of the Banking Act and FIEA with a more proscriptive direction as to the particular structural features or responsibilities that internal compliance functions must maintain.

In general, banks are subject to the Banking Act, relevant laws and regulations for banks, the Supervisory Guideline for banks, and the Inspection Manual for banks, while FIBOs are subject to the FIEA, relevant laws and regulations for FIBOs, Supervisory Guideline for FIBOs, and Inspection Manual for FIBOs.

Pursuant to Article 29 of the FIEA, any person that engages in trade activities that constitute "Financial Instruments Business"—which, among other things, includes over-the-counter transactions in derivatives ("OTC derivatives") or intermediary, brokerage (excluding brokerage for clearing of securities) or agency services therefor[22]—must register under the FIEA as a FIBO. Banks that conduct specified activities in the course of trade, including OTC derivatives, must register under the FIEA as RFIs pursuant to Article 33–2 of the FIEA. Banks registered as RFIs are required to comply with relevant laws and regulations for FIBOs regarding specified activities. Failure to comply with any relevant laws and regulations, Supervisory Guidelines or Inspection Manuals would subject the applicant to potential sanctions or corrective measures.

The applicant is a licensed bank in Japan that is also registered as an RFI under the supervision of the JFSA. In addition, the applicant is a member of several self-regulatory organizations, including the Japanese Securities

[12] 78 FR 45342–45345.

[13] See the Guidance, 78 FR 45342–44.

[14] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as a SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. *See* id. at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

[15] *See* e.g., sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[16] *See* e.g., §§ 23.203(b) and 23.606.

[17] *See supra* note 13.

[18] Order for Enforcement of the Banking Act and Order for Enforcement of the Financial Instruments and Exchange Act.

[19] Cabinet Office Ordinance on Financial Instruments Business ("FIB Ordinance") and Cabinet Office Ordinance on Regulation of OTC Derivatives Transaction.

[20] Comprehensive Guideline for Supervision of Major Banks, etc.("Supervisory Guideline for banks") and Comprehensive Guideline for Supervision of Financial Instruments Business Operators, etc.("Supervisory Guideline for FIBOs").

[21] Inspection Manual for Deposit Taking Institutions ("Inspection Manual for banks"), consisting of the Checklist for Business Management (Governance), Checklist for Legal Compliance, Checklist for Customer Protection Management, Checklist for Credit Risk Management, Checklist for Market Risk Management, Checklist for Liquidity Risk Management, Checklist for Operational Risk Management, etc.

[22] See Article 2(8)(iv) of the FIEA.

Dealers Association ("JSDA"). The JSDA is a "Financial Instruments Firms Association" authorized under FIEA by the Prime Minister of Japan.[23]

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the basis of the foreign regime as a whole.[24] In making its comparability determinations, the Commission may include conditions that take into account timing and other issues related to coordinating the implementation of reform efforts across jurisdictions.[25]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s),
- The scope and objectives of the relevant regulatory requirement(s),
- The comprehensiveness of the foreign regulator's supervisory compliance program, and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[26]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.*, the home jurisdiction's requirements do not have to be identical).[27] This approach recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis the Commission may determine that no comparability determination can be made[28] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is a SD or MSP with respect to its foreign branches, or non-registrant, to the extent applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[29] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swap market activities may not be clearly defined, or may not expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[30]

Finally, the Commission generally will rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities[31] of SDs and MSPs[32] in the relevant jurisdictions.[33] Further, as stated in the Guidance, the Commission expects that an applicant would notify the Commission of any

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[23] Because the applicant's request and the Commission's determinations herein are based on the comparability of Japanese requirements applicable to banks, FIBOs, and RFIs, an SD or MSP that is not a bank, FIBO, or RFI, or is otherwise not subject to the requirements applicable to banks, FIBOs, and RFIs upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein.

[24] 78 FR 45343.

[25] 78 FR 45343.

[26] 78 FR 45343.

[27] 78 FR 45343.

[28] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

[29] 78 FR 45343.

[30] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that [SDs] and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[31] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under Part 23 (17 CFR Part 23) are limited in scope to the swaps activities of SDs and MSPs.

[32] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is solely responsible for determining whether it is legally required to comply with the laws and regulations found comparable. Currently, there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outside the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[33] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. The Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurate description of foreign laws and regulations may not be valid.

material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[34]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted compliance[35] for the Business Conduct Requirements.

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement[36] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for information sharing and cooperation in the context of supervising SDs and MSPs."[37]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[38] provide for notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[39] and include protections related to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Business Conduct Requirements in the "risk mitigation and transparency" category that are the subject of this comparability determination and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Business Conduct Requirements that the applicant submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable to and as comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this release.

As was stated in the Guidance, the Commission understands the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Swap Trading Relationship Documentation (§ 23.504)

Commission Requirement: Section 4s(i) of the CEA requires each SD and MSP to conform to Commission standards for the timely and accurate confirmation, processing, netting, documentation, and valuation of swaps.[40] Pursuant to this requirement, the Commission adopted § 23.504.

Pursuant to § 23.504(a), SDs and MSPs must have policies and procedures reasonably designed to ensure that the SD or MSP enters into swap trading relationship documentation with each counterparty prior to executing any swap with such counterparty. Such requirement does not apply to cleared swaps.

Pursuant to § 23.504(b), SDs and MSPs must, at a minimum, document terms relating to:

- Payment obligations;
- Netting of payments;
- Events of default or other termination events;
- Netting of obligations upon termination;
- Transfer of rights/obligations;

[34] 78 FR 45345.

[35] *See* 78 FR 45348–50. The Commission notes that registrants and other market participants are responsible for determining whether substituted compliance is available pursuant to the Guidance based on the comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[36] An MOU is one type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or, for example, as independent bilateral arrangements, statements of intent, declarations, or letters.

[37] 78 FR 45344.

[38] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. § 6s(f); 17 CFR 23.203. In the Guidance, the Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; *see also id.* at 45342 n. 461 (affirming the Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto").

[39] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP. *See* 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

[40] *See* 7 U.S.C. § 6s(i).

- Governing law;
- Valuation—must be able to value swaps in a predictable and objective manner—complete and independently verifiable methodology for valuation;
- Dispute resolution procedures; and
- Credit support arrangements with initial/variation margin at least as high as set for SD/MSPs or prudential regulator (identifying haircuts and class of eligible assets).

Regulatory Objective: Through Commission regulation 23.504, the Commission seeks to reduce the legal, operational, counterparty credit, and market risk that can arise from undocumented swaps or undocumented terms of swaps. Inadequate documentation of swap transactions is more likely to result in collateral and legal disputes, thereby exposing counterparties to significant counterparty credit risk.

In particular, documenting agreements regarding valuation is critical because, as the Commission has noted, the ability to determine definitively the value of a swap at any given time lies at the center of many of the OTC derivatives market reforms contained in the Dodd-Frank Act and is a cornerstone of risk management. With respect to other SDs/MSPs and financial entities, or upon request of any other counterparty, the regulation requires agreement on the process (including alternatives and dispute resolution procedures) for determining the value of each swap for the duration of such swap for purposes of complying with the Commission's margin and risk management requirements, with such valuations based on objective criteria to the extent practicable.

Comparable Japanese Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as section 4s(i) of the CEA and Commission regulation 23.504.

Article 37–3 of the FIEA and Article 99 of the FIB Ordinance requires RFIs/FIBOs that intend to conclude a swap transaction to deliver to their customer documentation that outlines all relevant terms of the swap transaction. Such documentation must be delivered prior to execution in order to "ensure that the customer can make a decision on whether to conclude the contract with a full understanding on the content…of the contract." In addition to describing all relevant terms of the transactions, the pre-execution documentation must identify:

- How the obligations arising from the swap transactions will be performed;
- Settlement terms;
- Events on default or termination;
- The name or trade name of the designated dispute resolution organization (if any), or the details of the grievances settlement procedures and dispute resolution measures; and
- The types of and computation method of the amount of customer margins or other guarantee money which a customer is required to deposit regarding the swap transactions, the types of an prices applicable to properties, etc. which may be deposited as customer margins or other guarantee money and matters equivalent thereto, and how customer margins or other guarantee money will be deposited by or returned to the customer.

II–1–2.1(5)(i) and (ii) of the Inspection Manual for FIBOs requires RFIs/FIBOs to develop internal controls to verify compliance with these documentation requirements, including a system to verify that the written documents were issued before the agreements were concluded. Such internal controls must be approved by the RFI's/FIBO's board of directors. In addition, pursuant to IV(1) of the Checklist for Business Risk Management (Governance) of the Inspection Manual for banks, banks are required to develop an external audit system to review the effectiveness of these internal controls on at least an annual basis. II–1–1.4(1) of the Inspection Manual for FIBOs requires a RFI/FIBO's board of directors to establish an internal audit system to verify the appropriateness and effectiveness of these internal controls by setting up a highly independent internal audit division.

Commission Determination: The Japanese standards specified above require OTC derivative contracts entered into between RFIs/FIBOs and their customers to be confirmed in writing, which corresponds to the requirements of Commission regulation 23.504(b)(2).

Pursuant to the FIEA, RFIs and FIBOs are required to document the computation method of the customer margins or other guarantee money that the customer is required to deposit regarding the swap transactions. This corresponds with Commission regulation 23.504(b)(3) and (b)(4)(i), which requires SDs and MSPs to engage in daily valuation with other SDs and MSPs, and financial entities.

Under the Japanese standards, when concluding OTC derivative contracts with each other, counterparties must have agreed detailed procedures and processes in relation to: (a) identification, recording, and monitoring of disputes relating to the recognition or valuation of the contracts and to the exchange of collateral between counterparties, and (b) the resolution of disputes in a timely manner. These aspects of the Japanese standards correspond to the valuation documentation requirements under Commission regulation 23.504(b)(4), which also require use of market transactions for valuations to the extent practicable, or other objective criteria, and an agreement on detailed processes for valuation dispute resolution for purposes of complying with margin requirements.

Generally identical in intent to § 23.504(b)(2), (3), and (4), the Japanese confirmation and valuation documentation requirements are designed to reduce the legal, operational, counterparty credit, and market risk that can arise from undocumented transactions or terms, reducing the risk of collateral and legal disputes, and exposure of counterparties to significant counterparty credit risk.

Moreover, generally identical in intent to § 23.504(a)(2), (b)(1), (c), and (d), the Japanese standards require that SDs and MSPs establish policies and procedures, including audit procedures, approved in writing by senior management of the SD or MSP, reasonably designed to ensure that they have entered into swap trading relationship documentation in compliance with appropriate standards with each counterparty prior to or contemporaneously with entering into a swap transaction with such counterparty.

Based on the foregoing and the representations of the applicant, the Commission finds the confirmation and valuation documentation requirements of the Japanese standards specified above are comparable to and as comprehensive as the swap trading relationship documentation requirements of Commission regulations 23.504(a)(2), (b)(1), (2), (3), and (4), (c), and (d).

The foregoing comparability determination does not extend to the requirement that such documentation include notice of the status of the counterparty under the orderly liquidation procedures of Title II of the Dodd-Frank Act, and the effect of clearing on swaps executed bilaterally.[41]

[41] *See* § 23.504(b)(5) and (6).

B. Daily Trading Records (§ 23.202)

Commission Requirement: Section 4s(g)(1) of the CEA and Commission regulation 23.202 generally require that SDs and MSPs retain daily trading records for swaps and related cash and forward transactions, including:

- Documents on which transaction information is originally recorded;
- All information necessary to conduct a comprehensive and accurate trade reconstruction;
- Pre-execution trade information including records of all oral and written communications concerning quotes, solicitations, bids, offers, instructions, trading, and prices that lead to the execution of a swap or related cash and forward transactions, whether communicated by phone, fax, instant messaging, chat rooms, email, mobile device, or other digital or electronic media;
- Reliable timing date for the initiation of a trade;
- A record of the time, to the nearest minute using Coordinated Universal Time (UTC), of each quotation provided or received prior to trade execution;
- Execution trade information including the terms of each swap and related cash or forward transaction, terms regarding payment or settlement, initial and variation margin requirements, option premiums, and other cash flows;
- The trade ticket for each swap and related cash or forward transaction;
- The date and time of execution of each swap and related cash or forward transaction to the nearest minute using UTC;
- The identity of the counterparty and the date and title of the agreement to which each swap is subject, including any swap trading relationship documentation and credit support arrangements;
- The product name and identifier, the price at which the swap was executed, and the fees, commissions and other expenses applicable;
- Post-execution trade information including records of confirmation, termination, novation, amendment, assignment, netting, compression, reconciliation, valuation, margining, collateralization, and central clearing;
- The time of confirmation to the nearest minute using UTC;
- Ledgers of payments and interest received, moneys borrowed and loaned, daily swap valuations, and daily calculation of current and potential future exposure for each counterparty;
- Daily calculation of initial and variation margin requirements;
- Daily calculation of the value of collateral, including haircuts;
- Transfers of collateral, including substitutions, and the types of collateral transferred; and
- Credits and debits for each counterparty's account.

Daily trading records must be maintained in a form and manner identifiable and searchable by transaction and counterparty, and records of swaps must be maintained for the duration of the swap plus five years, and voice recordings for one year. Records must be "readily accessible" for the first two years of the five year retention period (consistent with § 1.31).

Regulatory Objective: Through § 23.202, the Commission seeks to ensure that an SD's or MSP's records include all information necessary to conduct a comprehensive and accurate trade reconstruction for each swap, which necessarily requires the records to be identifiable by transaction and counterparty. Complete and accurate trade reconstruction is critical for both regulatory oversight and investigations of illegal activity pursuant to the Commission's enforcement authority. The Commission believes that a comprehensive and accurate trade reconstruction requires records of pre-execution, execution, and post-execution trade information.

Comparable Japanese Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as section 4s(g) of the CEA and Commission regulation 23.202.

Article 156–64(1) and (2) of the FIEA, II–2–1 2.(1)(iv) of the FIBO Inspection Manual, and II.1.1(3)(iii) of the Checklist for Customer Protection Management, requires a RFI/FIBO to retain records for swaps and related cash and forward transactions, including:

- Documents prior to the conclusion of a contract that outline the terms of a swap transaction;
- 24-hour audio recordings of trading by dealers;
- Order tickets for each swap and related cash or forward transactions;
- The date and time the order was accepted and the date and time the order was filled, both of which must be recorded by time of day, of each swap and related cash or forward transaction;
- Product name (items to be listed in the books and documents may be entered using codes, brevity codes or any other symbols that have been standardized by the relevant RFI/FIBO);
- Price at which the swap was executed, and the fees, commissions and other expenses applicable;
- Documents upon conclusion of a contract that contain an outline of swap transactions, the name of the customer, as well as trading daily books and customer account ledgers that contain transaction histories;
- Ledgers of the customer fees, margin transaction payment interest, margin transactions receipt interest, security borrowing fee or security lending fee;
- Guarantee money on deposit, customer margin, trade margin or other matters regarding collateral property (the distinction between cash or security, etc. deposited as margin, date of receipt or date of return, issue name, volume or amount of money); and
- Debit or credit of money and balances of all accounts.

Pursuant to the OTC Derivative Ordinance, FIEA Enforcement Order, FIB Ordinance, and the Supervisory Guideline for FIBOs, records of swaps of RFIs/FIBOs must be in writing and maintained for a period from 5 to 10 years, depending on the specific record at issue. III–16(iv) of the Checklist for Market Risk Management of the Inspection Manual for banks assesses whether voice recordings are maintained for all traders on a 24-hour basis, recorded tapes are stored for a prescribed period of time, and retained "under the control of an organization segregated from the market and back-office divisions.".

III–2-(1)(viii) in Exhibit 1 of the Checklist for Operational Risk Management of the Inspection Manual for banks and II–2–1.2(1) of the Inspection Manual for FIBOs assesses whether documentary evidence such as transaction data are stored for a period specified by the internal rules and operational procedures, etc., but at least one year.

In addition, III–3–10–2(3) (iv) of Supervisory Guideline for banks specifically requires banks to have the personnel and systems to respond in a timely and appropriate manner to inspections and supervision provided by overseas regulatory authorities. In view of maintaining direct dialog and smooth communications with the relevant overseas regulatory authorities, this provision ensures the establishment of a reporting system which enables timely and appropriate reporting.

Similarly, IV–5–2(i) of Supervisory Guideline for FIBOs would ensure the availability of information to a regulator promptly upon request. Under this provision, the JFSA assesses whether a designated parent company of a FIBO

ensures group-wide compliance with the relevant laws, regulations and rules of each country in which it does business by establishing an appropriate control environment for legal compliance in accordance with the size of its overseas bases and the characteristics of its business operations.

The JFSA has informed the Commission that, in the process of its oversight and enforcement of the foregoing Japanese standards for FIBOs and RFIs, any SD or MSP would be subject to such standards and required to record pre-execution trade information, communicated by not only telephone but also other forms of communication comparable to those listed in § 23.202(a)(1) and (b)(1).

Commission Determination: The Commission finds that compliance with Japanese standards would enable the relevant competent authority to conduct a comprehensive and accurate trade reconstruction for each swap, which the Commission finds generally meets the regulatory objective of § 23.202.

In addition, the Commission finds that the Japanese standards specified above would ensure Commission access to the required books and records of SDs and MSPs by requiring personnel and systems necessary to respond in a timely and appropriate manner to inspections and supervision provided by overseas regulatory authorities.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the daily trading records requirements of Japan's standards are comparable to and as comprehensive as § 23.202.

Issued in Washington, DC on December 20, 2013, by the Commission.

Melissa D. Jurgens,

Secretary of the Commission.

Appendices to Comparability Determination for Japan: Certain Transaction-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler and Commissioners Chilton and Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Dissenting Statement of Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) Are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States . . ."[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad category-by-category basis, should

[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

[3] CEA section 2(i); 7 U.S.C. 2(i).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] *http://www.cftc.gov/PressRoom/PressReleases/pr6678–13.*

form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: the differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the full Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) The Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process; (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30977 Filed 12–26–13; 8:45 am]

BILLING CODE 6351–01–P

[6] *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf.* The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

[10] *http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomalia-29.*

[11] http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.

COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for Switzerland: Certain Entity-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Comparability Determination for Certain Requirements under Swiss Financial Market Regulation.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a request by UBS AG ("UBS") that the Commission determine that laws and regulations applicable in Switzerland provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to swap dealers ("SDs") and major swap participants ("MSPs") registered with the Commission: (i) Chief compliance officer; (ii) risk management; and (iii) swap data recordkeeping (collectively, the "Internal Business Conduct Requirements").

DATES: *Effective Date:* This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202–418–5977, *gbarnett@cftc.gov*, Frank Fisanich, Chief Counsel, 202–418–5949, *ffisanich@cftc.gov*, and Scott Lee, Special Counsel, 202–418–5090, *slee@cftc.gov*, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" (the "Guidance").[1] In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the "Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Entity-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3]

On July 11, 2013, UBS ("applicant") submitted a request that the Commission determine that laws and regulations applicable in Switzerland provide a sufficient basis for an affirmative finding of comparability with respect to certain Entity-Level Requirements, including the Internal Business Conduct Requirements.[4] On November 13, 2013, the application was supplemented with corrections and additional materials. The following is the Commission's analysis and determination regarding the Internal Business Conduct Requirements, as detailed below.[5]

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act[6] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[7]

In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the Commission.[8] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations, 78 FR 909 (Jan. 7, 2013).

[2] 78 FR 43785 (July 22, 2013).

[3] The Entity-Level Requirements under the Exemptive Order consist of 17 CFR 1.31, 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, 23.606, 23.608, 23.609, and parts 45 and 46 of the Commission's regulations.

[4] For purposes of this notice, the Internal Business Conduct Requirements consist of 17 CFR 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606.

[5] This notice does not address SDR Reporting. The Commission may provide a comparability determination with respect to the SDR Reporting requirement in a separate notice.

[6] Public Law 111–203, 124 Stat. 1376 (2010).

[7] 7 U.S.C. 2(i).

[8] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site available at: *http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm*.

applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[9]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime, subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[10]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[11] The Commission's direct access to the books and records required to be maintained by an SD or MSP registered with the Commission is a core requirement of the CEA[12] and the Commission's regulations,[13] and is a condition to registration.[14]

III. Regulation of SDs and MSPs in Switzerland

On July 11, 2013, UBS submitted a request that the Commission assess the comparability of laws and regulations applicable in Switzerland with the CEA and the Commission's regulations promulgated thereunder. On November 13, 2013, the application was supplemented with corrections and additional materials.

As represented to the Commission by the applicant, SDs in Switzerland are primarily regulated by the Swiss Financial Market Supervisory Authority ("FINMA"). FINMA protects creditors, investors, and policy holders, ensuring the smooth functioning of the financial markets and preserving the reputation of Swiss financial institutions. In its role as state supervisory authority, FINMA acts as an oversight authority of banks, insurance companies, exchanges, securities dealers, collective investment schemes, distributors, and insurance intermediaries. It issues operating licenses for companies in the supervised sectors. Through its supervisory activities, FINMA's role is to ensure that supervised institutions comply with the requisite laws, ordinances, directives and regulations, and continue at all times to fulfill the licensing requirements.[15]

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the basis of the foreign regime as a whole.[16] In making its comparability determinations, the Commission may include conditions that take into account timing and other issues related to coordinating the implementation of reform efforts across jurisdictions.[17]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s);
- The scope and objectives of the relevant regulatory requirement(s);
- The comprehensiveness of the foreign regulator's supervisory compliance program; and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[18]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.*, the home jurisdiction's requirements do not have to be identical).[19] This approach

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[9] 78 FR 45342–45.

[10] *See* the Guidance, 78 FR 45342–44.

[11] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as an SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. *See id.* at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

[12] *See, e.g.*, sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[13] *See, e.g.*, §§ 23.203(b) and 23.606.

[14] *Id.*

[15] Because the applicant's request and the Commission's determinations herein are based on the comparability of Swiss requirements applicable to FINMA supervised institutions, an SD or MSP that is not supervised by FINMA, or is otherwise not subject to the requirements applicable to FINMA supervised institutions upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein.

[16] 78 FR 45343.

[17] 78 FR 45343.

[18] 78 FR 45343.

[19] 78 FR 45343. The Commission's substituted compliance program would generally be available for swap data repository reporting ("SDR Reporting"), as outlined in the Guidance, only if the Commission has direct access to all of the data elements that are reported to a foreign trade repository pursuant to the substituted compliance

recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis the Commission may determine that no comparability determination can be made [20] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is an SD or MSP with respect to its foreign branches, or non-registrant, to the extent applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[21] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swaps market activities may not be clearly defined, or may not expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[22]

Finally, the Commission will generally rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities [23] of SDs and MSPs[24] in the relevant jurisdictions.[25]

Further, as stated in the Guidance, the Commission expects that an applicant would notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[26]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted compliance [27] for the Internal Business Conduct Requirements.[28]

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement [29] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for

program. Thus, direct access to swap data is a threshold matter to be addressed in a comparability evaluation for SDR Reporting. Moreover, the Commission explains in the Guidance that, due to its technical nature, a comparability evaluation for SDR Reporting "will generally entail a detailed comparison and technical analysis." A more particularized analysis will generally be necessary to determine whether data stored in a foreign trade repository provides for effective Commission use, in furtherance of the regulatory purposes of the Dodd-Frank Act. *See* 78 FR 45345.

[20] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

[21] 78 FR 45343.

[22] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that SDs and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[23] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[24] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is responsible for determining whether it is subject to the laws and regulations found comparable. Currently, there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outside the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[25] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. The Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurate description of foreign laws and regulations may not be valid.

[26] 78 FR 45345.

[27] *See* 78 FR 45348–50. The Commission notes that registrants and other market participants are responsible for determining whether substituted compliance is available pursuant to the Guidance based on the comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[28] The applicant did not request a compatibility determination for § 23.608 (Restrictions on counterparty clearing relationships), therefore, this notice does not address § 23.608. Additionally, this notice does not address § 23.609 (Clearing member risk management). The Commission declines to take up the request for a comparability determination with respect to § 23.609 due to the Commission's view that there are not laws or regulations applicable in Switzerland to compare with the prohibitions and requirements of § 23.609. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in Switzerland.

This notice also does not address capital adequacy because the Commission has not yet finalized rules for SDs and MSPs in this area, nor SDR Reporting. The Commission may provide a comparability determination with respect to these requirements at a later date or in a separate notice.

[29] An MOU is one type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or as, *e.g.*, independent bilateral arrangements, statements of intent, declarations, or letters.

information sharing and cooperation in the context of supervising [SDs] and MSPs." [30]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[31] provide for notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[32] and include protections related to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

[30] 78 FR 45344.

[31] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. § 6s(f); 17 CFR 23.203. In the Guidance, the Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; *see also id.* at 45342 n. 461 (affirming the Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto").

[32] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP. *See* 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Internal Business Conduct Requirements that are the subject of this comparability determination, and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Internal Business Conduct Requirements that the requestor submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable and comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this notice.

As was stated in the Guidance, the Commission recognizes the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Chief Compliance Officer (§ 3.3)

Commission Requirement: Implementing section 4s(k) of the CEA, Commission regulation 3.3 generally sets forth the following requirements for SDs and MSPs:

- An SD or MSP must designate an individual as Chief Compliance Officer ("CCO");
- The CCO must have the responsibility and authority to develop the regulatory compliance policies and procedures of the SD or MSP;
- The CCO must report to the board of directors or the senior officer of the SD or MSP;
- Only the board of directors or a senior officer may remove the CCO;
- The CCO and the board of directors must meet at least once per year;
- The CCO must have the background and skills appropriate for the responsibilities of the position;
- The CCO must not be subject to disqualification from registration under sections 8a(2) or (3) of the CEA;
- Each SD and MSP must include a designation of a CCO in its registration application;
- The CCO must administer the regulatory compliance policies of the SD or MSP;
- The CCO must take reasonable steps to ensure compliance with the CEA and Commission regulations, and resolve conflicts of interest;
- The CCO must establish procedures for detecting and remediating non-compliance issues;
- The CCO must annually prepare and sign an "annual compliance report" containing: (i) A description of policies and procedures reasonably designed to ensure compliance; (ii) an assessment of the effectiveness of such policies and procedures; (iii) a description of material non-compliance issues and the action taken; (iv) recommendations of improvements in compliance policies; and (v) a certification by the CCO or CEO that, to the best of such officer's knowledge and belief, the annual report is accurate and complete under penalty of law; and
- The annual compliance report must be furnished to the CFTC within 90 days after the end of the fiscal year of the SD or MSP, simultaneously with its annual financial condition report.

Regulatory Objective: The Commission believes that compliance by SDs and MSPs with the CEA and the Commission's rules greatly contributes to the protection of customers, orderly and fair markets, and the stability and integrity of the market intermediaries registered with the Commission. The Commission expects SDs and MSPs to strictly comply with the CEA and the Commission's rules and to devote sufficient resources to ensuring such compliance. Thus, through its CCO rule, the Commission seeks to ensure firms have designated a qualified individual as CCO that reports directly to the board

of directors or the senior officer of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually to the Commission and the board or senior officer on compliance of the firm.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Switzerland are in full force and effect in Switzerland, and comparable to and as comprehensive as section 4s(k) of the CEA and Commission regulation 3.3.

The applicant represented that Swiss law and FINMA regulations require a regulated entity within FINMA's jurisdiction to appoint a senior management member to act in the capacity of a CCO, with responsibility for the oversight of all of the entity's regulated businesses, including its swaps business. The CCO is required by law to report, directly or indirectly, to senior management of the regulated entity with respect to any material compliance issues in any of the banking entity's businesses.

Under Swiss law, compliance entails the adherence to legal, regulatory and internal policies, as well as the observance of the customary standards and rules of professional conduct within the market. The risk of violations of provisions, standards, or rules of professional conduct and the corresponding legal and regulatory sanctions, financial losses, or damage to one's reputation are deemed to be compliance risks.

Accordingly, FINMA Circular 2008/24 of November 20, 2008, Supervision and Internal Control of Banks,[33] requires banks to take the necessary operational measures and precautions to ensure compliance. Pursuant to such Circular, banks:

- Must designate one member of senior management to act in the capacity of the CCO with responsibility for oversight of the compliance function;
- Must maintain a compliance function with unrestricted access to information and independence from profit-generating business activities;
- Must allocate adequate resources and authority to the compliance function;
- Must not permit compensation of employees of the compliance function to contain incentives that could lead to conflicts of interest;
- Must conduct an annual assessment (at minimum) of compliance risk and compliance policies, approved by management;
- Must timely report to management regarding material changes to compliance risks, serious violations, and remediation; and
- Must prepare an annual report assessing compliance risks and activities and furnish such report to the board of directors, internal auditors, and outside auditors.

Commission Determination: The Commission finds that the Swiss law and regulations specified above are generally identical in intent to § 3.3 by seeking to ensure firms have designated a qualified individual as the compliance officer that reports directly to a sufficiently senior function of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually on compliance of the firm.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the CCO requirements of Swiss law and regulations are comparable to and as comprehensive as § 3.3, with the exception of § 3.3(f) concerning certifying and furnishing an annual compliance report to the Commission.

Notwithstanding that the Commission has not determined that the requirements of the Swiss standards specified above are comparable to and as comprehensive as § 3.3(f), any SD or MSP to which both § 3.3 and the Swiss law and regulations specified above are applicable would generally be deemed to be in compliance with § 3.3 if that SD or MSP complies with the Swiss law and regulations specified above, subject to certifying and furnishing the Commission with the annual report required under Swiss law and regulations specified above in accordance with § 3.3(f). The Commission notes that it generally expects registrants to submit required reports to the Commission in the English language.

B. Risk Mandgement Duties (§§ 23.600—23.609)

Section 4s(j) of the CEA requires each SD and MSP to establish internal policies and procedures designed to, among other things, address risk management, monitor compliance with position limits, prevent conflicts of interest, and promote diligent supervision, as well as maintain business continuity and disaster recovery programs.[34] The Commission adopted regulations 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606 to implement the statute.[35] The Commission also adopted regulation 23:609, which requires certain risk management procedures for SDs or MSPs that are clearing members of a derivatives clearing organization ("DCO").[36] Collectively, these requirements help to establish a robust and comprehensive internal risk management program for SDs and MSPs with respect to their swaps activities,[37] which is critical to effective systemic risk management for the overall swaps market. In making its comparability determination with regard to these risk management duties, the Commission will consider each regulation individually.

1. Risk Management Program for SDs and MSPs (§ 23.600)

Commission Requirement: Implementing section 4s(j)(2) of the CEA, Commission regulation 23.600 generally requires that:

- Each SD or MSP must establish and enforce a risk management program consisting of a system of written risk management policies and procedures designed to monitor and manage the risks associated with the swap activities of the firm, including without limitation, market, credit, liquidity, foreign currency, legal, operational, and settlement risks, and furnish a copy of such policies and procedures to the

[33] Text of English translation by KPMG available at: *https://www.kpmg.com/CH/de/library/Legislative-Texts/Documents/pub_20081120-FINMA_Circ_08-24.pdf.*

[34] 7 U.S.C. 6s(j).

[35] *See* Final Swap Dealer and MSP Recordkeeping Rule, 77 FR 20128 (April 3, 2012) (relating to risk management program, monitoring of position limits, business continuity and disaster recovery, conflicts of interest policies and procedures, and general information availability, respectively).

[36] *See* Customer Documentation Rule, 77 FR 21278 (April 9, 2012). Also, SDs must comply with Commission regulation 23.608, which prohibits SDs providing clearing services to customers from entering into agreements that would: (i) Disclose the identity of a customer's original executing counterparty; (ii) limit the number of counterparties a customer may trade with; (iii) impose counterparty-based position limits; (iv) impair a customer's access to execution of a trade on terms that have a reasonable relationship to the best terms available; or (v) prevent compliance with specified time frames for acceptance of trades into clearing.

[37] *See supra* note 20.

CFTC upon application for registration and upon request;

- The SD or MSP must establish a risk management unit independent from the business trading unit;
- The risk management policies and procedures of the SD or MSP must be approved by the firm's governing body;
- Risk tolerance limits and exceptions therefrom must be reviewed and approved quarterly by senior management and annually by the governing body;
- The risk management program must have a system for detecting breaches of risk tolerance limits and alerting supervisors and senior management, as appropriate;
- The risk management program must account for risks posed by affiliates and be integrated at the consolidated entity level;
- The risk management unit must provide senior management and the governing body with quarterly risk exposure reports and upon detection of any material change in the risk exposure of the SD or MSP;
- Risk exposure reports must be furnished to the CFTC within five business days following provision to senior management;
- The risk management program must have a new product policy for assessing the risks of new products prior to engaging in such transactions;
- The risk management program must have policies and procedures providing for trading limits, monitoring of trading, processing of trades, and separation of personnel in the trading unit from personnel in the risk management unit; and
- The risk management program must be reviewed and tested at least annually and upon any material change in the business of the SD or MSP.

Regulatory Objective: Through the required system of risk management, the Commission seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. To this end, the Commission believes the risk management program of an SD or MSP must contain at least the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Switzerland are in full force and effect in Switzerland, and comparable to and as comprehensive as section 4s(j)(2) of the CEA and Commission regulation 23.600.

Article 9 of the Swiss Banking Ordinance,[38] FINMA Circular 2008/24,[39] and Bank Liquidity Ordinance of the Swiss Federal Council, address specific forms of risk and detail requirements related to controls and management of those risks including, but not limited to: market risk, liquidity risk, operational and settlement risk, credit risk, reputational risk, and legal risk. Specifically, pursuant to such Swiss law and regulations, Swiss banks:

- Must have an internal audit function that annually assesses the effectiveness of risk management;
- Must segregate the risk management function from trading functions;
- Must make the board of directors responsible to regulate, establish, maintain, monitor, and regularly supervise an appropriate internal control function in conformity with the bank's risk profile;
- Must have internal documentation of the risk management function sufficient for an outside auditor to form a reliable opinion;
- Must keep internal auditors independent from management;
- Must have internal controls based on systematic risk analysis, and must ensure material risks are recorded, limited, and monitored, including risks posed by affiliates;
- Must establish an internal audit function that reports directly to the board or audit committee;
- Must have the board of directors regularly discuss with management its assessment of the adequacy and effectiveness of internal controls;
- Must maintain and regularly test internal control functions; and
- Must define the bank's capacity to assume liquidity risk (risk tolerance limits), monitor and manage intra-day liquidity risks, and monitor assets that are used to generate liquidity.

Commission Determination: The Commission finds that the Swiss law and regulations specified above are generally identical in intent to § 23.600 by requiring a system of risk management that seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. Specifically, the Commission finds that the Swiss law and regulations specified above comprehensively require SDs and MSPs to establish risk management programs containing the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the risk management program requirements of Swiss law and regulations, as specified above, are comparable to and as comprehensive as § 23.600. with the exception of § 23.600(c)(2) concerning the requirement that each SD and MSP produce a quarterly risk exposure report and provide such report to its senior management, governing body, and the Commission.

Notwithstanding that the Commission has not determined that the requirements of Swiss law and regulations are comparable to and as comprehensive as § 23.600(c)(2), any SD or MSP to which both § 23.600 and the Swiss law and regulations specified above are applicable would generally be deemed to be in compliance with § 23.600(c)(2) if that SD or MSP complies with Swiss law and regulations specified above, subject to compliance with the requirement that it produce quarterly risk exposure reports and provide such reports to its senior management, governing body, and the Commission in accordance with § 23.600(c)(2). The Commission notes that it generally expects reports furnished to the Commission by registrants to be in the English language.

2. Monitoring of Position Limits (§ 23.601)

Commission Requirement: Implementing section 4s(j)(1) of the CEA, Commission regulation 23.601 requires each SD or MSP to establish and enforce written policies and procedures that are reasonably designed

[38] Text of English translation by KPMG available at: *http://www.kpmg.com/CH/de/Library/Legislative-Texts/Documents/pub_20090101-BankO.pdf.*

[39] *See supra* note 31.

to monitor for, and prevent violations of, applicable position limits established by the Commission, a designated contract market ("DCM"), or a swap execution facility ("SEF").[40] The policies and procedures must include an early warning system and provide for escalation of violations to senior management (including the firm's governing body).

Regulatory Objective: Generally, position limits are implemented to ensure market integrity, fairness, orderliness, and accurate pricing in the commodity markets. Commission regulation 23.601 thus seeks to ensure that SDs and MSPs have established the necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by the Commission, a DCM, or a SEF. As part of its Risk Management Program, § 23.601 is intended to ensure that established position limits are not breached by the SD or MSP.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Switzerland are in full force and effect in Switzerland, and comparable to and as comprehensive as section 4s(j)(1) of the CEA and Commission regulation 23.601.

The applicant represented that Swiss law and regulations require banking entities under FINMA's supervision to comply with regulations in the jurisdictions in which they conduct business, which would include compliance with the position limit regimes imposed by the Commission, a DCM, or SEF, as applicable. Specifically, FINMA Circular 2008/24[41] requires banking entities whose compliance policies and procedures govern activities in multiple jurisdictions must ensure that such policies and procedures ensure compliance in each jurisdiction. Thus, activities of a Swiss banking entity that have an impact on United States territory must be in compliance with the Commission's position limit regime.

FINMA Newsletter 31 of December 13, 2011, Unauthorized Trading of Banks[42] and Swiss law address specific requirements relating to monitoring for and complying with applicable position limits. Pursuant to Swiss law and regulations, Swiss banks:

- Must manage for unauthorized trading and maintain oversight of trading activities and related risks, including compliance with applicable position limits; and
- Banking entities must devote adequate attention and management resources to identify, measure, and control compliance risks.

Commission Determination: The Commission finds that the Swiss law and regulations specified above are generally identical in intent to § 23.601 by requiring SDs and MSPs to establish necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by applicable laws and regulations, including those of the Commission, a DCM, or a SEF. Specifically, the Commission finds that the Swiss law and regulations specified above, comprehensively require SDs and MSPs to monitor for regulatory compliance with position limits set pursuant to applicable law and the responsibility of senior management (including the board of directors) for such compliance.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the compliance monitoring requirements of Swiss law and regulations, as specified above, are comparable to and as comprehensive as § 23.601. For the avoidance of doubt, the Commission notes that this determination may not be relied on to relieve an SD or MSP from its obligation to strictly comply with any applicable position limit established by the Commission, a DCM, or a SEF.

3. Diligent Supervision (§ 23.602)

Commission Requirement: Commission regulation 23.602 implements section 4s(h)(1)(B) of the CEA and requires each SD and MSP to establish a system to diligently supervise all activities relating to its business performed by its partners, members, officers, employees, and agents. The system must be reasonably designed to achieve compliance with the CEA and CFTC regulations. Commission regulation 23.602 requires that the supervisory system must specifically designate qualified persons with authority to carry out the supervisory responsibilities of the SD or MSP for all activities relating to its business as an SD or MSP.

Regulatory Objective: The Commission's diligent supervision rule seeks to ensure that SDs and MSPs strictly comply with the CEA and the Commission's rules. To this end, through § 23.602, the Commission seeks to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Switzerland are in full force and effect in Switzerland, and comparable to and as comprehensive as section 4s(h)(1)(B) of the CEA and Commission regulation 23.602.

- FINMA Circular 2008/24[43] requires segregation of duties and control activities. Management is required to ensure an appropriate segregation of duties and avoids assigning responsibilities which could lead to conflicting responsibilities or interests.
- Controlling activities are to be an integral part of all work processes, *e.g.*, process controls; results monitoring; and review of conduct of employees and organizational units where no quantitative results are observable.

As previously stated above, the applicant represents that Swiss law requires banking entities under FINMA's supervision to comply with regulations in the jurisdictions in which they conduct business, which would include compliance with the CEA and Commission regulations as applicable. Specifically, FINMA Circular 2008/24 requires banking entities whose compliance policies and procedures govern activities in multiple jurisdictions must ensure that such policies and procedures ensure compliance in each jurisdiction. Thus, activities of a Swiss banking entity that have an impact on United States territory must be in compliance with the CEA and Commission regulations.

Commission Determination: The Commission finds that the Swiss law and regulations specified above are generally identical in intent to § 23.602 because such standards seek to ensure that SDs and MSPs strictly comply with applicable law, which would include the CEA and the Commission's regulations. Through the Swiss laws and regulations specified above, Swiss laws and regulations seek to ensure that each SD and MSP not only establishes the

[40] The setting of position limits by the Commission, a DCM, or a SEF is subject to requirements under the CEA and Commission regulations other than § 23.601. The setting of position limits and compliance with such limits is not subject to the Commission's substituted compliance regime.

[41] *See supra* note 31.

[42] Text of English Translation available at: *http://www.finma.ch/e/finma/publikationen/Documents/finma-mitteilung-31-2011-e.pdf.*

[43] *See supra* note 31.

necessary policies and procedures that would lead to compliance with applicable law, which would include the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the internal supervision requirements of Swiss law and regulations, as specified above, are comparable to and as comprehensive as § 23.602.

4. Business Continuity and Disaster Recovery (§ 23.603)

Commission Requirement: To ensure the proper functioning of the swaps markets and the prevention of systemic risk more generally, Commission regulation 23.603 requires each SD and MSP, as part of its risk management program, to establish a business continuity and disaster recovery plan that includes procedures for, and the maintenance of, back-up facilities, systems, infrastructure, personnel, and other resources to achieve the timely recovery of data and documentation and to resume operations generally within the next business day after the disruption.

Regulatory Objective: Commission regulation 23.603 is intended to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, this requirement seeks to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan within one business day, if necessary.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Switzerland are in full force and effect in Switzerland, and comparable to and as comprehensive as Commission regulation 23.603.

- Annex 1 of FINMA's Circular on Operational Risk[44] requires banks to have contingency or business continuity plans to ensure their ability to operate under exceptional circumstances and to limit consequences of severe business disruptions.
- FINMA Circular 2008/10 of November 20, 2008, Self-regulation as a minimum standard,[45] and sections 5.4.1 (Business Impact Analysis) and 5.4.2 (Business Continuity Strategy) of the Swiss Bankers' Association Recommendations for Business Continuity Management,[46] establish minimum business continuity management standards for banks and securities dealers in Switzerland.

Commission Determination: The Commission finds that the Swiss law and regulations specified above are generally identical in intent to § 23.603 because such standards seek to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, the Commission finds that the Swiss laws and regulations specified above seek to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan in a timely manner.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the business continuity and disaster recovery requirements of Swiss law and regulations, as specified above, are comparable to and as comprehensive as § 23.603.

5. Conflicts of Interest (§ 23.605)

Commission Requirement: Section 4s(j)(5) of the CEA and Commission regulation 23.605(c) generally require each SD or MSP to establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any commodity or swap are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision.

In addition, section 4s(j)(5) of the CEA and Commission regulation 23.605(d)(1) generally prohibits an SD or MSP from directly or indirectly interfering with or attempting to influence the decision of any clearing unit of any affiliated clearing member of a DCO to provide clearing services and activities to a particular customer, including:

- Whether to offer clearing services to a particular customer;
- Whether to accept a particular customer for clearing derivatives;
- Whether to submit a customer's transaction to a particular DCO;
- Whether to set or adjust risk tolerance levels for a particular customer; or
- Whether to set a customer's fees based on criteria other than those generally available and applicable to other customers.

Commission regulation 23.605(d)(2) generally requires each SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of any affiliated clearing member of a DCO to reasonably ensure compliance with the Act and the prohibitions set forth in § 23.605(d)(1) outlined above.

The Commission observes that § 23.605(d) works in tandem with Commission regulation 1.71, which requires futures commission merchants ("FCMs") that are clearing members of a DCO and affiliated with an SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of the FCM to reasonably ensure compliance with the Act and the prohibitions set forth in § 1.71(d)(1), which are the same as the prohibitions set forth in § 23.605(d)(1) outlined above.

Finally, § 23.605(e) requires that each SD or MSP have policies and procedures that mandate the disclosure to counterparties of material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a swap execution facility or DCM or to clear a derivative through a DCO.

Regulatory Objective: Commission regulation 23.605(c) seeks to ensure that research provided to the general public by an SD or MSP is unbiased and free from the influence of the interests of an SD or MSP arising from the SD's or MSP's trading business.

In addition, the § 23.605(d) (working in tandem with § 1.71) seeks to ensure open access to the clearing of swaps by requiring that access to and the provision of clearing services provided by an affiliate of an SD or MSP are not influenced by the interests of an SD's or MSP's trading business.

Finally, § 23.605(e) seeks to ensure equal access to trading venues and clearinghouses, as well as orderly and fair markets, by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the

[44] Text of English translation by KPMG available at: *http://www.kpmg.com/CH/en/Library/Legislative-Texts/Documents/pub-20130408-finma-circular-***8-21-en.pdf.*

[45] Text of English translation available at: *http://finma.ch/e/regulierung/Documents/finma-rs-2008-10-e.pdf.*

[46] Text of English translation available at: *http://shop.sba.ch/11107_e.pdf.*

following provisions of law and regulations applicable in Switzerland are in full force and effect in Switzerland, and comparable to and as comprehensive as Commission regulation 23.605(c).

The FINMA Circular on market conduct rules [47] and the FINMA Circular on Self-regulation recognize the Swiss Bankers' Association Directives on the Independence of Financial Research [48] as minimum standards. These circulars require information partitions where necessary to prevent conflicts of interest. In particular, they require the research unit to be independent from business trading units. Adherence to information partitions is to be monitored and is a designated compliance function, while the ultimate responsibility for handling confidential price-sensitive information and conflicts of interest lies with executive management.

More generally, imposing restrictions on particular customers would contradict the open access principles outlined in art. 33 of the Swiss National Bank Ordinance. In addition, under Swiss law, a bank must comply with the Swiss competition laws, including the Federal Act on Cartels and other Restraints on Competition. An activity that violates the provision of these laws is a violation of these laws regardless of where the putative activity took place.

The applicant has represented to the Commission that FINMA, in the process of its oversight and enforcement of the foregoing Swiss standards, would require any SD or MSP subject to such standards to resolve or mitigate conflicts of interests in the provision of clearing services by a clearing member of a DCO that is an affiliate of the SD or MSP, or the decision of a counterparty to execute a derivative on a SEF or DCM, or clear a derivative through a DCO, through appropriate information firewalls and disclosures.

Commission Determination: The Commission finds that the Swiss law and regulations specified above with respect to conflicts of interest that may arise in producing or distributing research are generally identical in intent to § 23.605(c) because such standards seek to ensure that research provided to the general public by an SD is unbiased and free from the influence of the interests of an SD arising from the SD's trading business.

With respect to conflicts of interest that may arise in the provision of clearing services by an affiliate of an SD or MSP, the Commission further finds that although the general conflicts of interest prevention requirements under the Swiss standards specified above do not require with specificity that access to and the provision of clearing services provided by an affiliate of an SD or MSP not be improperly influenced by the interests of an SD's or MSP's trading business, such general requirements would require prevention and remediation of such improper influence when recognized or discovered. Thus such standards would ensure open access to clearing.

Finally, although not as specific as the requirements of § 23.605(e) (Undue influence on counterparties), the Commission finds that the general disclosure requirements of the Swiss standards specified above would ensure equal access to trading venues and clearinghouses by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

6. Availability of Information for Disclosure and Inspection (§ 23.606)

Commission Requirement: Commission regulation 23.606 implements sections 4s(j)(3) and (4) of the CEA, and requires each SD and MSP to disclose to the Commission, and an SD's or MSP's U.S. prudential regulator (if any) comprehensive information about its swap activities, and to establish and maintain reliable internal data capture, processing, storage, and other operational systems sufficient to capture, process, record, store, and produce all information necessary to satisfy its duties under the CEA and Commission regulations. Such systems must be designed to provide such information to the Commission and an SD's or MSP's U.S. prudential regulator within the time frames set forth in the CEA and Commission regulations and upon request.

Regulatory Objective: Commission regulation 23.606 seeks to ensure that each SD and MSP captures and maintains comprehensive information about their swap activities, and is able to retrieve and disclose such information to the Commission and its U.S. prudential regulator, if any, as necessary for compliance with the CEA and the Commission's regulations and for purposes of Commission oversight, as well as oversight by the SD's or MSP's U.S. prudential regulator, if any.

The Commission observes that it would be impossible to meet the regulatory objective of § 23.606 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.606 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Switzerland are in full force and effect in Switzerland, and comparable to and as comprehensive as Commission regulation 23.606.

The Swiss Code of Obligations,[49] Ordinance of the Swiss Federal Council on Business Record Keeping,[50] Swiss Financial Markets Supervisory Authority Act,[51] Swiss National Banking Ordinance,[52] National Bank Act,[53] and FINMA Circulars impose comprehensive requirements with respect to data retention and storage, and the availability of such data to regulatory authorities. These requirements apply to all of a banking entity's business, including its swaps business.

Collectively, these Swiss laws and regulations require a firm to maintain swaps data and related books and records in a systematic, logical, and chronological format so that the data cannot be damaged, altered, or deleted. Further, a firm is required to maintain account records, accounting records, and business correspondence for ten years. These records must contain all

[47] Text of English translation available at: *http://www.finma.ch/e/regulierung/Documents/finma-rs-2008-38-e.pdf* (stating that analysis or research departments are to be organized independently and be segregated as separate areas of confidentiality).

[48] Text of English translation available at: *http://www.swissbanking.org/12108.pdf.*

[49] Text of English translation available at: *http://www.admin.ch/opc/en/classified-compilation/19110009/201305280000/220.pdf.*

[50] Text of ordinance available at: *http://www.admin.ch/opc/de/classified-compilation/20001467/201301010000/221.431.pdf.*

[51] Text of English translation available at: *http://www.admin.ch/opc/en/classified-compilation/20052624/201307010000/956.1.pdf.*

[52] Text of English translation available at: *http://www.admin.ch/opc/en/classified-compilation/20040259/201307010000/951.131.pdf* (requiring banks to report OTC derivatives information biannually to the Bank of Internal Settlement).

[53] Text of English translation available at: *http://www.admin.ch/opc/en/classified-compilation/20021117/201203010000/951.11.pdf* (requiring the Swiss National Bank, pursuant to art. 14, to monitor financial market developments and requiring banks to provide statistical data about their activities to the Swiss National Bank).

necessary information to establish, review, and reconstruct the financial situation of the firm by FINMA, regulatory authorities, audit firms, and persons or companies legally authorized to review such records.

Commission Determination: The Commission finds that the Swiss law and regulations specified above are generally identical in intent to § 23.606 because such standards seek to ensure that each SD and MSP captures and stores comprehensive information about their swap activities, and are able to retrieve and disclose such information as necessary for compliance with applicable law and for purposes of regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements of Swiss law and regulations with respect to the availability of information for inspection and disclosure, as specified above, are comparable to, and as comprehensive as, § 23.606, with the exception of § 23.606(a)(2) concerning the requirement that an SD or MSP make information required by § 23.606(a)(1) available promptly upon request to Commission staff and the staff of an applicable prudential regulator. The applicant has not submitted any provision of law or regulations applicable in Switzerland, upon which the Commission could make a finding that SDs and MSPs would be required to retrieve and disclose comprehensive information about their swap activities to the Commission or any U.S. prudential regulator as necessary for compliance with the CEA and Commission regulations, and for purposes of Commission oversight and the oversight of any U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of Swiss law and regulations are comparable to and as comprehensive as § 23.606(a)(2), any SD or MSP to which both § 23.606 and the Swiss standards specified above are applicable would generally be deemed to be in compliance with § 23.606(a)(2) if that SD or MSP complies with the Swiss standards specified above, subject to compliance with the requirement that it produce information to Commission staff and the staff of an applicable U.S. prudential regulator in accordance with § 23.606(a)(2).

C. Swap Data Recordkeeping (§§ 23.201 and 23.203)

Commission Requirement: Sections 4s(f)(1)(B) and 4s(g)(1) of the CEA, and Commission regulation 23.201 generally require SDs and MSPs to retain records of each transaction, each position held, general business records (including records related to complaints and sales and marketing materials), records related to governance, financial records, records of data reported to swap data repositories ("SDRs"), and records of real-time reporting data along with a record of the date and time the SD or MSP made such reports. Transaction records must be kept in a form and manner identifiable and searchable by transaction and counterparty.

Commission regulation 23.203, requires SDs and MSPs to maintain records of a swap transaction until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction, and for a period of five years after such date. Records must be "readily accessible" for the first 2 years of the 5 year retention period (consistent with § 1.31).

The Commission notes that the comparability determination below with respect to §§ 23.201 and 23.203 encompasses both swap data recordkeeping generally and swap data recordkeeping relating to complaints and marketing and sales materials in accordance with § 23.201(b)(3) and (4).[54]

Regulatory Objective: Through the Commission's regulations requiring SDs and MSPs to keep comprehensive records of their swap transactions and related data, the Commission seeks to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

The Commission's regulations require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

By requiring comprehensive records of swap data, the Commission seeks to ensure that SDs and MSPs employ effective risk management, and strictly comply with Commission regulations. Further, such records facilitate effective regulatory oversight.

The Commission observes that it would be impossible to meet the regulatory objective of §§ 23.201 and 23.203 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.203 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Swiss Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in Switzerland are in full force and effect Switzerland, and comparable to and as comprehensive as sections 4s(f)(1)(B) and 4s(g)(1) of the CEA and §§ 23.201 and 23.203.

Under Swiss law and FINMA Circulars, a banking entity is subject to extensive requirements regarding accounting records, which cover records of transactions in all areas of the bank's business, including its swaps business. Under the Swiss Code of Obligations,[55] for example:

- According to art. 957, a Swiss firm has to properly capture and maintain its books necessary to provide a fair view of its kind and size of business. Accounting records and business correspondence can be maintained in written or electronic format, provided the format ensures that the records adequately reflect business transactions;
- According to art. 962, accounts, accounting records, and business correspondence have to be retained for ten years;
- Pursuant to art. 713, all deliberations and decisions by the supervisory body have to be recorded in a protocol, signed by the Chairman and the secretary; and
- Pursuant to art. 747, the accounting records of a dissolved company are kept for ten years at a location designated by the liquidators or, if the liquidators cannot reach agreement, by the commercial registry.

Commission Determination: The Commission finds that the Swiss law and regulations specified above are generally identical in intent to §§ 23.201 and 23.202 because such standards seek to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

In addition, the Commission finds that the Swiss laws and regulations specified above require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

[54] *See* the Guidance for a discussion of the availability of substituted compliance with respect to swap data recordkeeping, 78 FR 45332–33.

[55] *See supra* note 51.

Finally, the Commission finds that Swiss laws and regulations specified above, by requiring comprehensive records of swap data, seek to ensure that SDs and MSPs employ effective risk management, seek to ensure that SDs and MSPs strictly comply with applicable regulatory requirements (including the CEA and Commission regulations), and that such records facilitate effective regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements of Swiss law and regulations with respect to the swap data recordkeeping, as specified above, are comparable to, and as comprehensive as, §§ 23.201 and 23.203, with the exception of § 23.203(b)(2) concerning the requirement that an SD or MSPs make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator. The applicant has not submitted any provision of law or regulations applicable in Switzerland, upon which the Commission could make a finding that SDs and MSPs would be required to make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of Swiss law and regulations are comparable to and as comprehensive as § 23.203(b)(2), any SD or MSP to which both § 23.203 and the Swiss law and regulations specified above are applicable would generally be deemed to be in compliance with § 23.203(b)(2) if that SD or MSP complies with the Swiss law and regulations specified above, subject to compliance with the requirement that it make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator in accordance with § 23.203(b)(2).

Issued in Washington, DC on December 20, 2013, by the Commission.

Christopher J. Kirkpatrick,

Deputy Secretary of the Commission.

Appendices to Comparability Determination for Switzerland: Certain Entity-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Joint Statement of Chairman Gary Gensler and Commissioners Bart Chilton and Mark Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Statement of Dissent by Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) Are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States * * *."[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad

[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

[3] CEA section 2(i); 7 U.S.C. 2(i).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] *http://www.cftc.gov/PressRoom/PressReleases/pr6678-13.*

category-by-category basis, should form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: the differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the *full* Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) The Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process; (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30978 Filed 12–26–13; 8:45 am]
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[6] *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf.* The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

[10] *http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomalia-29.*

[11] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for Japan: Certain Entity-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of comparability determination for certain requirements under the laws of Japan.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a joint request by the Bank of Tokyo-Mitsubishi UFJ, Ltd ("BTMU"), Goldman Sachs Japan Co., Ltd., Merrill Lynch Japan Securities Co., Ltd., and Morgan Stanley MUFG Securities Co., Ltd. that the Commission determine that laws and regulations applicable in Japan provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to swap dealers ("SDs") and major swap participants ("MSPs") registered with the Commission: (i) Chief compliance officer; (ii) risk management; and (iii) swap data recordkeeping (collectively, the "Internal Business Conduct Requirements").

DATES: *Effective Date:* This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202 418–5977, *gbarnett@cftc.gov*, Frank Fisanich, Chief Counsel, 202–418–5949, ffisanich@cftc.gov, and Jason Shafer, Special Counsel, 202–418–5097, jshafer@cftc.gov, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" (the "Guidance").[1] In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the "Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Entity-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3]

On June 24, 2013, BTMU submitted a request that the Commission determine that laws and regulations applicable in Japan provide a sufficient basis for an affirmative finding of comparability with respect to certain Entity-Level Requirements, including the Internal Business Conduct Requirements.[4] BTMU provided Commission staff with a supplement on October 8, 2013. On October 29, 2013, the application was further supplemented with corrections and additional materials. On November 12, 2013, Goldman Sachs Japan Co., Ltd., Merrill Lynch Japan Securities Co., Ltd., and Morgan Stanley MUFG Securities Co., Ltd. requested that they be permitted to rely upon BTMU's submission as the basis for their request for a substituted compliance determination (BTMU, Goldman Sachs Japan Co., Ltd., Merrill Lynch Japan Securities Co., Ltd., and Morgan Stanley MUFG Securities Co., Ltd., are referred to herein as, collectively, the "applicants"). The following is the Commission's analysis and determination regarding the Internal Business Conduct Requirements, as detailed below.[5]

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act[6] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[7] In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the Commission.[8] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations, 78 FR 909 (Jan. 7, 2013).

[2] 78 FR 43785 (July 22, 2013).

[3] The Entity-Level Requirements under the Exemptive Order consist of 17 CFR 1.31, 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, 23.606, 23.608, 23.609, and parts 45 and 46 of the Commission's regulations.

[4] For purposes of this notice, the Internal Business Conduct Requirements consist of 17 CFR 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606. The applicants subsequently submitted a separate application for the applicable Transaction-Level Requirements on September 20, 2013. This notice addresses only the Entity-Level Requirements.

[5] This notice does not address swap data repository reporting ("SDR Reporting"). The Commission may provide a comparability determination with respect to the SDR Reporting requirement in a separate notice.

[6] Public Law 111–203, 124 Stat. 1376 (2010).

[7] 7 U.S.C. 2(i).

[8] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site. (http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm.)

applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[9]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime, subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[10]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[11] The Commission's direct access to the books and records required to be maintained by an SD or MSP registered with the Commission is a core requirement of the CEA[12] and the Commission's regulations,[13] and is a condition to registration.[14]

III. Regulation of SDs and MSPs in Japan

As represented to the Commission by the applicants, swap activities in Japan may be governed by the Banking Act of Japan, No. 59 of 1981 ("Banking Act"), covering banks and bank holding companies, and the Financial Instruments and Exchange Act, No. 25 of 1948 ("FIEA"), covering, among others, Financial Instrument Business Operators ("FIBOs") and Registered Financial Institutions ("RFIs"). The Japanese Prime Minister delegated broad authority to implement these laws to the Japanese Financial Services Agency ("JFSA"). Pursuant to this authority, the JFSA has promulgated the Order for Enforcement,[15] Cabinet Office Ordinance, [16] Supervisory Guidelines[17] and Inspection Manuals.[18] The Securities and Exchange Surveillance Commission ("SESC") is within the JFS and has promulgated, among other things, the Inspection Manual for FIBOs.

These requirements supplement the requirements of the Banking Act and FIEA with a more proscriptive direction as to the particular structural features or responsibilities that internal compliance functions must maintain.

In general, banks are subject to the Banking Act, relevant laws and regulations for banks, Supervisory Guidelines for banks, and Inspection Manual for banks, while FIBOs are subject to the FIEA, relevant laws and regulations for FIBOs, Supervisory Guidelines for FIBOs, and Inspection Manual for FIBOs.

Pursuant to Article 29 of the FIEA, any person that engages in trade activities that constitute "Financial Instruments Business"—which, among other things, includes over-the-counter transactions in derivatives ("OTC derivatives") or intermediary, brokerage (excluding brokerage for clearing of securities) or agency services therefor[19]—must register under the FIEA as a FIBO. Banks that conduct specified activities in the course of trade, including OTC derivatives must register under the FIEA as RFIs pursuant to Article 33–2 of the FIEA. Banks registered as RFIs are required to comply with relevant laws and regulations for FIBOs regarding specified activities. Failure to comply with any relevant laws and regulations, Supervisory Guidelines or Inspection Manuals would subject the applicant to potential sanctions or corrective measures.

The applicants are each registered in Japan as RFIs or FIBOs under the supervision of the JFSA. In addition, each applicant is a member of several self-regulatory organizations, including the Japanese Securities Dealers Association ("JSDA"). The JSDA is a "Financial Instruments Firms Association" authorized under FIEA by the Prime Minister of Japan.[20]

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the basis of the foreign regime as a whole.[21] In making its comparability determinations, the Commission may include conditions that take into account timing and other issues related

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[9] 78 FR 45342–45.

[10] *See* the Guidance, 78 FR 45342–44.

[11] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as an SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. *See* id. at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

[12] *See e.g.*, sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[13] *See e.g.*, §§ 23.203(b) and 23.606.

[14] *See supra* note 10.

[15] Order for Enforcement of the Banking Act and Order for Enforcement of the Financial Instruments and Exchange Act.

[16] Cabinet Office Ordinance on Financial Instruments Business ("FIB Ordinance") and Cabinet Office Ordinance on Regulation of OTC Derivatives Transaction.

[17] Comprehensive Guideline for Supervision of Major Banks, etc.("Supervisory Guideline for banks") and Comprehensive Guideline for Supervision of Financial Instruments Business Operators, etc.("Supervisory Guideline for FIBOs").

[18] Inspection Manual for Deposit Taking Institutions ("Inspection Manual for banks"), consisting of the Checklist for Business Management (Governance), Checklist for Legal Compliance, Checklist for Customer Protection Management, Checklist for Credit Risk Management, Checklist for Market Risk Management, Checklist for Liquidity Risk Management, Checklist for Operational Risk Management, etc.

[19] *See* Article 2(8)(iv) of the FIEA.

[20] Because the applicants' request and the Commissions determinations herein are based on the comparability of Japanese requirements applicable to banks, FIBOs, and RFIs, an SD or MSP that is not a bank, FIBO, or RFI, or is otherwise not subject to the requirements applicable to banks, FIBOs, and RFIs upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein.

[21] 78 FR 45343.

to coordinating the implementation of reform efforts across jurisdictions.[22]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s),
- The scope and objectives of the relevant regulatory requirement(s);
- The comprehensiveness of the foreign regulator's supervisory compliance program, and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[23]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.,* the home jurisdiction's requirements do not have to be identical).[24] This approach recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis the Commission may determine that no comparability determination can be made[25] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is an SD or MSP with respect to its foreign branches, or non-registrant, to the extent applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[26] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swaps market activities may not be clearly defined, or may not expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[27]

Finally, the Commission will generally rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities[28] of SDs and MSPs[29] in the relevant jurisdictions.[30] Further, as stated in the Guidance, the Commission expects that an applicant would notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[31]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted

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[22] 78 FR 45343.

[23] 78 FR 45343.

[24] 78 FR 45343. The Commission's substituted compliance program would generally be available for SDR Reporting, as outlined in the Guidance, only if the Commission has direct access to all of the data elements that are reported to a foreign trade repository pursuant to the substituted compliance program. Thus, direct access to swap data is a threshold matter to be addressed in a comparability evaluation for SDR Reporting. Moreover, the Commission explains in the Guidance that, due to its technical nature, a comparability evaluation for SDR Reporting "will generally entail a detailed comparison and technical analysis." A more particularized analysis will generally be necessary to determine whether data stored in a foreign trade repository provides for effective Commission use, in furtherance of the regulatory purposes of the Dodd-Frank Act. *See* 78 FR 45345.

[25] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

[26] 78 FR 45343.

[27] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that [SDs] and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[28] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[29] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is responsible for determining whether it is subject to the laws and regulations found comparable. Currently, there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outside the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[30] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. The Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurate description of foreign laws and regulations may not be valid.

[31] 78 FR 45345.

compliance[32] for the Internal Business Conduct Requirements.[33]

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement[34] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for information sharing and cooperation in the context of supervising [SDs] and MSPs."[35]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[36] provide for notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[37] and include protections related to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Internal Business Conduct Requirements that are the subject of this comparability determination, and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Internal Business Conduct Requirements that the applicants submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable and comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this notice.

As was stated in the Guidance, the Commission recognizes the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Chief Compliance Officer (§ 3.3).

Commission Requirement: Implementing section 4s(k) of the CEA, Commission regulation 3.3 generally sets forth the following requirements for SDs and MSPs:

- An SD or MSP must designate an individual as Chief Compliance Officer ("CCO");
- The CCO must have the responsibility and authority to develop the regulatory compliance policies and procedures of the SD or MSP;
- The CCO must report to the board of directors or the senior officer of the SD or MSP;
- Only the board of directors or a senior officer may remove the CCO;
- The CCO and the board of directors must meet at least once per year;
- The CCO must have the background and skills appropriate for the responsibilities of the position;
- The CCO must not be subject to disqualification from registration under sections 8a(2) or (3) of the CEA;
- Each SD and MSP must include a designation of a CCO in its registration application;

[32] *See* 78 FR 45348–50. The Commission notes that registrants and other market participants are responsible for determining whether substituted compliance is available pursuant to the Guidance based on the comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[33] This notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in Japan to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in Japan.

This notice also does not address capital adequacy because the Commission has not yet finalized rules for SDs and MSPs in this area, nor SDR Reporting. The Commission may provide a comparability determination with respect to these requirements at a later date or in a separate notice.

[34] An MOU is one type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or, for example, as independent bilateral arrangements, statements of intent, declarations, or letters.

[35] 78 FR 45344.

[36] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. 6s(f); 17 CFR 23.203. In the Guidance, the Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; see *also id.* at 45342 n. 461 (affirming the Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto").

[37] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP. *See* 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

• The CCO must administer the regulatory compliance policies of the SD or MSP;

• The CCO must take reasonable steps to ensure compliance with the CEA and Commission regulations, and resolve conflicts of interest;

• The CCO must establish procedures for detecting and remediating non-compliance issues;

• The CCO must annually prepare and sign an "annual compliance report" containing: (i) A description of policies and procedures reasonably designed to ensure compliance; (ii) an assessment of the effectiveness of such policies and procedures; (iii) a description of material non-compliance issues and the action taken; (iv) recommendations of improvements in compliance policies; and (v) a certification by the CCO or chief executive officer that, to the best of such officer's knowledge and belief, the annual report is accurate and complete under penalty of law; and

• The annual compliance report must be furnished to the CFTC within 90 days after the end of the fiscal year of the SD or MSP, simultaneously with its annual financial condition report.

Regulatory Objective: The Commission believes that compliance by SDs and MSPs with the CEA and the Commission's rules greatly contributes to the protection of customers, orderly and fair markets, and the stability and integrity of the market intermediaries registered with the Commission. The Commission expects SDs and MSPs to strictly comply with the CEA and the Commission's rules and to devote sufficient resources to ensuring such compliance. Thus, through its CCO rule, the Commission seeks to ensure firms have designated a qualified individual as CCO that reports directly to the board of directors or the senior officer of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually to the Commission and the board or senior officer on compliance of the firm.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as section 4s(k) of the CEA and Commission regulation 3.3.

The Banking Act, FIEA, Order for Enforcement, Cabinet Office Ordinance, Supervisory Guidelines and Inspection Manuals for banks and FIBOs, collectively, require each bank and FIBO to:

• Designate an individual to serve as a CCO in its registration application as a bank/FIBO;

• Provide the CCO with the responsibility and authority to develop the regulatory compliance policies and procedures of the bank/FIBO;

• Have the CCO report to the board of directors of the bank/FIBO;

• Ensure the CCO has the background and skills appropriate for the position;

• Ensure the CCO is not disqualified from registration;[38]

• Have the CCO administer the regulatory compliance policies of the bank/FIBO;

• Have the CCO take reasonable steps to ensure compliance and resolve conflicts of interest for the bank/FIBO;

• Have the CCO detect and remediate non-compliance issues for the bank/FIBO;

• Report regulatory compliance status to the board of directors as necessary and appropriate on behalf of the bank/FIBO; and

• Submit an annual business report to JFSA which contains compliance facts, preventative and corrective actions taken, and other issues regarding the firm's compliance framework.

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to § 3.3 by seeking to ensure firms have designated a qualified individual as the compliance officer that reports directly to a sufficiently senior function of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually on compliance of the firm.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the CCO requirements of the Japanese standards specified above are comparable to and as comprehensive as § 3.3, with the exception of § 3.3(f) concerning certifying and furnishing an annual compliance report to the Commission.

Notwithstanding that the Commission has not determined that the requirements of Japan's laws and regulations are comparable to and as comprehensive as § 3.3(f), any SD or MSP to which both § 3.3 and the Japanese standards specified above are applicable would generally be deemed to be in compliance with § 3.3(f) if that SD or MSP complies with the Japanese standards specified above, subject to certifying and furnishing the Commission with the annual report required under the Japanese standards specified above in accordance with § 3.3(f). The Commission notes that it generally expects registrants to submit required reports to the Commission in the English language.

B. Risk Management Duties (§§ 23.600—23.609)

Section 4s(j) of the CEA requires each SD and MSP to establish internal policies and procedures designed to, among other things, address risk management, monitor compliance with position limits, prevent conflicts of interest, and promote diligent supervision, as well as maintain business continuity and disaster recovery programs.[39] The Commission adopted regulations 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606 to implement the statute.[40] The Commission also adopted regulation 23.609, which requires certain risk management procedures for SDs or MSPs that are clearing members of a derivatives clearing organization ("DCO").[41] Collectively, these requirements help to establish a robust and comprehensive internal risk management program for SDs and MSPs with respect to their swaps activities,[42]

[38] *See* Article 29–4 of FIEA and Article 15–4 of the Order for Enforcement of FIEA, Article 33–5(1)(iii) of FIEA; Article 33–3(1)(vii) of FIEA, Article 47(1)(i) of the FIB Ordinance, Article 33–3(2)(iv) of FIEA, Article 47(1)(i)(ii) of the FIB Ordinance, and Article 4(2)(ii) of Banking Act. Pursuant to Article 33–5(1)(iii) of FIEA and its relevant provisions, RFIs are required to have a personnel structure sufficient to conduct RFI business in an appropriate manner. Accordingly, if the CCO is subject to disqualification, registration for the RFI would be refused.

[39] 7 U.S.C. § 6s(j).

[40] *See* Final Swap Dealer and MSP Recordkeeping Rule, 77 FR 20128 (April 3, 2012) (relating to risk management program, monitoring of position limits, business continuity and disaster recovery, conflicts of interest policies and procedures, and general information availability, respectively).

[41] *See* Customer Documentation Rule, 77 FR 21278. Also, SDs must comply with Commission regulation 23.608, which prohibits SDs providing clearing services to customers from entering into agreements that would: (i) Disclose the identity of a customer's original executing counterparty; (ii) limit the number of counterparties a customer may trade with; (iii) impose counterparty-based position limits; (iv) impair a customer's access to execution of a trade on terms that have a reasonable relationship to the best terms available; or (v) prevent compliance with specified time frames for acceptance of trades into clearing.

[42] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a

Continued

which is critical to effective systemic risk management for the overall swaps market. In making its comparability determination with regard to these risk management duties, the Commission will consider each regulation individually.[43]

1. Risk Management Program for SDs and MSPs (§ 23.600)

Commission Requirement: Implementing section 4s(j)(2) of the CEA, Commission regulation 23.600 generally requires that:

- Each SD or MSP must establish and enforce a risk management program consisting of a system of written risk management policies and procedures designed to monitor and manage the risks associated with the swap activities of the firm, including without limitation, market, credit, liquidity, foreign currency, legal, operational, and settlement risks, and furnish a copy of such policies and procedures to the CFTC upon application for registration and upon request;
- The SD or MSP must establish a risk management unit independent from the business trading unit;
- The risk management policies and procedures of the SD or MSP must be approved by the firm's governing body;
- Risk tolerance limits and exceptions therefrom must be reviewed and approved quarterly by senior management and annually by the governing body;
- The risk management program must have a system for detecting breaches of risk tolerance limits and alerting supervisors and senior management, as appropriate;
- The risk management program must account for risks posed by affiliates and be integrated at the consolidated entity level;
- The risk management unit must provide senior management and the governing body with quarterly risk exposure reports and upon detection of any material change in the risk exposure of the SD or MSP;
- Risk exposure reports must be furnished to the CFTC within five business days following provision to senior management;
- The risk management program must have a new product policy for assessing the risks of new products prior to engaging in such transactions;
- The risk management program must have policies and procedures providing for trading limits, monitoring of trading, processing of trades, and separation of personnel in the trading unit from personnel in the risk management unit; and
- The risk management program must be reviewed and tested at least annually and upon any material change in the business of the SD or MSP.

Regulatory Objective: Through the required system of risk management, the Commission seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. To this end, the Commission believes the risk management program of an SD or MSP must contain at least the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as section 4s(j)(2) of the CEA and Commission regulation 23.600.

III–2–3–1–3(1) and III–3–7–1–2(1)(ii) of the Supervisory Guidelines and Inspection Manuals for banks and III–1(1)(ii) of the Supervisory Guideline for FIBOs generally require the board of directors of a bank/FIBO to establish a comprehensive risk management program aligned with the bank's/FIBO's strategic target. The risk management program required by the Supervisory Guidelines and Inspectional Manuals must be designed to monitor and manage risk, including without limitation, market (including foreign currency), credit, liquidity, legal, operational, and settlement risks.[44]

The review of a bank's/FIBO's overall risk management program must take into account how frequently the risk management division reports to the board of directors and whether reports are also filed on an as-needed basis. Pursuant to Article 19 of the Banking Act and Article 46–3 of the FIEA, a bank/FIBO must submit to the JFSA a business report referring to the risk management of derivative transactions annually within three months after the end of year period. In addition, pursuant to Article 24 of the Banking Act and Article 56–2 of the FIEA, JFSA requires a bank/FIBO to report to JFSA on a quarterly basis the data of derivative transactions such as the volume and profit and loss amounts within fifty days after the end of every quarter period.

Pursuant to the above Supervisory Guidelines and Inspection Manuals, a bank/FIBO must arrange for the approval of new products in a manner befitting the scale and nature of its business. III–1(1)(iv) of the Supervisory Guidelines for FIBOs and III–2–3–1–3(5)(6) of the Supervisory Guidelines for banks require JSFA to evaluate whether a bank's/FIBO's risk management program established a sufficient internal audit system. As part of this oversight, a bank/FIBO must receive an external audit by corporate auditors at least once a year.

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to § 23.600 by requiring a system of risk management that seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. Specifically, the Commission finds that the Japanese standards specified above comprehensively require SDs and MSPs to establish risk management programs containing the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;

registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[43] As stated above, this notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in Japan to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in Japan.

[44] *See, e.g.* Supervisory Guideline: Checklist for Comprehensive Risk Management, Checklist for Business Management, Checklist for Legal Compliance, Checklist for Market Risk Management, Checklist for Credit Risk Management, Checklist for Liquidity Risk Management, and Checklist for Operational Risk Management.

• An independent risk management unit to administer a risk management program; and

• Periodic oversight of risk exposures by senior management and the governing body.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the risk management program requirements of Japan's laws and regulations, as specified above, are comparable to and as comprehensive as § 23.600, with the exception of § 23.600(c)(2) concerning the requirement that each SD and MSP produce a quarterly risk exposure report and provide such report to its senior management, governing body, and the Commission.

Notwithstanding that the Commission has not determined that the requirements of Japan's laws and regulations are comparable to and as comprehensive as § 23.600(c)(2), any SD or MSP to which both § 23.600 and the Japanese standards specified above are applicable would generally be deemed to be in compliance with § 23.600(c)(2) if that SD or MSP complies with the Japanese standards specified above, subject to compliance with the requirement that it produce quarterly risk exposure reports and provide such reports to its senior management, governing body, and the Commission in accordance with § 23.600(c)(2). The Commission notes that it generally expects reports furnished to the Commission by registrants to be in the English language.

2. Monitoring of Position Limits (§ 23.601)

Commission Requirement: Implementing section 4s(j)(1) of the CEA, Commission regulation 23.601 requires each SD or MSP to establish and enforce written policies and procedures that are reasonably designed to monitor for, and prevent violations of, applicable position limits established by the Commission, a designated contract market ("DCM"), or a swap execution facility ("SEF").[45] The policies and procedures must include an early warning system and provide for escalation of violations to senior management (including the firm's governing body).

Regulatory Objective: Generally, position limits are implemented to ensure market integrity, fairness, orderliness, and accurate pricing in the commodity markets. Commission regulation 23.601 thus seeks to ensure that SDs and MSPs have established the necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by the Commission, a DCM, or a SEF. As part of its Risk Management Program, § 23.601 is intended to ensure that established position limits are not breached by the SD or MSP.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as section 4s(j)(1) of the CEA and Commission regulation 23.601.

IV–2–3 of the Supervisory Guidelines for FIBOs and III–2–3–3–2(2)(vii) and (viii) of the Supervisory Guideline for banks of the Inspection Manuals generally require a bank/FIBO to establish internal position limits, risk limits, and loss limits for all financial products, including derivatives. The policies established by the bank/FIBO must provide a system to provide "alarm points" to the board of directors. Moreover, in accordance with Article 29–2 of the Business Rules of Japan Securities Clearing Corporation ("JSCC") with respect to listed products, JSCC can take an appropriate action against clearing participants (RFIs or FIBOs) if JSCC finds their position is excessive compared with their net assets. Therefore, clearing participants have to monitor their positions in relation to their net assets. CCP's Business Rules, which are subject to JFSA's approval, are legally binding requirements.

The applicants represent that the position limits set internally by banks and FIBOs may not exceed position limits set by applicable law, including position limits set by the Commission, SEFs, or DCMs.[46]

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to § 23.601 by requiring SDs and MSPs to establish necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by applicable laws and regulations, including those of the Commission, a DCM, or a SEF. Specifically, the Commission finds that the Japanese standards specified above, while not specific to the issue of position limit compliance, nevertheless comprehensively require SDs and MSPs to monitor for regulatory compliance generally, which includes monitoring for compliance with position limits set pursuant to applicable law and the responsibility of senior management (including the board of directors) for such compliance.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the compliance monitoring requirements of the Japanese standards, as specified above, are comparable to and as comprehensive as § 23.601. For the avoidance of doubt, the Commission notes that this determination may not be relied on to relieve an SD or MSP from its obligation to strictly comply with any applicable position limit established by the Commission, a DCM, or a SEF.

3. Diligent Supervision (§ 23.602)

Commission Requirement: Commission regulation 23.602 implements section 4s(h)(1)(B) of the CEA and requires each SD and MSP to establish a system to diligently supervise all activities relating to its business performed by its partners, members, officers, employees, and agents. The system must be reasonably designed to achieve compliance with the CEA and CFTC regulations. Commission regulation 23.602 requires that the supervisory system must specifically designate qualified persons with authority to carry out the supervisory responsibilities of the SD or MSP for all activities relating to its business as an SD or MSP.

Regulatory Objective: The Commission's diligent supervision rule seeks to ensure that SDs and MSPs strictly comply with the CEA and the Commission's rules. To this end, through § 23.602, the Commission seeks to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as

[45] The setting of position limits by the Commission, a DCM, or a SEF is subject to requirements under the CEA and Commission regulations other than § 23.601. The setting of position limits and compliance with such limits is not subject to the Commission's substituted compliance regime.

[46] *See* III–3–10 of the Supervisory Guideline for banks and IV–5–2(i) of the Supervisory Guideline for FIBOs for rules regarding management of overseas business by banks and FIBOs.

section 4s(h)(1)(B) of the CEA and Commission regulation 23.602.

III–1–2–1–(2)(xi) and III–1–2–1–(2)(xiii) of the Supervisory Guideline for banks, the Checklist for Business Management (Governance) of the Bank Inspection Manual, III–1(1)(ii)C and IV–1–2–(1)(i) of the Supervisory Guideline for FIBOs, and II–1–1–3(3) and II–2–1 of the FIBO Inspection Manual generally require a bank/FIBO to ensure appropriate officers and employees are in place in order to properly conduct business, and to establish legal compliance and internal control systems.

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to § 23.602 because such standards seek to ensure that SDs and MSPs strictly comply with applicable law, which would include the CEA and the Commission's regulations.[47]

Through the Supervisory Guidelines and Inspection Manuals, Japan's laws and regulations seek to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with applicable law, which would include the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the internal supervision requirements set forth in the Japanese standards, as specified above, are comparable to and as comprehensive as § 23.602.

4. Business Continuity and Disaster Recovery (§ 23.603)

Commission Requirement: To ensure the proper functioning of the swaps markets and the prevention of systemic risk more generally, Commission regulation 23.603 requires each SD and MSP, as part of its risk management program, to establish a business continuity and disaster recovery plan that includes procedures for, and the maintenance of, back-up facilities, systems, infrastructure, personnel, and other resources to achieve the timely recovery of data and documentation and to resume operations generally within the next business day after the disruption.

Regulatory Objective: Commission regulation 23.603 is intended to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, this requirement seeks to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan within one business day, if necessary.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as Commission regulation 23.603.

IV–3–1–6 of the Supervisory Guideline for FIBOs and sections III–6–1 and III–6–2(2)(i)(iii)–(v) of the Supervisory Guideline for banks require a bank/FIBO to establish a crisis management manual and a business continuity and disaster recovery plan that include procedures for, and the maintenance of, back-up facilities, systems, infrastructure, personnel, and other resources to achieve the timely recovery of data and documentation and to resume operations.

Pursuant to III–8–2–(2)–(v) of the Supervisory Guideline for banks, JFSA requires banks to resume operation within the day of the event, especially for important settlement functions. Pursuant to IV–3–1–6(2) of the Supervisory Guideline for FIBOs, JFSA checks whether a FIBO's business continuity plan ensures quick recovery from damage caused by acts of terrorism, large-scale disasters, etc., as well as continuance of the minimum necessary business operations and services for the maintenance of the functions of the financial system.

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to § 23.603 because such standards seek to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, the Commission finds that the Japanese standards specified above seek to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan in a timely manner.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the business continuity and disaster recovery requirements of the Japanese standards, as specified above, are comparable to and as comprehensive as § 23.603.

5. Conflicts of Interest (§ 23.605)

Commission Requirement: Section 4s(j)(5) of the CEA and Commission regulation 23.605(c) generally require each SD or MSP to establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any commodity or swap are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision.

In addition, section 4s(j)(5) of the CEA and Commission regulation 23.605(d)(1) generally prohibits an SD or MSP from directly or indirectly interfering with or attempting to influence the decision of any clearing unit of any affiliated clearing member of a derivatives clearing organization (DCO) to provide clearing services and activities to a particular customer, including:

- Whether to offer clearing services to a particular customer;
- Whether to accept a particular customer for clearing derivatives;
- Whether to submit a customer's transaction to a particular DCO;
- Whether to set or adjust risk tolerance levels for a particular customer; or
- Whether to set a customer's fees based on criteria other than those generally available and applicable to other customers.

Commission regulation 23.605(d)(2) generally requires each SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of any affiliated clearing member of a DCO to reasonably ensure compliance with the Act and the prohibitions set forth in § 23.605(d)(1) outlined above.

The Commission observes that § 23.605(d) works in tandem with Commission regulation 1.71, which requires FCMs that are clearing members of a DCO and affiliated with an SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of the FCM to reasonably ensure compliance with the Act and the prohibitions set forth in § 1.71(d)(1), which are the same as the prohibitions set forth in § 23.605(d)(1) outlined above.

Finally, § 23.605(e) requires that each SD or MSP have policies and procedures that mandate the disclosure

[47] *See* III–3–10 of the Supervisory Guideline for banks and IV–5–2(i) of the Supervisory Guideline for FIBOs for rules regarding management of overseas business by banks and FIBOs.

to counterparties of material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a swap execution facility or designated contract market (DCM) or to clear a derivative through a DCO.

Regulatory Objective: Commission regulation 23.605(c) seeks to ensure that research provided to the general public by an SD or MSP is unbiased and free from the influence of the interests of an SD or MSP arising from the SD's or MSP's trading business.

In addition, the § 23.605(d) (working in tandem with § 1.71) seeks to ensure open access to the clearing of swaps by requiring that access to and the provision of clearing services provided by an affiliate of an SD or MSP are not influenced by the interests of an SD's or MSP's trading business.

Finally, § 23.605(e) seeks to ensure equal access to trading venues and clearinghouses, as well as orderly and fair markets, by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as Commission regulation 23.605.

Regulations Concerning the Handling of Analysts Reports have been developed by the JSDA to require JSDA members to appropriately manage the content of any unpublished analyst report that is considered to have a material impact on investors (to include the presentation of any conflicts) and to establish an appropriate compensation system to ensure the independence of the opinions of analysts.

More generally, FIEA and the Financial Instruments Business Ordinance require a FIBO/RFI to conduct business "in good faith and fairly to customers." Specifically, I.2.(3)(iv) of the Checklist for Legal Compliance of the Bank Inspection Manual and II–1–2–1(4)(iii) of the FIBO Inspection Manual require each bank/FIBO to establish firewalls and take other measures to block the flow of information when necessary. Article 70–3(1)(ii)(d) of the Financial Instruments Business Ordinance and IV–1–3(3)(i)C of the Supervisory Guidelines for FIBOs require a FIBO/RFI to develop a control environment wherein it can choose or combine appropriate method(s), for example, notifying the customer of a conflict risk to establish a system for protection of customers.

The JFSA has informed the Commission that, in the process of its oversight and enforcement of the foregoing Japanese standards for FIBOs and RFIs, any SD or MSP would be subject to such standards and required to resolve or mitigate conflicts of interests in the provision of clearing services by a clearing member of a DCO that is an affiliate of the SD or MSP, or the decision of a counterparty to execute a derivative on a SEF or DCM, or clear a derivative through a DCO, through appropriate information firewalls and disclosures.

Commission Determination: The Commission finds that the Japanese standards specified above with respect to conflicts of interest that may arise in producing or distributing research are generally identical in intent to § 23.605(c) because such standards seek to ensure that research provided to the general public by an SD is unbiased and free from the influence of the interests of an SD arising from the SD's trading business.

With respect to conflicts of interest that may arise in the provision of clearing services by an affiliate of an SD or MSP, the Commission further finds that although the general conflicts of interest prevention requirements under the Japanese standards specified above do not require with specificity that access to and the provision of clearing services provided by an affiliate of an SD or MSP not be improperly influenced by the interests of an SD's or MSP's trading business, such general requirements would require prevention and remediation of such improper influence when recognized or discovered. Thus such standards would ensure open access to clearing.

Finally, although not as specific as the requirements of § 23.605(e) (Undue influence on counterparties), the Commission finds that the general disclosure requirements of the Japanese standards specified above would ensure equal access to trading venues and clearinghouses by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the requirements found in Japan's laws and regulations specified above in relation to conflicts of interest are comparable to and as comprehensive as § 23.605.

6. Availability of Information for Disclosure and Inspection (§ 23.606)

Commission Requirement: Commission regulation 23.606 implements sections 4s(j)(3) and (4) of the CEA, and requires each SD and MSP to disclose to the Commission, and an SD's or MSP's U.S. prudential regulator (if any) comprehensive information about its swap activities, and to establish and maintain reliable internal data capture, processing, storage, and other operational systems sufficient to capture, process, record, store, and produce all information necessary to satisfy its duties under the CEA and Commission regulations. Such systems must be designed to provide such information to the Commission and an SD's or MSP's U.S. prudential regulator within the time frames set forth in the CEA and Commission regulations and upon request.

Regulatory Objective: Commission regulation 23.606 seeks to ensure that each SD and MSP captures and maintains comprehensive information about their swap activities, and is able to retrieve and disclose such information to the Commission and its U.S. prudential regulator, if any, as necessary for compliance with the CEA and the Commission's regulations and for purposes of Commission oversight, as well as oversight by the SD's or MSP's U.S. prudential regulator, if any.

The Commission observes that it would be impossible to meet the regulatory objective of § 23.606 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.606 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as Commission regulation 23.606.

Under the JFSA annual supervisory policies for banks and FIBOs for program year 2013, a bank/FIBO is required to enhance their management information systems through various initiatives such as implementing BCBS "Principles for effective risk data

aggregation and risk reporting," which enable banks/FIBOs to meet the information requests of relevant regulators.

III–3–3(6) of Supervisory Guideline for FIBOs states that each FIBO must maintain electronic media storage systems that can accommodate internal audits and be responsive to client referrals and questions. Moreover, III.1.(6) of the Checklist for Market Risk Management of the Bank Inspection Manual requires that records be readily available for reconciliation with trade tickets, etc.

III–3–10–2(3) (iv) of Supervisory Guideline for banks specifically requires banks to have the personnel and systems to respond in a timely and appropriate manner to inspections and supervision provided by overseas regulatory authorities. In view of maintaining direct dialog and smooth communications with the relevant overseas regulatory authorities, this provision ensures the establishment of a reporting system which enables timely and appropriate reporting.

Similarly, IV–5–2(i) of Supervisory Guideline for FIBOs would ensure the availability of information to a regulator promptly upon request. Under this provision, the JFSA assesses whether a parent company of a FIBO ensures group-wide compliance with the relevant laws, regulations and rules of each country in which it does business by establishing an appropriate control environment for legal compliance in accordance with the size of its overseas bases and the characteristics of its business operations.

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to § 23.606 because such standards seek to ensure that each SD and MSP captures and stores comprehensive information about their swap activities, and are able to retrieve and disclose such information as necessary for compliance with applicable law and for purposes of regulatory oversight.

In addition, the Commission finds that the Japanese standards specified above would ensure Commission access to the required books and records of SDs and MSPs by requiring personnel and systems necessary to respond in a timely and appropriate manner to inspections and supervision provided by overseas regulatory authorities.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the requirements of the Japanese standards with respect to the availability of information for inspection and disclosure, as specified above, are comparable to, and as comprehensive as, § 23.606.

7. Clearing Member Risk Management (§ 23.609)

Commission Requirement: Commission regulation 23.609 generally requires each SD or MSP that is a clearing member of a DCO to:

- Establish risk-based limits based on position size, order size, margin requirements, or similar factors;
- Screen orders for compliance with the risk-based limits;
- Monitor for adherence to the risk-based limits intra-day and overnight;
- Conduct stress tests under extreme but plausible conditions of all positions at least once per week;
- Evaluate its ability to meet initial margin requirements at least once per week;
- Evaluate its ability to meet variation margin requirements in cash at least once per week;
- Evaluate its ability to liquidate positions it clears in an orderly manner, and estimate the cost of liquidation; and
- Test all lines of credit at least once per year.

Regulatory Objective: Through Commission regulation § 23.609, the Commission seeks to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds. Effective risk management by SDs and MSPs that are clearing members is essential to achieving these objectives. A failure of risk management can cause a clearing member to become insolvent and default to a DCO. Such default can disrupt the markets and the clearing system and harm customers.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as Commission regulation 23.609.

III–2–3–2–1–2 (9) and (10)(i) of the Supervisory Guideline for banks and III.(8) and (9)(i) of the Checklist for Credit Risk Management of the Inspection Manual for banks generally require a bank to properly manage the credit risks of major counterparties to derivatives transactions, as well as the risks associated with the clearing of derivatives transactions with a central counterparty. More specifically, the Supervisory Guidelines for banks require a bank to properly manage the risks associated with cleared derivative transactions with central counterparties ("CCPs"), including the inherent risk of transactions with a CCP, the risk associated with material defects of regulations or supervisory schemes to which a CCP is subject, and the risk of loss of the bank's contribution to the default fund of a CCP.

IV–2–4 of the Supervisory Guideline for FIBOs and I–2-(4) of the Inspection Manual for FIBOs require FIBOs to properly manage counterparty risk. Counterparty risk is the risk of incurring losses due to a failure by a counterparty to fulfill its contractual obligations.

The JFSA evaluates a FIBO on whether it properly manages counterparty risk by developing a comprehensive control environment for risk management, properly recognizing and evaluating the risks, conducting internal screening when a new product or a new business is introduced and establishing a system of checks and balances based on the clear allocation of roles and responsibilities.

The JFSA strives to identify and keep track of the status of a FIBO's counterparty risk and its risk management through monthly offsite monitoring reports and hearings based thereon and, when necessary, requiring FIBOs to submit a report based on Article 56–2(1) of the FIEA and urge it to make improvement efforts.

The foregoing requirements apply to bank and FIBO risk management as clearing members.

In addition, if FIBOs/RFIs are clearing members of the JSCC, in accordance with the business rules of the JSCC, they are required to develop an appropriate structure for management of the risk of loss.

Finally, the JFSA has represented to the Commission that, in the process of its oversight and enforcement of the foregoing Japanese standards for banks, FIBOs, and RFIs, any SD or MSP subject to such standards that is a clearing member of a DCO would be required to comply with clearing member risk management requirements comparable to Commission regulation 23.609.

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to § 23.609 because such standards seek to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds.

The Commission notes that the Japanese standards specified above are not as specific as § 23.609 with respect to ensuring that SDs and MSPs that are clearing members of a DCO establish detailed procedures and limits for clearing member risk management purposes. Nevertheless, the Commission finds that the general requirements

under the Japanese standards, implemented in the context of clearing member risk management and pursuant to the representations of the JFSA, meet the Commission's regulatory objective specified above.

Based on the foregoing and the representations above, the Commission hereby determines that the clearing member risk management requirements of the Japanese standards specified above are comparable to and as comprehensive as § 23.609.

C. Swap Data Recordkeeping (§§ 23.201 and 23.203)

Commission Requirement: Sections 4s(f)(1)(B) and 4s(g)(1) of the CEA, and Commission regulation 23.201 generally require SDs and MSPs to retain records of each transaction, each position held, general business records (including records related to complaints and sales and marketing materials), records related to governance, financial records, records of data reported to SDRs, and records of real-time reporting data along with a record of the date and time the SD or MSP made such reports. Transaction records must be kept in a form and manner identifiable and searchable by transaction and counterparty.

Commission regulation 23.203, requires SDs and MSPs to maintain records of a swap transaction until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction, and for a period of five years after such date. Records must be "readily accessible" for the first 2 years of the 5 year retention period (consistent with § 1.31).

The Commission notes that the comparability determination below with respect to §§ 23.201 and 23.203 encompasses both swap data recordkeeping generally and swap data recordkeeping relating to complaints and marketing and sales materials in accordance with § 23.201(b)(3) and (4).[48]

Regulatory Objective: Through the Commission's regulations requiring SDs and MSPs to keep comprehensive records of their swap transactions and related data, the Commission seeks to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

The Commission's regulations require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

By requiring comprehensive records of swap data, the Commission seeks to ensure that SDs and MSPs employ effective risk management, and strictly comply with Commission regulations. Further, such records facilitate effective regulatory oversight.

The Commission observes that it would be impossible to meet the regulatory objective of §§ 23.201 and 23.203 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.203 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable Japanese Law and Regulations: The applicants have represented to the Commission that the following provisions of law and regulations applicable in Japan are in full force and effect in Japan, and comparable to and as comprehensive as sections 4s(f)(1)(B) and 4s(g)(1) of the CEA and §§ 23.201 and 23.203.

A FIBO/RFI is required by provisions set forth in the FIEA, the OTC Derivatives Ordinance, and the Financial Instruments Business Ordinance to retain all records related to swaps transactions.

Articles 371, 381, 394, 396, and 436 of the Company Act require governance records including minutes of board of directors and audit reports of auditors to be retained for ten years. Also, Article 432, 435, and 444 of the Company Act require financial records including financial statements, business reports, and annexed detailed statements to be retained for five years.

Articles 12–3 and 52–71 of the Banking Act and Articles 37–7 and 156–48 of the FIEA further require each bank/FIBO to prepare and maintain records as part of its "complaint processing procedures." Specific details regarding the storage of records detailing customer complaints are set forth in III–3–5–2–2(5)(ii) of the Supervisory Guideline for banks, II–2.1(3–4) and III–2.1(4) of the Checklist for Customer Protection Management of the Bank Inspection Manual, III–2–5 of the Supervisory Guideline for FIBOs, and II–1–2–1(7) of the FIBO Inspection Manual.

Article 37 of the FIEA and Article 72 of the Financial Instruments Business Ordinance require maintenance of records regarding marketing and sales materials.

III–3–3(6) of Supervisory Guideline for FIBOs states that each FIBO must maintain electronic media storage systems that can accommodate internal audits and be responsive to client referrals and questions. Moreover, III.1.(6) of the Checklist for Market Risk Management of the Bank Inspection Manual requires the records be readily available for reconciliation with trade tickets, etc.

FIEA and the Financial Instruments Business Ordinance generally require records to be kept for a minimum of five years, but certain records must be maintained from seven to ten years. III–1(vi) of the Checklist for Market Risk Management of the Bank Inspection Manual assesses whether voice recordings are maintained for all traders on a 24-hour basis and retained "under the control of an organization segregated from the market and back-office divisions."

III–3–10–2(3) (iv) of Supervisory Guideline for banks specifically requires banks to have the personnel and systems to respond in a timely and appropriate manner to inspections and supervision provided by overseas regulatory authorities. In view of maintaining direct dialog and smooth communications with the relevant overseas regulatory authorities, this provision ensures the establishment of a reporting system which enables timely and appropriate reporting.

Similarly, IV–5–2(i) of Supervisory Guideline for FIBOs would ensure the availability of information to a regulator promptly upon request. Under this provision, the JFSA assesses whether a parent company of a FIBO ensures group-wide compliance with the relevant laws, regulations and rules of each country in which it does business by establishing an appropriate control environment for legal compliance in accordance with the size of its overseas bases and the characteristics of its business operations.

Commission Determination: The Commission finds that the Japanese standards specified above are generally identical in intent to §§ 23.201 and 23.203 because such standards seek to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

In addition, the Commission finds that the Japanese standards specified above require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps

[48] *See* the Guidance for a discussion of the availability of substituted compliance with respect to swap data recordkeeping, 78 FR 45332–33.

business and to assess its swaps exposure.

Further, the Commission finds that the Japanese standards specified above, by requiring comprehensive records of swap data, seek to ensure that SDs and MSPs employ effective risk management, seek to ensure that SDs and MSPs strictly comply with applicable regulatory requirements (including the CEA and Commission regulations), and that such records facilitate effective regulatory oversight.

Finally, the Commission finds that the Japanese standards specified above would ensure Commission access to the required books and records of SDs and MSPs by requiring personnel and systems necessary to respond in a timely and appropriate manner to inspections and supervision provided by overseas regulatory authorities.

Based on the foregoing and the representations of the applicants, the Commission hereby determines that the Japanese requirements with respect to swap data recordkeeping, as specified above, are comparable to, and as comprehensive as, §§ 23.201 and 23.203.

Issued in Washington, DC on December 20, 2013, by the Commission.

Melissa D. Jurgens,

Secretary of the Commission.

Appendices to Comparability Determination for Japan: Certain Entity-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler and Commissioners Chilton and Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Dissenting Statement of Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) Are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States * * *"[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad category-by-category basis, should form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or

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[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

[3] CEA section 2(j); 7 U.S.C. 2(j).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] *http://www.cftc.gov/PressRoom/PressReleases/pr6678–13.*

[6] *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf.* The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: the differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the full Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) The Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process: (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30976 Filed 12–26–13; 8:45 am]

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[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

[10] *http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomalia-29.*

[11] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

COMMODITY FUTURES TRADING COMMISSION

Comparability Determination for the European Union: Certain Entity-Level Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Comparability Determination for Certain Requirements under the European Market Infrastructure Regulation.

SUMMARY: The following is the analysis and determination of the Commodity Futures Trading Commission ("Commission") regarding certain parts of a joint request by the European Commission ("EC") and the European Securities and Markets Authority ("ESMA") that the Commission determine that laws and regulations applicable in the European Union ("EU") provide a sufficient basis for an affirmative finding of comparability with respect to the following regulatory obligations applicable to swap dealers ("SDs") and major swap participants ("MSPs") registered with the Commission: (i) Chief compliance officer; (ii) risk management; and (iii) swap data recordkeeping; (collectively, the "Internal Business Conduct Requirements").

DATES: *Effective Date:* This determination will become effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Gary Barnett, Director, 202–418–5977, *gbarnett@cftc.gov*, Frank Fisanich, Chief Counsel, 202–418–5949, *ffisanich@cftc.gov*, and Ellie Jester, Special Counsel, 202–418–5874, *ajester@cftc.gov*, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 26, 2013, the Commission published in the **Federal Register** its "Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations" (the "Guidance").[1] In the Guidance, the

[1] 78 FR 45292 (July 26, 2013). The Commission originally published proposed and further proposed guidance on July 12, 2012 and January 7, 2013, respectively. *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41214 (July 12, 2012) and Further Proposed Guidance Regarding Compliance with Certain Swap Regulations, 78 FR 909 (Jan. 7, 2013).

Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act ("CEA") applies Title VII's swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the "Exemptive Order").[2] Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as "Entity-Level Requirements" in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.[3]

On May 7, 2013, the EC and ESMA (collectively, the "applicant") submitted a request that the Commission determine that laws and regulations applicable in the EU provide a sufficient basis for an affirmative finding of comparability with respect to certain Entity-Level Requirements, including the Internal Business Conduct Requirements.[4] The applicant provided Commission staff with an updated submission on August 6, 2013. On November 11, 2013, the application was further supplemented with corrections and additional materials. The following is the Commission's analysis and determination regarding the Internal Business Conduct Requirements, as detailed below.[5]

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act[6] ("Dodd-Frank Act" or "Dodd-Frank"), which, in Title VII, established a new regulatory framework for swaps.

Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a "direct and significant connection with activities in, or effect on, commerce of the United States" or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.[7] In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission's regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the Commission.[8] Notably, the requirements under Title VII of the Dodd-Frank Act related to SDs and MSPs by their terms apply to all registered SDs and MSPs, irrespective of where they are located, albeit subject to the limitations of CEA section 2(i).

To provide guidance as to the Commission's views regarding the scope of the cross-border application of Title VII of the Dodd-Frank Act, the Commission set forth in the Guidance its interpretation of the manner in which it believes that Title VII's swap provisions apply to activities outside the U.S. pursuant to section 2(i) of the CEA. Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission's regulations. With respect to the standards forming the basis for any determination of comparability ("comparability determination" or "comparability finding"), the Commission stated:

> In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the applicable requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including but not limited to, the comprehensiveness of those requirement(s), the scope and objectives of the relevant regulatory requirement(s), the comprehensiveness of the foreign regulator's supervisory compliance program, as well as the home jurisdiction's authority to support and enforce its oversight of the registrant. In this context, comparable does not necessarily mean identical. Rather, the Commission would evaluate whether the home jurisdiction's regulatory requirement is comparable to and as comprehensive as the corresponding U.S. regulatory requirement(s).[9]

Upon a comparability finding, consistent with CEA section 2(i) and comity principles, the Commission's policy generally is that eligible entities may comply with a substituted compliance regime, subject to any conditions the Commission places on its finding, and subject to the Commission's retention of its examination authority and its enforcement authority.[10]

In this regard, the Commission notes that a comparability determination cannot be premised on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction, but rather on whether information relevant to the Commission's oversight of an SD or MSP would be directly available to the Commission and any U.S. prudential regulator of the SD or MSP.[11] The

[2] 78 FR 43785 (July 22, 2013).

[3] The Entity-Level Requirements under the Exemptive Order consist of 17 CFR 1.31, 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, 23.606, 23.608, 23.609, and parts 45 and 46 of the Commission's regulations.

[4] For purposes of this notice, the Internal Business Conduct Requirements consist of 17 CFR 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606.

[5] This notice does not address swap data repository reporting ("SDR Reporting"). The Commission may provide a comparability determination with respect to the SDR Reporting requirement in a separate notice.

[6] Public Law 111–203, 124 Stat. 1376 (2010).

[7] 7 U.S.C. 2(i).

[8] The compliance dates are summarized on the Compliance Dates page of the Commission's Web site. (*http://www.cftc.gov/LawRegulation/DoddFrankAct/ComplianceDates/index.htm.*)

[9] 78 FR 45342–45.

[10] *See* the Guidance, 78 FR 45342–44.

[11] Under §§ 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered SD or

Commission's direct access to the books and records required to be maintained by an SD or MSP registered with the Commission is a core requirement of the CEA[12] and the Commission's regulations,[13] and is a condition to registration.[14]

III. Regulation of SDs and MSPs in the EU

On May 7, 2013, the EC and ESMA submitted a request that the Commission assess the comparability of laws and regulations applicable in the EU with the CEA and the Commission's regulations promulgated thereunder. The applicant provided Commission staff with an updated submission on August 6, 2013. On November 11, 2013, the application was further supplemented with corrections and additional materials.

As represented to the Commission by the applicant, swap activities in the EU member states is governed primarily by the European Market Infrastructure Regulation ("EMIR").[15]

EMIR and the Regulatory Technical Standards ("RTS") are regulations with immediate, binding, and direct effect in all EU member states (*i.e.*, no transposition into domestic law required). EMIR entered into force on August 16, 2012.

In addition, as represented to the Commission by the applicant, swap activities in the EU are also governed by a number of regulatory requirements other than EMIR.

Markets in Financial Instruments Directive ("MiFID"):[16] MiFID is a directive and in accordance with the Treaty on the Functioning of the European Union, all Member States of the EU are legally bound to implement the provisions of MiFID by November 1, 2007, by transposing them into their national laws. MiFID applies in particular to investment firms, which comprise any legal person whose regular occupation or business is the provision of one or more investment services to third parties and/or the performance of one or more investment activities on a professional basis. Investment services and activities means any of the services and activities listed in Section A of Annex I of MiFID relating to any of the instruments listed in Section C of Annex I of MiFID. Section C of Annex 1 refers explicitly to swaps as well as "other derivative financial instruments".

Capital Requirements Directive ("CRD"):[17] CRD is also a directive and in accordance with the Treaty on the Functioning of the European Union, all Member States of the EU are legally bound to implement the provisions of CRD by December 31, 2006, by transposing them into their national laws.[18]

Due to the requirement that each EU Member State transpose MiFID and CRD into its national law, the comparability determinations in this notice are based on the representations of the applicant to the Commission that (i) each Member State of the EU where an SD or MSP would seek to rely on substituted compliance on the basis of the comparability of the MiFID or CRD standards has completed the process of transposing MiFID and CRD into its national law;[19] (ii) such national laws have transposed MiFID and CRD without change in any aspect that is material for a comparability determination contained herein; and (iii) such transposed law is in full force and effect as of the time that any SD or MSP seeks to rely on a relevant comparability determination contained herein. The Commission notes that to the extent that any of the foregoing representations are incorrect, an affected comparability determination will not be valid.

In addition to MiFID and CRD, the applicant noted that there are a number of proposed laws and regulations that, when implemented, would affect the regulation of SDs and MSPs in the EU.[20]

IV. Comparable and Comprehensiveness Standard

The Commission's comparability analysis will be based on a comparison of specific foreign requirements against the specific related CEA provisions and Commission regulations as categorized and described in the Guidance. As explained in the Guidance, within the framework of CEA section 2(i) and principles of international comity, the Commission may make a comparability determination on a requirement-by-requirement basis, rather than on the basis of the foreign regime as a whole.[21] In making its comparability determinations, the Commission may include conditions that take into

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MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable prudential regulator.

In its Final Exemptive Order Regarding Compliance with Certain Swap Regulations, 78 FR 858 (Jan. 7, 2013), the Commission noted that an applicant for registration as an SD or MSP must file a Form 7–R with the National Futures Association and that Form 7–R was being modified at that time to address existing blocking, privacy, or secrecy laws of foreign jurisdictions that applied to the books and records of SDs and MSPs acting in those jurisdictions. See id. at 871–72 n. 107. The modifications to Form 7–R were a temporary measure intended to allow SDs and MSPs to apply for registration in a timely manner in recognition of the existence of the blocking, privacy, and secrecy laws. In the Guidance, the Commission clarified that the change to Form 7–R impacts the registration application only and does not modify the Commission's authority under the CEA and its regulations to access records held by registered SDs and MSPs. Commission access to a registrant's books and records is a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto. The Commission has maintained an ongoing dialogue on a bilateral and multilateral basis with foreign regulators and with registrants to address books and records access issues and may consider appropriate measures where requested to do so.

[12] See e.g., sections 4s(f)(1)(C), 4s(j)(3) and (4) of the CEA.

[13] See e.g., §§ 23.203(b) and 23.606.

[14] See supra note 10.

[15] *EMIR:* Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories. *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0001:0059:EN:PDF*

[16] Directive 2004/39/EC and the relevant implementing measures (Directive 2006/73/EC and Regulation 1287/2006). *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0039:EN:NOT*

[17] Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions.*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006L0048;20100330:EN:PDF.*The current version of CRD will soon be replaced by CRD IV. CRD IV entered into force on June 28, 2013, and shall apply in most of its parts from January 1, 2014.

[18] Because the applicant's request and the Commission's determinations herein are based on the comparability of EU requirements applicable to entities subject to EMIR, MiFID, and CRD, an SD or MSP that is not subject to the requirements of EMIR, MiFID, or CRD upon which the Commission bases its determinations, may not be able to rely on the Commission's comparability determinations herein. The applicant has noted for the Commission that the concept of an MSP is not explicitly mirrored in EU legislation and so it cannot be confirmed that MSPs would always be covered by EMIR, MiFID, or CRD. However, the applicant states that the definition of an "investment firm" under MiFID is considerably wider than that of an SD, and thus MSP's should, in most cases, be caught within the definition of "investment firm."

[19] See the Web site of the European Commission for confirmation of the transposition of MiFID into the national law of each Member State, available here: *http://ec.europa.eu/internal_market/securities/docs/transposition/table_en.pdf.* Note that the issue of partial implementation in the Netherlands was resolved in 2008, *http://ec.europa.eu/eu_law/eulaw/decisions/dec_08_05_06.htm.* The Commission notes that the EC has certified to the Commission that each Member State in which a registered SD or MSP is organized has completed the transposition process (e.g., Ireland, UK, France, Spain, and Germany).

[20] The applicant provided information regarding MiFID II and the Markets in Financial Instruments Regulation ("MiFIR"), *http://ec.europa.eu/internal_market/securities/isd/mifid/index_en.htm,* stating that these two proposals are part of the legislative package for the review of MiFID, and that the legislative process may be concluded with the adoption of the final political agreement by the end of 2013. The applicant further stated that an additional 18 to 24 months will be needed to adopt implementing measures, with the overall package to be applied by the end of 2015.

[21] 78 FR 45343.

account timing and other issues related to coordinating the implementation of reform efforts across jurisdictions.[22]

In evaluating whether a particular category of foreign regulatory requirement(s) is comparable and comprehensive to the corollary requirement(s) under the CEA and Commission regulations, the Commission will take into consideration all relevant factors, including, but not limited to:

- The comprehensiveness of those requirement(s),
- The scope and objectives of the relevant regulatory requirement(s),
- The comprehensiveness of the foreign regulator's supervisory compliance program, and
- The home jurisdiction's authority to support and enforce its oversight of the registrant.[23]

In making a comparability determination, the Commission takes an "outcome-based" approach. An "outcome-based" approach means that when evaluating whether a foreign jurisdiction's regulatory requirements are comparable to, and as comprehensive as, the corollary areas of the CEA and Commission regulations, the Commission ultimately focuses on regulatory outcomes (*i.e.*, the home jurisdiction's requirements do not have to be identical).[24] This approach recognizes that foreign regulatory systems differ and their approaches vary and may differ from how the Commission chose to address an issue, but that the foreign jurisdiction's regulatory requirements nonetheless achieve the regulatory outcome sought to be achieved by a certain provision of the CEA or Commission regulation.

In doing its comparability analysis the Commission may determine that no comparability determination can be made[25] and that the non-U.S. SD or non-U.S. MSP, U.S. bank that is an SD or MSP with respect to its foreign branches, or non-registrant, to the extent applicable under the Guidance, may be required to comply with the CEA and Commission regulations.

The starting point in the Commission's analysis is a consideration of the regulatory objectives of the foreign jurisdiction's regulation of swaps and swap market participants. As stated in the Guidance, jurisdictions may not have swap specific regulations in some areas, and instead have regulatory or supervisory regimes that achieve comparable and comprehensive regulation to the Dodd-Frank Act requirements, but on a more general, entity-wide, or prudential, basis.[26] In addition, portions of a foreign regulatory regime may have similar regulatory objectives, but the means by which these objectives are achieved with respect to swaps market activities may not be clearly defined, or may not expressly include specific regulatory elements that the Commission concludes are critical to achieving the regulatory objectives or outcomes required under the CEA and the Commission's regulations. In these circumstances, the Commission will work with the regulators and registrants in these jurisdictions to consider alternative approaches that may result in a determination that substituted compliance applies.[27]

Finally, the Commission will generally rely on an applicant's description of the laws and regulations of the foreign jurisdiction in making its comparability determination. The Commission considers an application to be a representation by the applicant that the laws and regulations submitted are in full force and effect, that the description of such laws and regulations is accurate and complete, and that, unless otherwise noted, the scope of such laws and regulations encompasses the swaps activities[28] of SDs and MSPs[29] in the relevant jurisdictions.[30] Further, as stated in the Guidance, the Commission expects that an applicant would notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant supervisory or regulatory regime) as, depending on the nature of the change, the Commission's comparability determination may no longer be valid.[31]

The Guidance provided a detailed discussion of the Commission's policy regarding the availability of substituted

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[22] 78 FR 45343.

[23] 78 FR 45343.

[24] 78 FR 45343. The Commission's substituted compliance program would generally be available for SDR Reporting, as outlined in the Guidance, only if the Commission has direct access to all of the data elements that are reported to a foreign trade repository pursuant to the substituted compliance program. Thus, direct access to swap data is a threshold matter to be addressed in a comparability evaluation for SDR Reporting. Moreover, the Commission explains in the Guidance that, due to its technical nature, a comparability evaluation for SDR Reporting "will generally entail a detailed comparison and technical analysis." A more particularized analysis will generally be necessary to determine whether data stored in a foreign trade repository provides for effective Commission use, in furtherance of the regulatory purposes of the Dodd-Frank Act. *See* 78 FR 45345.

[25] A finding of comparability may not be possible for a number of reasons, including the fact that the foreign jurisdiction has not yet implemented or finalized particular requirements.

[26] 78 FR 45343.

[27] As explained in the Guidance, such "approaches used will vary depending on the circumstances relevant to each jurisdiction. One example would include coordinating with the foreign regulators in developing appropriate regulatory changes or new regulations, particularly where changes or new regulations already are being considered or proposed by the foreign regulators or legislative bodies. As another example, the Commission may, after consultation with the appropriate regulators and market participants, include in its substituted compliance determination a description of the means by which certain swaps market participants can achieve substituted compliance within the construct of the foreign regulatory regime. The identification of the means by which substituted compliance is achieved would be designed to address the regulatory objectives and outcomes of the relevant Dodd-Frank Act requirements in a manner that does not conflict with a foreign regulatory regime and reduces the likelihood of inconsistent regulatory obligations. For example, the Commission may specify that [SDs] and MSPs in the jurisdiction undertake certain recordkeeping and documentation for swap activities that otherwise is only addressed by the foreign regulatory regime with respect to financial activities generally. In addition, the substituted compliance determination may include provisions for summary compliance and risk reporting to the Commission to allow the Commission to monitor whether the regulatory outcomes are being achieved. By using these approaches, in the interest of comity, the Commission would seek to achieve its regulatory objectives with respect to the Commission's registrants that are operating in foreign jurisdictions in a manner that works in harmony with the regulatory interests of those jurisdictions." 78 FR 45343–44.

[28] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[29] No SD or MSP that is not legally required to comply with a law or regulation determined to be comparable may voluntarily comply with such law or regulation in lieu of compliance with the CEA and the relevant Commission regulation. Each SD or MSP that seeks to rely on a comparability determination is responsible for determining whether it is subject to the laws and regulations found comparable. Currently, there are no MSPs organized outside the U.S. and the Commission therefore cautions any non-financial entity organized outside the U.S. and applying for registration as an MSP to carefully consider whether the laws and regulations determined to be comparable herein are applicable to such entity.

[30] The Commission has provided the relevant foreign regulator(s) with opportunities to review and correct the applicant's description of such laws and regulations on which the Commission will base its comparability determination. The Commission relies on the accuracy and completeness of such review and any corrections received in making its comparability determinations. A comparability determination based on an inaccurate description of foreign laws and regulations may not be valid.

[31] 78 FR 45345.

compliance [32] for the Internal Business Conduct Requirements.[33]

V. Supervisory Arrangement

In the Guidance, the Commission stated that, in connection with a determination that substituted compliance is appropriate, it would expect to enter into an appropriate memorandum of understanding ("MOU") or similar arrangement [34] with the relevant foreign regulator(s). Although existing arrangements would indicate a foreign regulator's ability to cooperate and share information, "going forward, the Commission and relevant foreign supervisor(s) would need to establish supervisory MOUs or other arrangements that provide for information sharing and cooperation in the context of supervising [SDs] and MSPs." [35]

The Commission is in the process of developing its registration and supervision regime for provisionally-registered SDs and MSPs. This new initiative includes setting forth supervisory arrangements with authorities that have joint jurisdiction over SDs and MSPs that are registered with the Commission and subject to U.S. law. Given the developing nature of the Commission's regime and the fact that the Commission has not negotiated prior supervisory arrangements with certain authorities, the negotiation of supervisory arrangements presents a unique opportunity to develop close working relationships between and among authorities, as well as highlight any potential issues related to cooperation and information sharing.

Accordingly, the Commission is negotiating such a supervisory arrangement with each applicable foreign regulator of an SD or MSP. The Commission expects that the arrangement will establish expectations for ongoing cooperation, address direct access to information,[36] provide for notification upon the occurrence of specified events, memorialize understandings related to on-site visits,[37] and include protections related to the use and confidentiality of non-public information shared pursuant to the arrangement.

These arrangements will establish a roadmap for how authorities will consult, cooperate, and share information. As with any such arrangement, however, nothing in these arrangements will supersede domestic laws or resolve potential conflicts of law, such as the application of domestic secrecy or blocking laws to regulated entities.

VI. Comparability Determination and Analysis

The following section describes the requirements imposed by specific sections of the CEA and the Commission's regulations for the Internal Business Conduct Requirements that are the subject of this comparability determination, and the Commission's regulatory objectives with respect to such requirements. Immediately following a description of the requirement(s) and regulatory objective(s) of the specific Internal Business Conduct Requirements that the requestor submitted for a comparability determination, the Commission provides a description of the foreign jurisdiction's comparable laws, regulations, or rules and whether such laws, regulations, or rules meet the applicable regulatory objective.

The Commission's determinations in this regard and the discussion in this section are intended to inform the public of the Commission's views regarding whether the foreign jurisdiction's laws, regulations, or rules may be comparable and comprehensive as those requirements in the Dodd-Frank Act (and Commission regulations promulgated thereunder) and therefore, may form the basis of substituted compliance. In turn, the public (in the foreign jurisdiction, in the United States, and elsewhere) retains its ability to present facts and circumstances that would inform the determinations set forth in this notice.

As was stated in the Guidance, the Commission recognizes the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime. In this regard, the Commission may review, modify, or expand the determinations herein in light of comments received and future developments.

A. Chief Compliance Officer (§ 3.3).

Commission Requirement: Implementing section 4s(k) of the CEA, Commission regulation 3.3 generally sets forth the following requirements for SDs and MSPs:

- An SD or MSP must designate an individual as Chief Compliance Officer ("CCO");
- The CCO must have the responsibility and authority to develop the regulatory compliance policies and procedures of the SD or MSP;
- The CCO must report to the board of directors or the senior officer of the SD or MSP;
- Only the board of directors or a senior officer may remove the CCO;
- The CCO and the board of directors must meet at least once per year;
- The CCO must have the background and skills appropriate for the responsibilities of the position;
- The CCO must not be subject to disqualification from registration under sections 8a(2) or (3) of the CEA;
- Each SD and MSP must include a designation of a CCO in its registration application;

[32] *See* 78 FR 45348–50. The Commission notes that registrants and other market participants are responsible for determining whether substituted compliance is available pursuant to the Guidance based on the comparability determination contained herein (including any conditions or exceptions), and its particular status and circumstances.

[33] This notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in the EU to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in the EU.

This notice also does not address capital adequacy because the Commission has not yet finalized rules for SDs and MSPs in this area, nor SDR Reporting. The Commission may provide a comparability determination with respect to these requirements at a later date or in a separate notice.

[34] An MOU is one type of arrangement between or among regulators. Supervisory arrangements could include, as appropriate, cooperative arrangements that are memorialized and executed as addenda to existing MOUs or, for example, as independent bilateral arrangements, statements of intent, declarations, or letters.

[35] 78 FR 45344.

[36] Section 4s(j)(3) and (4) of the CEA and Commission regulation 23.606 require a registered SD or MSP to make all records required to be maintained in accordance with Commission regulation 1.31 available promptly upon request to, among others, representatives of the Commission. *See also* 7 U.S.C. 6s(f); 17 CFR 23.203. In the Guidance, the Commission states that it "reserves this right to access records held by registered [SDs] and MSPs, including those that are non-U.S. persons who may comply with the Dodd-Frank recordkeeping requirement through substituted compliance." 78 FR 45345 n. 472; *see also id.* at 45342 n. 461 (affirming the Commission's authority under the CEA and its regulations to access books and records held by registered SDs and MSPs as "a fundamental regulatory tool necessary to properly monitor and examine each registrant's compliance with the CEA and the regulations adopted pursuant thereto").

[37] The Commission retains its examination authority, both during the application process as well as upon and after registration of an SD or MSP. *See* 78 FR 45342 (stating Commission policy that "eligible entities may comply with a substituted compliance regime under certain circumstances, subject, however, to the Commission's retention of its examination authority") and 45344 n. 471 (stating that the "Commission may, as it deems appropriate and necessary, conduct an on-site examination of the applicant").

- The CCO must administer the regulatory compliance policies of the SD or MSP;
- The CCO must take reasonable steps to ensure compliance with the CEA and Commission regulations, and resolve conflicts of interest;
- The CCO must establish procedures for detecting and remediating non-compliance issues;
- The CCO must annually prepare and sign an "annual compliance report" containing: (i) A description of policies and procedures reasonably designed to ensure compliance; (ii) an assessment of the effectiveness of such policies and procedures; (iii) a description of material non-compliance issues and the action taken; (iv) recommendations of improvements in compliance policies; and (v) a certification by the CCO or chief executive officer that, to the best of such officer's knowledge and belief, the annual report is accurate and complete under penalty of law; and
- The annual compliance report must be furnished to the CFTC within 90 days after the end of the fiscal year of the SD or MSP, simultaneously with its annual financial condition report.

Regulatory Objective: The Commission believes that compliance by SDs and MSPs with the CEA and the Commission's rules greatly contributes to the protection of customers, orderly and fair markets, and the stability and integrity of the market intermediaries registered with the Commission. The Commission expects SDs and MSPs to strictly comply with the CEA and the Commission's rules and to devote sufficient resources to ensuring such compliance. Thus, through its CCO rule, the Commission seeks to ensure firms have designated a qualified individual as CCO that reports directly to the board of directors or the senior officer of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually to the Commission and the board or senior officer on compliance of the firm.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(k) of the CEA and Commission regulation 3.3.

MiFID Articles 13(2), 13(3) and 18 set forth the general obligation for investment firms (which would include SDs) to establish adequate policies and procedures to ensure compliance with requirements and to identify and properly manage conflicts of interests.

MiFID implementing measure (Commission Directive "MiFID L2D") Articles 5, 6, 9, 21 to 23 clarify, along with ESMA guidelines, the application of some aspects of the MiFID articles, to ensure common, uniform, and consistent application of MiFID and the MiFID L2D across the EU. The main principles are the following:

- Investment firms must appoint a person as compliance officer ("CO") responsible for the compliance function ("CF");
- The CO must have sufficiently broad knowledge/experience and high level of expertise to assume responsibility for the CF and ensure it is effective;
- Written reports must be sent to senior management (which includes boards of directors) on a regular basis (at least annually as well as on an ad-hoc basis when significant compliance matters are discovered);
- The CO must only be appointed and replaced by senior management or supervisory function;
- The CO, but also compliance staff, must have specific knowledge, skills and expertise relevant to the tasks and to the business of the firm;
- Supervisors must ensure compliance with above requirements in the authorization process of investment firms and during on-going supervision;
- CF, under the responsibility of the CO, must monitor and assess the adequacy and effectiveness of measures and procedures to ensure compliance with regulatory obligations and to address any deficiencies, including the obligation to identify and manage conflicts of interests and maintain effective conflicts of interest policies;
- Written report to address, at least annually: The description of implementation and effectiveness of the overall control environment; the summary of major findings of the review of policies and procedures; the summary of inspections and reviews carried out; the risk identified; and the advice on any necessary remedial action;
- The CF must be involved in all material non-routine correspondence with supervisors;
- The CF must be involved in all significant modifications of the organization of the investment firm;
- The CF must be independent;
- Senior management retains ultimate responsibility to ensure firms' compliance with obligations; and
- Investment firms must arrange for all records necessary to enable supervisors to monitor compliance with requirements.

Commission Determination: The Commission finds that the MiFID standards specified above are generally identical in intent to § 3.3 by seeking to ensure firms have designated a qualified individual as the compliance officer that reports directly to a sufficiently senior function of the firm and that has the independence, responsibility, and authority to develop and administer compliance policies and procedures reasonably designed to ensure compliance with the CEA and Commission regulations, resolve conflicts of interest, remediate noncompliance issues, and report annually on compliance of the firm.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the CCO requirements of MiFID are comparable to and as comprehensive as § 3.3, with the exception of § 3.3(f) concerning certifying and furnishing an annual compliance report to the Commission.

Notwithstanding that the Commission has not determined that the requirements of MiFID are comparable to and as comprehensive as § 3.3(f), any SD or MSP to which both § 3.3 and the MiFID standards specified above are applicable would generally be deemed to be in compliance with § 3.3(f) if that SD or MSP complies with the MiFID standards specified above, subject to certifying and furnishing the Commission with the annual report required under the MiFID standards specified above in accordance with § 3.3(f). The Commission notes that it generally expects registrants to submit required reports to the Commission in the English language.

B. Risk Management Duties (§§ 23.600–23.609)

Section 4s(j) of the CEA requires each SD and MSP to establish internal policies and procedures designed to, among other things, address risk management, monitor compliance with position limits, prevent conflicts of interest, and promote diligent supervision, as well as maintain business continuity and disaster recovery programs.[38] The Commission adopted regulations 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606 to implement the statute.[39] The

[38] 7 U.S.C. 6s(j).

[39] *See* Final Swap Dealer and MSP Recordkeeping Rule, 77 FR 20128 (April 3, 2012) (relating to risk management program, monitoring of position

Commission also adopted regulation 23.609, which requires certain risk management procedures for SDs or MSPs that are clearing members of a derivatives clearing organization ("DCO").[40] Collectively, these requirements help to establish a robust and comprehensive internal risk management program for SDs and MSPs with respect to their swaps activities,[41] which is critical to effective systemic risk management for the overall swaps market. In making its comparability determination with regard to these risk management duties, the Commission will consider each regulation individually.[42]

1. Risk Management Program for SDs and MSPs (§ 23.600)

Commission Requirement: Implementing section 4s(j)(2) of the CEA, Commission regulation 23.600 generally requires that:

- Each SD or MSP must establish and enforce a risk management program consisting of a system of written risk management policies and procedures designed to monitor and manage the risks associated with the swap activities of the firm, including without limitation, market, credit, liquidity, foreign currency, legal, operational, and settlement risks, and furnish a copy of such policies and procedures to the CFTC upon application for registration and upon request;
- The SD or MSP must establish a risk management unit independent from the business trading unit;
- The risk management policies and procedures of the SD or MSP must be approved by the firm's governing body;
- Risk tolerance limits and exceptions therefrom must be reviewed and approved quarterly by senior management and annually by the governing body;
- The risk management program must have a system for detecting breaches of risk tolerance limits and alerting supervisors and senior management, as appropriate;
- The risk management program must account for risks posed by affiliates and be integrated at the consolidated entity level;
- The risk management unit must provide senior management and the governing body with quarterly risk exposure reports and upon detection of any material change in the risk exposure of the SD or MSP;
- Risk exposure reports must be furnished to the CFTC within five business days following provision to senior management;
- The risk management program must have a new product policy for assessing the risks of new products prior to engaging in such transactions;
- The risk management program must have policies and procedures providing for trading limits, monitoring of trading, processing of trades, and separation of personnel in the trading unit from personnel in the risk management unit; and
- The risk management program must be reviewed and tested at least annually and upon any material change in the business of the SD or MSP.

Regulatory Objective: Through the required system of risk management, the Commission seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. To this end, the Commission believes the risk management program of an SD or MSP must contain at least the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(j)(2) of the CEA and Commission regulation 23.600.

- Under MiFID Article 13(5) & MiFID L2D Article 5, investment firms must have effective procedures for risk assessment, effective control, and safeguard arrangements for information processing systems, sound administrative and accounting procedures, and internal control mechanisms.
- Under MiFID L2D Article 6, investment firms (including SDs) must, subject to a proportionality principle dependent on the size and nature of a firm's business, establish and maintain an independent risk management function that is responsible for the implementation of risk management policies and procedures and that provides reports and advice to senior management regarding risk management.
- MiFID L2D Article 9: Senior management (which includes boards of directors) must take responsibility for firms' compliance with regulatory obligations including risk management.
- MiFID L2D Article 9: Senior management must receive on a frequent basis, and at least annually, written reports on risk management issues, including any appropriate action taken in the event of deficiencies;
- MiFID L2D Article 7: Investment firms must identify the risks relating to the firms' activities, processes and systems, and set the level of risk tolerated by the firm in appropriate instances; must adopt effective arrangements, processes, and mechanisms to manage the risks relating to the firm's activities, processes and systems, in light of the established level of risk tolerance; must monitor the adequacy and effectiveness of its risk management policies and procedures, the level of compliance with arrangements, processes and mechanisms for risk management; and must monitor the adequacy and effectiveness of measures taken to address any deficiencies. The risk management strategy should address credit and counterparty risk; residual risk; market risk; interest rate risk; operational risk; liquidity risk; securitization risk; concentration risk; and risk of excessive leverage.
- Directive 2002/87/EC Article 9: In the case of financial conglomerates, risk management processes must include

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limits, business continuity and disaster recovery, conflicts of interest policies and procedures, and general information availability, respectively).

[40] *See* Customer Documentation Rule, 77 FR 21278. Also, SDs must comply with Commission regulation 23.608, which prohibits SD providing clearing services to customers from entering into agreements that would: (i) Disclose the identity of a customer's original executing counterparty; (ii) limit the number of counterparties a customer may trade with; (iii) impose counterparty-based position limits; (iv) impair a customer's access to execution of a trade on terms that have a reasonable relationship to the best terms available; or (v) prevent compliance with specified time frames for acceptance of trades into clearing.

[41] "Swaps activities" is defined in Commission regulation 23.600(a)(7) to mean, "with respect to a registrant, such registrant's activities related to swaps and any product used to hedge such swaps, including, but not limited to, futures, options, other swaps or security-based swaps, debt or equity securities, foreign currency, physical commodities, and other derivatives." The Commission's regulations under 17 CFR Part 23 are limited in scope to the swaps activities of SDs and MSPs.

[42] As stated above, this notice does not address § 23.608 (Restrictions on counterparty clearing relationships). The Commission declines to take up the request for a comparability determination with respect to this regulation due to the Commission's view that there are not laws or regulations applicable in the EU to compare with the prohibitions and requirements of § 23.608. The Commission may provide a comparability determination with respect to this regulation at a later date in consequence of further developments in the law and regulations applicable in the EU.

approval and periodical review of the strategies and policies by governing bodies with respect to all the risks assumed; adequate capital adequacy policies to anticipate impacts on risk profiles and capital requirements; risk monitoring and controls at the level of the conglomerates.

- ESMA Guidelines on compliance function requirements (ESMA/2012/388) specify that the assessment of compliance risk should involve the compliance function, including in the case of new business lines or new financial products. Identified risks should be reviewed on a regular basis as well as ad-hoc when necessary to ensure that any emerging risks are taken into consideration. A monitoring program covering all areas of the investment firm's activities should ensure that compliance risk is comprehensively monitored. Specific measures ensure the effectiveness, the permanence and the independence of the compliance function.
- MiFID L2D Articles 21 to 23: Requirements on conflicts of interests include the obligation to adopt measures to ensure the appropriate level of independence to any person working in the firm. This includes measures preventing or controlling the exchange of information, separating the supervision of relevant persons, preventing or limiting the possibility for a person to exercise inappropriate influence over others. Furthermore, firms must ensure that performance of multiple functions does not prevent persons from acting soundly, honestly, and professionally.
- MiFID Article 50: Supervisors can access documents for the discharge of their supervisory duties.
- CRD Annex V: Credit institutions and investment firms must have in place risk management procedures that cover credit, operational, counterparty, market, concentration, securitization, liquidity and interest rate risk.
- CRD Article 22: Credit institution's conformity with regulation is the responsibility of the institution's management body and is subject to ongoing supervisory review.[43]

Commission Determination: The Commission finds that the MiFID, ESMA, and CRD standards specified above are generally identical in intent to § 23.600 by requiring a system of risk management that seeks to ensure that firms are adequately managing the risks of their swaps activities to prevent failure of the SD or MSP, which could result in losses to counterparties doing business with the SD or MSP, and systemic risk more generally. Specifically, the Commission finds that the MiFID, ESMA, and CRD standards specified above comprehensively require SDs and MSPs to establish risk management programs containing the following critical elements:

- Identification of risk categories;
- Establishment of risk tolerance limits for each category of risk and approval of such limits by senior management and the governing body;
- An independent risk management unit to administer a risk management program; and
- Periodic oversight of risk exposures by senior management and the governing body.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the risk management program requirements of MiFID, ESMA, and CRD, as specified above, are comparable to and as comprehensive as § 23.600, with the exception of § 23.600(c)(2) concerning the requirement that each SD and MSP produce a quarterly risk exposure report and provide such report to its senior management, governing body, and the Commission.

Notwithstanding that the Commission has not determined that the requirements of MiFID, ESMA, and CRD are comparable to and as comprehensive as § 23.600(c)(2), any SD or MSP to which both § 23.600 and the MiFID, ESMA, and CRD standards specified above are applicable would generally be deemed to be in compliance with § 23.600(c)(2) if that SD or MSP complies with the MiFID, ESMA, and CRD standards specified above, subject to compliance with the requirement that it produce quarterly risk exposure reports and provide such reports to its senior management, governing body, and the Commission in accordance with § 23.600(c)(2). The Commission notes that it generally expects reports furnished to the Commission by registrants to be in the English language.

2. Monitoring of Position Limits (§ 23.601)

Commission Requirement: Implementing section 4s(j)(1) of the CEA, Commission regulation 23.601 requires each SD or MSP to establish and enforce written policies and procedures that are reasonably designed to monitor for, and prevent violations of, applicable position limits established by the Commission, a designated contract market ("DCM"), or a swap execution facility ("SEF").[44] The policies and procedures must include an early warning system and provide for escalation of violations to senior management (including the firm's governing body).

Regulatory Objective: Generally, position limits are implemented to ensure market integrity, fairness, orderliness, and accurate pricing in the commodity markets. Commission regulation 23.601 thus seeks to ensure that SDs and MSPs have established the necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by the Commission, a DCM, or a SEF. As part of its Risk Management Program, § 23.601 is intended to ensure that established position limits are not breached by the SD or MSP.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(j)(1) of the CEA and Commission regulation 23.601.

The applicant requests that the Commission look to the general risk management function requirements outlined in subsection VI(B)(1) (Risk Management Program) above and the general compliance function requirements outlined in subsection VI(A) (Chief Compliance Officer) above for comparable EU law and regulations that would require an SD or MSP to monitor for and comply with applicable position limits. For example:

- MiFID L2D: A firm's compliance function, under the responsibility of the compliance officer, must monitor and assess the adequacy and effectiveness of measures and procedures to ensure compliance with regulatory obligations and to address any deficiencies,

[43] The current version of CRD will soon be replaced by CRD IV. CRD IV entered into force on June 28, 2013, and shall apply in most of its parts from January 1, 2014. The new reference is Article 74 and there will be additional detailed technical rules specifying the arrangements, processes and mechanisms that must be adopted to fulfill this requirement. Article 88 of Directive 2013/36/EU specifies that " the management body defines, oversees and is accountable for the implementation of the governance arrangements that ensure effective and prudent management of an institution." Article 76 specifies tasks assigned to the management body as regards risk management. *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=:Oj:L:2013:176:0338:0436:EN:PDF.*

[44] The setting of position limits by the Commission, a DCM, or a SEF is subject to requirements under the CEA and Commission regulations other than § 23.601. The setting of position limits and compliance with such limits is not subject to the Commission's substituted compliance regime.

including obligations to identify and manage conflicts of interests and maintain effective conflicts of interest policies; and

- MiFID L2D Article 9: Senior management (which includes boards of directors) must take responsibility for firms' compliance with regulatory obligations including risk management.

The applicant states that the foregoing MiFID standards to monitor the effectiveness of procedures to ensure compliance with regulatory obligations includes regulatory obligations of an SD or MSP, that is subject to such MiFID standards, to comply with applicable standards under the CEA, Commission regulations, and position limits set by the Commission, a DCM, or a SEF.

Commission Determination: The Commission finds that the MiFID standards specified above are generally identical in intent to § 23.601 by requiring SDs and MSPs to establish necessary policies and procedures to monitor the trading of the firm to prevent violations of applicable position limits established by applicable laws and regulations, including those of the Commission, a DCM, or a SEF. Specifically, the Commission finds that the MiFID standards specified above, while not specific to the issue of position limit compliance, nevertheless comprehensively require SDs and MSPs to monitor for regulatory compliance generally, which includes monitoring for compliance with position limits set pursuant to applicable law and the responsibility of senior management (including the board of directors) for such compliance.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the compliance monitoring requirements of MiFID, as specified above, are comparable to and as comprehensive as § 23.601. For the avoidance of doubt, the Commission notes that this determination may not be relied on to relieve an SD or MSP from its obligation to strictly comply with any applicable position limit established by the Commission, a DCM, or a SEF.

3. Diligent Supervision (§ 23.602)

Commission Requirement: Commission regulation 23.602 implements section 4s(h)(1)(B) of the CEA and requires each SD and MSP to establish a system to diligently supervise all activities relating to its business performed by its partners, members, officers, employees, and agents. The system must be reasonably designed to achieve compliance with the CEA and CFTC regulations. Commission regulation 23.602 requires that the supervisory system must specifically designate qualified persons with authority to carry out the supervisory responsibilities of the SD or MSP for all activities relating to its business as an SD or MSP.

Regulatory Objective: The Commission's diligent supervision rule seeks to ensure that SDs and MSPs strictly comply with the CEA and the Commission's rules. To this end, through § 23.602, the Commission seeks to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as section 4s(h)(1)(B) of the CEA and Commission regulation 23.602.

Under MiFID Article 13, MiFID L2D Articles 5, 6, 11, and 12, and ESMA/2012/388, firms must establish policies and procedures sufficient to ensure compliance of the firm, as well as its managers, employees and agents, with all of their compliance obligations as well as rules on personal transactions by these persons. The applicant represents to the Commission that the compliance obligations of firms that are subject to MiFID would cover those of an SD or MSP under the CEA and the Commission's regulations.

Under MiFID Article 9, directors are subject to fit and proper criteria. Under MiFID Article 13, firms must establish and maintain decision-making processes and an organizational structure specifying reporting lines and allocate functions and responsibilities; personnel must have skills, knowledge and expertise necessary for the discharge of their responsibilities; and internal control mechanisms must be maintained to secure compliance as well as internal reporting and communication of information at all relevant levels of the firm.

Commission Determination: The Commission finds that the MiFID standards specified above are generally identical in intent to § 23.602 because such standards seek to ensure that SDs and MSPs strictly comply with applicable law, which would include the CEA and the Commission's regulations. Through the MiFID standards specified above, EU laws and regulations seek to ensure that each SD and MSP not only establishes the necessary policies and procedures that would lead to compliance with applicable law, which would include the CEA and Commission regulations, but also establishes an effective system of internal oversight and enforcement of such policies and procedures to ensure that such policies and procedures are diligently followed.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the internal supervision requirements of MiFID, as specified above, are comparable to and as comprehensive as § 23.602.

4. Business Continuity and Disaster Recovery (§ 23.603)

Commission Requirement: To ensure the proper functioning of the swaps markets and the prevention of systemic risk more generally, Commission regulation 23.603 requires each SD and MSP, as part of its risk management program, to establish a business continuity and disaster recovery plan that includes procedures for, and the maintenance of, back-up facilities, systems, infrastructure, personnel, and other resources to achieve the timely recovery of data and documentation and to resume operations generally within the next business day after the disruption.

Regulatory Objective: Commission regulation 23.603 is intended to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, this requirement seeks to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan within one business day, if necessary.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as Commission regulation 23.603.

- Under MiFID L2D Article 5(3), firms must establish, implement, and maintain an adequate business continuity policy aimed at insuring the preservation of essential data and functions, the maintenance of services, and the timely recovery of such data and functions and timely resumption of services.
- Under MiFID Article 13(4), firms must take reasonable steps to ensure continuity and regularity in the

performance of investment services and activities, including employing appropriate systems, resources, and procedures to accomplish this requirement.

Commission Determination: The Commission finds that the MiFID standards specified above are generally identical in intent to § 23.603 because such standards seek to ensure that any market disruption affecting SDs and MSPs, whether caused by natural disaster or otherwise, is minimized in length and severity. To that end, the Commission finds that the MiFID standards specified above seek to ensure that entities adequately plan for disruptions and devote sufficient resources capable of carrying out an appropriate plan in a timely manner.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the business continuity and disaster recovery requirements of MiFID, as specified above, are comparable to and as comprehensive as § 23.603.

5. Conflicts of Interest (§ 23.605)

Commission Requirement: Section 4s(j)(5) of the CEA and Commission regulation 23.605(c) generally require each SD or MSP to establish structural and institutional safeguards to ensure that the activities of any person within the firm relating to research or analysis of the price or market for any commodity or swap are separated by appropriate informational partitions within the firm from the review, pressure, or oversight of persons whose involvement in pricing, trading, or clearing activities might potentially bias their judgment or supervision.

In addition, section 4s(j)(5) of the CEA and Commission regulation 23.605(d)(1) generally prohibits an SD or MSP from directly or indirectly interfering with or attempting to influence the decision of any clearing unit of any affiliated clearing member of a DCO to provide clearing services and activities to a particular customer, including:

- Whether to offer clearing services to a particular customer;
- Whether to accept a particular customer for clearing derivatives;
- Whether to submit a customer's transaction to a particular DCO;
- Whether to set or adjust risk tolerance levels for a particular customer; or
- Whether to set a customer's fees based on criteria other than those generally available and applicable to other customers.

Commission regulation 23.605(d)(2) generally requires each SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of any affiliated clearing member of a DCO to reasonably ensure compliance with the Act and the prohibitions set forth in § 23.605(d)(1) outlined above.

The Commission observes that § 23.605(d) works in tandem with Commission regulation 1.71, which requires futures commission merchants ("FCMs") that are clearing members of a DCO and affiliated with an SD or MSP to create and maintain an appropriate informational partition between business trading units of the SD or MSP and clearing units of the FCM to reasonably ensure compliance with the Act and the prohibitions set forth in § 1.71(d)(1), which are the same as the prohibitions set forth in § 23.605(d)(1) outlined above.

Finally, § 23.605(e) requires that each SD or MSP have policies and procedures that mandate the disclosure to counterparties of material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM or to clear a derivative through a DCO.

Regulatory Objective: Commission regulation 23.605(c) seeks to ensure that research provided to the general public by an SD or MSP is unbiased and free from the influence of the interests of an SD or MSP arising from the SD's or MSP's trading business.

In addition, § 23.605(d) (working in tandem with § 1.71) seeks to ensure open access to the clearing of swaps by requiring that access to and the provision of clearing services provided by an affiliate of an SD or MSP are not influenced by the interests of an SD's or MSP's trading business.

Finally, § 23.605(e) seeks to ensure equal access to trading venues and clearinghouses, as well as orderly and fair markets, by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as Commission regulation 23.605(c).

- MiFID Articles 13(3) and 18 require that SDs maintain and operate effective organizational and administrative arrangements with a view to preventing conflicts of interest from adversely affecting the interests of its clients.
- Under MiFID L2D Articles 21 to 23, SDs are obligated to adopt measures to ensure the appropriate level of independence of any person working in the firm. This includes measures preventing or controlling the exchange of information, separating the supervision of relevant persons, and preventing or limiting the possibility for a person to exercise inappropriate influence over others. Furthermore, firms must ensure that performance of multiple functions does not prevent persons from acting soundly, honestly, and professionally.
- Under MiFID L2D Articles 24 to 25, SDs must maintain and operate effective organizational and administrative arrangements and take all reasonable steps designed to prevent conflicts of interest from adversely affecting the interests of its clients.
- Under MiFID Articles 18 and MiFID L2D Article 22, SDs must develop a written conflicts of interest policy appropriate to the size and organization of the firm that identifies circumstances that might give rise to conflicts entailing a material risk of damage to the interests of one or more clients and specify procedures to be followed to manage such conflicts. The general conflicts policy has to be disclosed to clients. Disclosure is also needed when organizational arrangements to manage conflicts are not sufficient to ensure, with reasonable confidence, that the risk of damage to client interests will be prevented.
- Under MiFID L2D Article 25, an SD that prepares or disseminates research recommendations must take reasonable care to ensure that research recommendations are fairly presented and must disclose its interests or indicate conflicts of interest concerning relevant investments.
- Under MiFID L2D Article 25, in addition to the conflicts of interest requirements set out above, steps must be taken to ensure that restrictions are in place to avoid conflicts with respect to research personnel (*e.g.*, financial analysts), including restrictions on personal account dealing and inducements.
- Under MiFID L2D Article 24, research recommendations must also include a disclosure of interests or indicate conflicts of interests concerning the relevant investments.

The applicant states that the foregoing MiFID standards would require any SD or MSP that is subject to such MiFID standards to resolve or mitigate conflicts of interests in the provision of clearing services by a clearing member that is linked to that SD or MSP, or conflicts of interests in the execution of a derivative

by a client on a particular execution venue, including an eligible SEF or DCM, or conflicts of interests in the clearing of a derivative through a CCP, including an eligible DCO, through measures including appropriate information firewalls and disclosures.

Commission Determination: The Commission finds that the MiFID standards specified above with respect to conflicts of interest that may arise in producing or distributing research are generally identical in intent to § 23.605(c) because such standards seek to ensure that research provided to the general public by an SD is unbiased and free from the influence of the interests of an SD arising from the SD's trading business.

With respect to conflicts of interest that may arise in the provision of clearing services by an affiliate of an SD or MSP, the Commission further finds that although the general conflicts of interest prevention requirements under the MiFID standards specified above do not require with specificity that access to and the provision of clearing services provided by an affiliate of an SD or MSP not be improperly influenced by the interests of an SD's or MSP's trading business, such general requirements would require prevention and remediation of such improper influence when recognized or discovered. Thus such standards would ensure open access to clearing.

Finally, although not as specific as the requirements of § 23.605(e) (Undue influence on counterparties), the Commission finds that the general disclosure requirements of the MiFID standards specified above would ensure equal access to trading venues and clearinghouses by requiring that each SD and MSP disclose to counterparties any material incentives or conflicts of interest regarding the decision of a counterparty to execute a derivative on a SEF or DCM, or to clear a derivative through a DCO.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements found in the MiFID standards specified above in relation to conflicts of interest are comparable to and as comprehensive as § 23.605.

6. Availability of Information for Disclosure and Inspection (§ 23.606)

Commission Requirement: Commission regulation 23.606 implements sections 4s(j)(3) and (4) of the CEA, and requires each SD and MSP to disclose to the Commission, and an SD's or MSP's U.S. prudential regulator (if any) comprehensive information about its swap activities, and to establish and maintain reliable internal data capture, processing, storage, and other operational systems sufficient to capture, process, record, store, and produce all information necessary to satisfy its duties under the CEA and Commission regulations. Such systems must be designed to provide such information to the Commission and an SD's or MSP's U.S. prudential regulator within the time frames set forth in the CEA and Commission regulations and upon request.

Regulatory Objective: Commission regulation 23.606 seeks to ensure that each SD and MSP captures and maintains comprehensive information about their swap activities, and is able to retrieve and disclose such information to the Commission and its U.S. prudential regulator, if any, as necessary for compliance with the CEA and the Commission's regulations and for purposes of Commission oversight, as well as oversight by the SD's or MSP's U.S. prudential regulator, if any.

The Commission observes that it would be impossible to meet the regulatory objective of § 23.606 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.606 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as Commission regulation 23.606.

Under MiFID Article 13(6) & 25(2) & 50, investment firms are required to maintain adequate and orderly records of their business and internal organization. Firms must maintain at the disposal of the regulator, for at least five years, the relevant data relating to their transactions in financial instruments. Among other things, supervisors have the authority to access any document in any form whatsoever and to receive a copy of it, to demand information from any person, and to carry out on-site inspections.

Commission Determination: The Commission finds that the MiFID standards specified above are generally identical in intent to § 23.606 because such standards seek to ensure that each SD and MSP captures and stores comprehensive information about their swap activities, and are able to retrieve and disclose such information as necessary for compliance with applicable law and for purposes of regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements of MiFID with respect to the availability of information for inspection and disclosure, as specified above, are comparable to, and as comprehensive as, § 23.606, with the exception of § 23.606(a)(2) concerning the requirement that an SD or MSP make information required by § 23.606(a)(1) available promptly upon request to Commission staff and the staff of an applicable prudential regulator. The applicant has not submitted any provision of law or regulations applicable in the EU upon which the Commission could make a finding that SDs and MSPs would be required to retrieve and disclose comprehensive information about their swap activities to the Commission or any U.S. prudential regulator as necessary for compliance with the CEA and Commission regulations, and for purposes of Commission oversight and the oversight of any U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the requirements of MiFID are comparable to and as comprehensive as § 23.606(a)(2), any SD or MSP to which both § 23.606 and the MiFID standards specified above are applicable would generally be deemed to be in compliance with § 23.606(a)(2) if that SD or MSP complies with the MiFID standards specified above, subject to compliance with the requirement that it produce information to Commission staff and the staff of an applicable U.S. prudential regulator in accordance with § 23.606(a)(2).

7. Clearing Member Risk Management (§ 23.609)

Commission Requirement: Commission regulation 23.609 generally requires each SD or MSP that is a clearing member of a DCO to:

- Establish risk-based limits based on position size, order size, margin requirements, or similar factors;
- Screen orders for compliance with the risk-based limits;
- Monitor for adherence to the risk-based limits intra-day and overnight;
- Conduct stress tests under extreme but plausible conditions of all positions at least once per week;

- Evaluate its ability to meet initial margin requirements at least once per week;
- Evaluate its ability to meet variation margin requirements in cash at least once per week;
- Evaluate its ability to liquidate positions it clears in an orderly manner, and estimate the cost of liquidation; and
- Test all lines of credit at least once per year.

Regulatory Objective: Through Commission regulation 23.609, the Commission seeks to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds. Effective risk management by SDs and MSPs that are clearing members is essential to achieving these objectives. A failure of risk management can cause a clearing member to become insolvent and default to a DCO. Such default can disrupt the markets and the clearing system and harm customers.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as Commission regulation 23.609.

- Under MiFID Article 13(5) & MiFID L2D Article 5, investment firms must have effective procedures for risk assessment, effective control, and safeguard arrangements for information processing systems, sound administrative and accounting procedures, and internal control mechanisms.
- Under MiFID L2D Article 6, investment firms must, subject to a proportionality principle dependent on the size and nature of a firm's business, establish and maintain an independent risk management function that is responsible for the implementation of risk management policies and procedures and that provides reports and advice to senior management regarding risk management.
- MiFID L2D Article 9: Senior management (which includes boards of directors) must take responsibility for firms' compliance with regulatory obligations including risk management.
- MiFID L2D Article 9: Senior management must receive on a frequent basis, and at least annually, written reports on risk management issues, including any appropriate action taken in the event of deficiencies;
- MiFID L2D Article 7: Investment firms must identify the risks relating to the firms' activities, processes and systems, and set the level of risk tolerated by the firm in appropriate instances; must adopt effective arrangements, processes, and mechanisms to manage the risks relating to the firm's activities, processes and systems, in light of the established level of risk tolerance; must monitor the adequacy and effectiveness of its risk management policies and procedures, the level of compliance with arrangements, processes and mechanisms for risk management; and must monitor the adequacy and effectiveness of measures taken to address any deficiencies. The risk management strategy should address credit and counterparty risk; residual risk; market risk; interest rate risk; operational risk; liquidity risk; securitization risk; concentration risk; and risk of excessive leverage.
- Directive 2002/87/EC Article 9: In the case of financial conglomerates, risk management processes must include approval and periodical review of the strategies and policies by governing bodies with respect to all the risks assumed; adequate capital adequacy policies to anticipate impacts on risk profiles and capital requirements; risk monitoring and controls at the level of the conglomerates.
- ESMA Guidelines on compliance function requirements (ESMA/2012/388) specify that the assessment of compliance risk should involve the compliance function, including in the case of new business lines or new financial products. Identified risks should be reviewed on a regular basis as well as ad-hoc when necessary to ensure that any emerging risks are taken into consideration. A monitoring program covering all areas of the investment firm's activities should ensure that compliance risk is comprehensively monitored. Specific measures ensure the effectiveness, the permanence and the independence of the compliance function.
- MiFID L2D Articles 21 to 23: Requirements on conflicts of interests include the obligation to adopt measures to ensure the appropriate level of independence to any person working in the firm. This includes measures preventing or controlling the exchange of information, separating the supervision of relevant persons, preventing or limiting the possibility for a person to exercise inappropriate influence over others. Furthermore, firms must ensure that performance of multiple functions does not prevent persons from acting soundly, honestly, and professionally.
- MiFID Article 50: Supervisors can access documents for the discharge of their supervisory duties.
- CRD Annex V: Credit institutions and investment firms must have in place risk management procedures that cover credit, operational, counterparty, market, concentration, securitization, liquidity and interest rate risk.
- CRD Article 22: Credit institution's conformity with regulation is the responsibility of the institution's management body and is subject to ongoing supervisory review.[45]

Specifically, the applicants state that any SD or MSP subject to MiFID and CRD that is a clearing member of a CCP, including an eligible DCO, would be required under the foregoing EU law and regulations to:

- Establish risk-based limits based on position size, order size, margin requirements, or similar factors;
- Screen orders for compliance with the risk-based limits;
- Monitor for adherence to the risk-based limits intra-day and overnight;
- Conduct stress tests under extreme but plausible conditions of all positions at least once per week;
- Evaluate its ability to meet initial margin requirements at least once per week;
- Evaluate its ability to meet variation margin requirements in cash at least once per week;
- Evaluate its ability to liquidate positions it clears in an orderly manner, and estimate the cost of liquidation; and
- Test all lines of credit at least once per year.

Commission Determination: The Commission finds that the MiFID, ESMA, and CRD standards specified above are generally identical in intent to § 23.609 because such standards seek to ensure the financial integrity of the markets and the clearing system, to avoid systemic risk, and to protect customer funds.

The Commission notes that the MiFID, ESMA, and CRD standards specified above are not as specific as § 23.609 with respect to ensuring that SDs and MSPs that are clearing members of a DCO establish detailed procedures and limits for clearing member risk management purposes.

[45] The current version of CRD will soon be replaced by CRD IV. CRD IV entered into force on June 28, 2013, and shall apply in most of its parts from January 1, 2014. The new reference is Article 74 and there will be additional detailed technical rules specifying the arrangements, processes and mechanisms that must be adopted to fulfill this requirement. Article 88 of Directive 2013/36/EU specifies that " the management body defines, oversees and is accountable for the implementation of the governance arrangements that ensure effective and prudent management of an institution." Article 76 specifies tasks assigned to the management body as regards risk management. *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:176:0338:0436:EN:PDF.*

Nevertheless, the Commission finds that the general requirements under the MiFID, ESMA, and CRD standards specified above, implemented in the context of clearing member risk management and pursuant to the statements of the applicants, meet the Commission's regulatory objective specified above.

Based on the foregoing and the statements of the applicants above, the Commission hereby determines that the clearing member risk management requirements of the MiFID, ESMA, and CRD standards specified above are comparable to and as comprehensive as § 23.609.

C. Swap Data Recordkeeping (§§ 23.201 and 23.203)

Commission Requirement: Sections 4s(f)(1)(B) and 4s(g)(1) of the CEA, and Commission regulation 23.201 generally require SDs and MSPs to retain records of each transaction, each position held, general business records (including records related to complaints and sales and marketing materials), records related to governance, financial records, records of data reported to SDRs, and records of real-time reporting data along with a record of the date and time the SD or MSP made such reports. Transaction records must be kept in a form and manner identifiable and searchable by transaction and counterparty.

Commission regulation 23.203, requires SDs and MSPs to maintain records of a swap transaction until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction, and for a period of five years after such date. Records must be "readily accessible" for the first two years of the five year retention period (consistent with § 1.31).

The Commission notes that the comparability determination below with respect to §§ 23.201 and 23.203 encompasses both swap data recordkeeping generally and swap data recordkeeping relating to complaints and marketing and sales materials in accordance with § 23.201(b)(3) and (4).[46]

Regulatory Objective: Through the Commission's regulations requiring SDs and MSPs to keep comprehensive records of their swap transactions and related data, the Commission seeks to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

The Commission's regulations require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

By requiring comprehensive records of swap data, the Commission seeks to ensure that SDs and MSPs employ effective risk management, and strictly comply with Commission regulations. Further, such records facilitate effective regulatory oversight.

The Commission observes that it would be impossible to meet the regulatory objective of §§ 23.201 and 23.203 unless the required information is available to the Commission and any U.S. prudential regulator under the foreign legal regime. Thus, a comparability determination with respect to the information access provisions of § 23.203 would be premised on whether the relevant information would be available to the Commission and any U.S. prudential regulator of the SD or MSP, not on whether an SD or MSP must disclose comprehensive information to its regulator in its home jurisdiction.

Comparable EU Law and Regulations: The applicant has represented to the Commission that the following provisions of law and regulations applicable in the EU are in full force and effect in the EU, and comparable to and as comprehensive as sections 4s(f)(1)(B) and 4s(g)(1) of the CEA and §§ 23.201 and 23.203.

- MiFID Article 13(6): Firms are required to maintain records of all services and transactions undertaken by the firm that are sufficient to enable regulatory authorities to monitor compliance with MiFID and to ascertain whether the firm has complied with all obligations with respect to clients or potential clients.
- MiFID L2R Article 7: Firms are required to keep detailed records in relation to every client order and decision to deal, and every client order executed or transmitted.
- MiFID L2D Article 51: All required records must be retained in a medium available for future reference by the regulator, and in a form/manner that:
  - o Allows the regulator to access them readily and reconstitute each key stage of processing each transaction;
  - o Allows corrections or other amendments, and the contents of the records prior to such corrections or amendments, to be easily ascertained; and
  - o Ensures that records are not manipulated or altered.
- MiFID Article 25(2): Firms must keep at the disposal of the regulator, for at least five years, the relevant data relating to all transactions in financial instruments which they have carried out, whether on their own account or on behalf of a client.
- CESR (now ESMA) developed recommendations on the list of minimum records to be kept by firms in accordance with MiFID L2D and the point in time at which the record should be created. It includes marketing communications, client information, internal procedures, complaints records, complaints handling, etc.

Commission Determination: The Commission finds that the MiFID and ESMA standards specified above are generally identical in intent to §§ 23.201 and 23.203 because such standards seek to ensure the effectiveness of the internal controls of SDs and MSPs, and transparency in the swaps market for regulators and market participants.

In addition, the Commission finds that the MiFID and ESMA standards specified above require SDs and MSPs to keep swap data in a level of detail sufficient to enable regulatory authorities to understand an SD's or MSP's swaps business and to assess its swaps exposure.

Finally, the Commission finds that the MiFID and ESMA standards specified above, by requiring comprehensive records of swap data, seek to ensure that SDs and MSPs employ effective risk management, seek to ensure that SDs and MSPs strictly comply with applicable regulatory requirements (including the CEA and Commission regulations), and that such records facilitate effective regulatory oversight.

Based on the foregoing and the representations of the applicant, the Commission hereby determines that the requirements of MiFID and ESMA with respect to swap data recordkeeping, as specified above, are comparable to, and as comprehensive as, §§ 23.201 and 23.203, with the exception of § 23.203(b)(2) concerning the requirement that an SD or MSPs make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator. The applicant has not submitted any provision of law or regulations applicable in the EU upon which the Commission could make a finding that SDs and MSPs would be required to make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator.

Notwithstanding that the Commission has not determined that the

[46] *See* the Guidance for a discussion of the availability of substituted compliance with respect to swap data recordkeeping, 78 FR 45332–33.

requirements of MiFID and ESMA are comparable to and as comprehensive as § 23.203(b)(2), any SD or MSP to which both § 23.203 and the MiFID and ESMA standards specified above are applicable would generally be deemed to be in compliance with § 23.203(b)(2) if that SD or MSP complies with the MiFID and ESMA standards specified above, subject to compliance with the requirement that it make records required by § 23.201 open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable U.S. prudential regulator in accordance with § 23.203(b)(2).

Issued in Washington, DC on December 20, 2013, by the Commission.

Christopher J. Kirkpatrick,

Deputy Secretary of the Commission.

Appendices to Comparability Determination for the European Union: Certain Entity-Level Requirements

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton and Wetjen voted in the affirmative. Commissioner O'Malia voted in the negative.

Appendix 2—Joint Statement of Chairman Gary Gensler and Commissioners Bart Chilton and Mark Wetjen

We support the Commission's approval of broad comparability determinations that will be used for substituted compliance purposes. For each of the six jurisdictions that has registered swap dealers, we carefully reviewed each regulatory provision of the foreign jurisdictions submitted to us and compared the provision's intended outcome to the Commission's own regulatory objectives. The resulting comparability determinations for entity-level requirements permit non-U.S. swap dealers to comply with regulations in their home jurisdiction as a substitute for compliance with the relevant Commission regulations.

These determinations reflect the Commission's commitment to coordinating our efforts to bring transparency to the swaps market and reduce its risks to the public. The comparability findings for the entity-level requirements are a testament to the comparability of these regulatory systems as we work together in building a strong international regulatory framework.

In addition, we are pleased that the Commission was able to find comparability with respect to swap-specific transaction-level requirements in the European Union and Japan.

The Commission attained this benchmark by working cooperatively with authorities in Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland to reach mutual agreement. The Commission looks forward to continuing to collaborate with both foreign authorities and market participants to build on this progress in the months and years ahead.

Appendix 3—Statement of Dissent by Commissioner Scott D. O'Malia

I respectfully dissent from the Commodity Futures Trading Commission's ("Commission") approval of the Notices of Comparability Determinations for Certain Requirements under the laws of Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland (collectively, "Notices"). While I support the narrow comparability determinations that the Commission has made, moving forward, the Commission must collaborate with foreign regulators to harmonize our respective regimes consistent with the G–20 reforms.

However, I cannot support the Notices because they: (1) Are based on the legally unsound cross-border guidance ("Guidance");[1] (2) are the result of a flawed substituted compliance process; and (3) fail to provide a clear path moving forward. If the Commission's objective for substituted compliance is to develop a narrow rule-by-rule approach that leaves unanswered major regulatory gaps between our regulatory framework and foreign jurisdictions, then I believe that the Commission has successfully achieved its goal today.

Determinations Based on Legally Unsound Guidance

As I previously stated in my dissent, the Guidance fails to articulate a valid statutory foundation for its overbroad scope and inconsistently applies the statute to different activities.[2] Section 2(i) of the Commodity Exchange Act ("CEA") states that the Commission does not have jurisdiction over foreign activities unless "those activities have a direct and significant connection with activities in, or effect on, commerce of the United States * * *"[3] However, the Commission never properly articulated how and when this limiting standard on the Commission's extraterritorial reach is met, which would trigger the application of Title VII of the Dodd-Frank Act[4] and any Commission regulations promulgated thereunder to swap activities that are outside of the United States. Given this statutorily unsound interpretation of the Commission's extraterritorial authority, the Commission often applies CEA section 2(i) inconsistently and arbitrarily to foreign activities.

Accordingly, because the Commission is relying on the legally deficient Guidance to make its substituted compliance determinations, and for the reasons discussed below, I cannot support the Notices. The Commission should have collaborated with foreign regulators to agree on and implement a workable regime of substituted compliance, and then should have made determinations pursuant to that regime.

[1] Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

[3] CEA section 2(j); 7 U.S.C. 2(j).

[4] Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

Flawed Substituted Compliance Process

Substituted compliance should not be a case of picking a set of foreign rules identical to our rules, determining them to be "comparable," but then making no determination regarding rules that require extensive gap analysis to assess to what extent each jurisdiction is, or is not, comparable based on overall outcomes of the regulatory regimes. While I support the narrow comparability determinations that the Commission has made, I am concerned that in a rush to provide some relief, the Commission has made substituted compliance determinations that only afford narrow relief and fail to address major regulatory gaps between our domestic regulatory framework and foreign jurisdictions. I will address a few examples below.

First, earlier this year, the OTC Derivatives Regulators Group ("ODRG") agreed to a number of substantive understandings to improve the cross-border implementation of over-the-counter derivatives reforms.[5] The ODRG specifically agreed that a flexible, outcomes-based approach, based on a broad category-by-category basis, should form the basis of comparability determinations.[6]

However, instead of following this approach, the Commission has made its comparability determinations on a rule-by-rule basis. For example, in Japan's Comparability Determination for Transaction-Level Requirements, the Commission has made a positive comparability determination for some of the detailed requirements under the swap trading relationship documentation provisions, but not for other requirements.[7] This detailed approach clearly contravenes the ODRG's understanding.

Second, in several areas, the Commission has declined to consider a request for a comparability determination, and has also failed to provide an analysis regarding the extent to which the other jurisdiction is, or is not, comparable. For example, the Commission has declined to address or provide any clarity regarding the European Union's regulatory data reporting determination, even though the European Union's reporting regime is set to begin on February 12, 2014. Although the Commission has provided some limited relief with respect to regulatory data reporting, the lack of clarity creates unnecessary uncertainty, especially when the European Union's reporting regime is set to begin in less than two months.

Similarly, Japan receives no consideration for its mandatory clearing requirement, even though the Commission considers Japan's

[5] *http://www.cftc.gov/PressRoom/PressReleases/pr6678-13.*

[6] *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/odrgreport.pdf.* The ODRG agreed to six understandings. Understanding number 2 states that "[a] flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance."

[7] The Commission made a positive comparability determination for Commission regulations 23.504(a)(2), (b)(1), (b)(2), (b)(3), (b)(4), (c), and (d), but not for Commission regulations 23.504(b)(5) and (b)(6).

legal framework to be comparable to the U.S. framework. While the Commission has declined to provide even a partial comparability determination, at least in this instance the Commission has provided a reason: the differences in the scope of entities and products subject to the clearing requirement.[8] Such treatment creates uncertainty and is contrary to increased global harmonization efforts.

Third, in the Commission's rush to meet the artificial deadline of December 21, 2013, as established in the Exemptive Order Regarding Compliance with Certain Swap Regulations ("Exemptive Order"),[9] the Commission failed to complete an important piece of the cross-border regime, namely, supervisory memoranda of understanding ("MOUs") between the Commission and fellow regulators.

I have previously stated that these MOUs, if done right, can be a key part of the global harmonization effort because they provide mutually agreed-upon solutions for differences in regulatory regimes.[10] Accordingly, I stated that the Commission should be able to review MOUs alongside the respective comparability determinations and vote on them at the same time. Without these MOUs, our fellow regulators are left wondering whether and how any differences, such as direct access to books and records, will be resolved.

Finally, as I have consistently maintained, the substituted compliance process should allow other regulatory bodies to engage with the full Commission.[11] While I am pleased that the Notices are being voted on by the Commission, the full Commission only gained access to the comment letters from foreign regulators on the Commission's comparability determination draft proposals a few days ago. This is hardly a transparent process.

Unclear Path Forward

Looking forward to next steps, the Commission must provide answers to several outstanding questions regarding these comparability determinations. In doing so, the Commission must collaborate with foreign regulators to increase global harmonization.

First, there is uncertainty surrounding the timing and outcome of the MOUs. Critical questions regarding information sharing, cooperation, supervision, and enforcement will remain unanswered until the Commission and our fellow regulators execute these MOUs.

Second, the Commission has issued time-limited no-action relief for the swap data repository reporting requirements. These comparability determinations will be done as separate notices. However, the timing and process for these determinations remain uncertain.

Third, the Commission has failed to provide clarity on the process for addressing the comparability determinations that it declined to undertake at this time. The Notices only state that the Commission may address these requests in a separate notice at a later date given further developments in the law and regulations of other jurisdictions. To promote certainty in the financial markets, the Commission must provide a clear path forward for market participants and foreign regulators.

The following steps would be a better approach: (1) The Commission should extend the Exemptive Order to allow foreign regulators to further implement their regulatory regimes and coordinate with them to implement a harmonized substituted compliance process; (2) the Commission should implement a flexible, outcomes-based approach to the substituted compliance process and apply it similarly to all jurisdictions; and (3) the Commission should work closely with our fellow regulators to expeditiously implement MOUs that resolve regulatory differences and address regulatory oversight issues.

Conclusion

While I support the narrow comparability determinations that the Commission has made, it was my hope that the Commission would work with foreign regulators to implement a substituted compliance process that would increase the global harmonization effort. I am disappointed that the Commission has failed to implement such a process.

I do believe that in the longer term, the swaps regulations of the major jurisdictions will converge. At this time, however, the Commission's comparability determinations have done little to alleviate the burden of regulatory uncertainty and duplicative compliance with both U.S. and foreign regulations.

The G–20 process delineated and put in place the swaps market reforms in G–20 member nations. It is then no surprise that the Commission must learn to coordinate with foreign regulators to minimize confusion and disruption in bringing much needed clarity to the swaps market. For all these shortcomings, I respectfully dissent from the Commission's approval of the Notices.

[FR Doc. 2013–30980 Filed 12–26–13; 8:45 am]
BILLING CODE 6351–01–P

[8] Yen-denominated interest rate swaps are subject to the mandatory clearing requirement in both the U.S. and Japan.

[9] Exemptive Order Regarding Compliance With Certain Swap Regulations, 78 FR 43785 (Jul. 22, 2013).

[10] *http://www.cftc.gov/PressRoom/SpeechesTestimony/opaomalia-29.*

[11] *http://www.cftc.gov/PressRoom/SpeechesTestimony/omaliastatement071213b.*

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. Sec. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its new AmeriCorps VISTA Sponsor Recruitment Practices Survey. AmeriCorps VISTA sponsor organizations will provide information about their approach to VISTA member recruitment in order for CNCS to design recruitment strategies and materials for the VISTA program. Completion of this information collection is not required to be considered for or to obtain grant funding support.

Copies of the information collection request can be obtained by contacting the office listed in the Addresses section of this notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by February 25, 2014.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, AmeriCorps VISTA; Elizabeth Matthews, Outreach Specialist, 9110B; 1201 New York Avenue NW., Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Elizabeth Matthews, (202–606–6774) or by email at *ematthews@cns.gov.*

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the

functions of CNCS, including whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submissions of responses).

Background

AmeriCorps VISTA sponsor organizations will provide information about their approach to VISTA member recruitment in order for CNCS to design recruitment strategies and materials for the VISTA program. The information will be collected through the tool, SurveyGizmo, which will be delivered electronically through an email.

Current Action

This is a new information collection request. CNCS would like to submit AmeriCorps VISTA Sponsor Recruitment Practices Survey. AmeriCorps VISTA sponsor organizations will provide information about their approach to VISTA member recruitment in order for CNCS to design recruitment strategies and materials for the VISTA program. Completion of this information collection is not required to be considered for or to obtain grant funding support.

The information collection will otherwise be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: AmeriCorps VISTA Sponsor Recruitment Practices Survey.

OMB Number: None.

Agency Number: None.

Affected Public: AmeriCorps VISTA sponsor organizations. Sponsor organizations direct the VISTA project, supervise the AmeriCorps VISTA members, and provide necessary administrative support to complete the goals and objectives of the project.

Total Respondents: 1,800.

Frequency: Once per respondent.

Average Time Per Response: Averages 10 minutes.

Estimated Total Burden Hours: 18,000 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: December 19, 2013.

Mary Strasser,

Director, AmeriCorps VISTA.

[FR Doc. 2013–30921 Filed 12–26–13; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0233]

Proposed Collection; Comment Request

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Notice and request for comments.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, and as part of an effort to streamline the process to seek feedback from the public on service delivery, the Department of Defense announces a proposed generic information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 25, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Information Management Division, ATTN: Public Collections Team, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Office of the Secretary of Defense Generic Clearance; OMB Control Number 0704–TBD.

Needs and Uses: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

Affected Public: Individuals or Households; Business or Other For-Profit; Not-For-Profit Institutions; Farms; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 175,000.

Average Annual Burden

Average Expected Annual Number of Activities: 10.
Average Number of Respondents per Activity: 5,833.
Annual Responses: 58,330.
Responses per Respondent: 1.
Average Time per Response: 15 minutes.
Annual Burden Hours: 14,583.

Three Year Burden

Average Expected Number of Activities: 30.
Total Respondents: 175,000.
Total Responses: 175,000.
Responses per Respondent: 1.
Average Time per Response: 15 minutes.
Total Burden Hours: 43,750.
Frequency: On occasion.

Dated: December 20, 2013.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2013–30926 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0157]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by January 27, 2014.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Veterans' Community Reintegration Focus Groups; OMB Control Number: 0704–TBD.
Type of Request: New.
Number of Respondents: 150.
Responses per Respondent: 1.
Annual Responses: 150.
Average Burden per Response: 120 minutes.
Annual Burden Hours: 300.
Needs and Uses: The information collection requirement is necessary to help the Transition to Veterans Program Office identify the particular challenges and issues veterans face in reintegrating with their communities. These focus groups are necessary since there is no single, existing dataset that captures veterans' community reintegration, beyond measuring employment or education. Our findings will help inform the development and implementation of their new transition program, Transition GPS (Goals, Plans, Success).
Affected Public: Individuals or households.
Frequency: On occasion.
Respondent's Obligation: Voluntary.
OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD Information Management Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: December 20, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–30947 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 13–68]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 13–68 with attached transmittal and policy justification.

Dated: December 23, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

DEC 18 2013

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 13-68, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Norway for defense articles and services estimated to cost $107 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

For J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification

Transmittal No. 13–68

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Norway

(ii) *Total Estimated Value:*

Major Defense Equipment*	$ 0 million
Other (includes SME)	$107 million
TOTAL	$107 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* C–130J technical, engineering and software support; software updates and patches; familiarization training for Portable Flight Planning System (PFPS) and Joint Mission Planning System (JMPS); spare and repair parts; U.S. Government and contractor technical support services; and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (QAT, Amendment 01)

(v) *Prior Related Cases, if any:* FMS Case QAT-$98M

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* N/A

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services*

Proposed to be Sold: N/A

(viii) *Date Report Delivered to Congress:* 18 December 2013

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Norway—Technical, Engineering, and Software Support for C–130J

The Government of Norway has requested a possible sale of C–130J technical, engineering and software support; software updates and patches; familiarization training for the Portable Flight Planning System (PFPS) and Joint Mission Planning System (JMPS); spare and repair parts; U.S. Government and contractor technical support services; and other related elements of logistics and program support. The estimated cost is $107 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a NATO ally. Norway intends to use this technical, engineering, and software support to provide successful operation of the PFPS and JMPS. This program will increase Norway's ability to contribute to future NATO, operations and supports U.S. national security interests. This support will continue to strengthen a critical, long-term strategic military partnership.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be Lockheed Martin Corporation, DBA Lockheed Martin Aeronautics in Marietta, Georgia; Rolls Royce Corporation in Indianapolis, Indiana; and GE Aviation Systems LLC, DBA Dowty Propellers in Sterling, Virginia. There are no known offset agreements associated with the proposed sale.

Implementation of this proposed sale will not require the assignment of additional U.S. Government or contract representatives to Norway.

There will be no adverse impact on the U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2013–31054 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 13–70]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 13–70 with attached transmittal and policy justification.

Dated: December 23, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

DEC 19 2013

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 13-70, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Pakistan for defense articles and services estimated to cost $100 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification

Transmittal No. 13–70

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Pakistan

(ii) *Total Estimated Value:*

Major Defense Equipment§ *.	$ 0 million
Other	$100 million
TOTAL	$100 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* to provide technical support services, and other related logistics support to assist in the oversight of operations in support of the Pakistan Peace Drive F–16 program.

(iv) *Military Department:* Air Force (GAF)

(v) *Prior Related Cases, if any:* FMS Case GAC—$82M—12Mar10

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* 19 December 2013

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Pakistan—Technical Support Team (TST)

The Government of Pakistan has requested a possible sale to provide technical support services at Shahbaz and Mushaf Air Bases to assist in the oversight of operations in support of the Pakistan Peace Drive F–16 program. Also included: U.S. Government and contractor technical and logistics support services, and other related elements of logistics support. The estimated cost is $100 million.

This proposed sale will support continuation of the Peace Drive program, which contributes to the foreign policy and national security of the United States by helping to improve the security of a country that has been and continues to be a partner in overseas contingency operations. Pakistan is vital to U.S. foreign policy and national security goals in South Asia.

The proposed sale of this support will not alter the basic military balance in the region.

Implementation of this proposed sale will require the assignment of two U.S. Government and 40 contractor representatives to Pakistan for a period of approximately five years to assist in the oversight of operations as part of the Peace Drive F–16 Program.

The principal contractor is not known at this time and will be determined during contract negotiations. There are no known offset agreements proposed in connection with this potential sale.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2013–31055 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0232]

Notice of Availability (NOA) of an Environmental Assessment (EA) for the Temporary Storage of Wheeled Tactical Vehicles at Defense Supply Center Richmond, Virginia

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice of Availability (NOA) of an Environmental Assessment (EA) for the Temporary Storage of Wheeled Tactical Vehicles at Defense Supply Center Richmond, Virginia.

SUMMARY: The Defense Logistics Agency (DLA) announces the availability of an environmental assessment (EA) for the potential environmental impacts associated with the proposed action to temporarily store wheeled tactical vehicles at Defense Supply Center Richmond, Virginia. The EA has been prepared as required under the National Environmental Policy Act (NEPA) (1969). In addition, the EA complies with DLA Regulation 1000.22. DLA has determined that the proposed action would not have a significant impact on the human environment within the context of NEPA. Therefore, the preparation of an environmental impact statement is not required.

DATES: The public comment period will end 30 days after publication of this NOA in the **Federal Register**. Comments received by the end of the 30-day period will be considered when preparing the final version of the document. The EA is available electronically at *http://www.dla.mil/Documents/WTV_DEA_12022013.pdf.*

ADDRESSES: You may submit comments to one of the following:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd floor, Suite 02G09, Alexandria, VA 22350–3100.

FOR FURTHER INFORMATION CONTACT: Ann Engelberger at (703) 767–0705 during normal business hours Monday through Friday, from 8:00 a.m. to 4:30 p.m. (EST) or by email: *Ann.Engelberger@dla.mil.*

Dated: December 20, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–30868 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the National Commission on the Structure of the Air Force

AGENCY: Director of Administration and Management, DoD.

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: The Department of Defense is publishing this notice to announce a closed Federal advisory committee meeting of the National Commission on the Structure of the Air Force ("the Commission").

DATES: *Date of Closed Meeting:* Wednesday, January 8, 2014, from 10:00 a.m. to 5:00 p.m.

ADDRESSES: 2521 South Clark Street, Suite 525, Arlington, VA 22202 and, as necessary, a secure video teleconferencing line.

FOR FURTHER INFORMATION CONTACT: Mrs. Marcia Moore, Designated Federal Officer, National Commission on the Structure of the Air Force, 1950 Defense Pentagon, Room 3A874, Washington, DC 20301–1950. Email: *marcia.l.moore12.civ@mail.mil.* Desk (703) 545–9113. Facsimile (703) 692–5625.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: The meeting on January 8, 2014 is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150. The Commission will address, correct, and approve the content of the classified annex to their unclassified report. The purpose of the classified annex is to allow individuals access to the classified analyses that contributed to and support the Commission's recommendations, as granted by the Congress and the President of the United States.

Agenda: The agenda and classified annex will cover the following topics:

— The changing mix of active and reserve component force structures.

— Whether the contribution of the reserve component to operational plans has increased since 1980.

— Specific reserve component contributions to Operation Iraqi Freedom and Operation Enduring Freedom.

— The increase of reserve component structure for classified mission areas.

— Descriptions of emerging, future capabilities.

— Integrated Security Construct scenarios and the environment that shapes the requirements and subsequent resource allocation decisions.

— Representative force-mix models using actual data from Integrated Security Construct scenarios, whereby variables, such as numbers of aircraft, deploy to dwell and mob to dwell ratios, and budget targets are manipulated.

— Various strategic-basing scenarios, some of which may have classified implications.

— Projected challenges to the U.S. Air Force's ability to meet the demands of multiple scenarios.

— Classified documents that address financial, personnel, organizational and other factors for the Commission's recommendations, including the Strategic Choices and Management Review, Program Objective

Memorandums, Defense Planning Guidance.

— Other classified analyses as required.

Meeting Accessibility: In accordance with section 10(d) of the FACA, 5 U.S.C. 552b, and 41 CFR 102–3.155, the DoD determined that the Wednesday, January 8, 2014 meeting will be closed to the public in its entirety. Specifically, the Director of Administration and Management, with the coordination of the DoD FACA Attorney, has determined in writing that this meeting will be closed to the public because classified information and matters covered by 5 U.S.C. 552b(c)(1) will be discussed.

Written Comments: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, the public or interested organizations may submit written comments to the Commission in response to the stated agenda of the closed meeting or the Commission's mission. The Designated Federal Officer (DFO) will review all submitted written statements before forwarding to the Commission. Written comments should be submitted to Mrs. Marcia Moore, DFO, via facsimile or electronic mail, the preferred modes of submission. Each page of the comment must include the author's name, title or affiliation, address, and daytime phone number. All contact information may be found in the **FOR FURTHER INFORMATION CONTACT** section. While written comments are forwarded to the Commissioners upon receipt, note that all written comments on the Commission's charge, as described in the "Background" section, must be received by 5:00 p.m. on January 7, 2014 to be considered by the Commissioners. This deadline for emailed and faxed comments has been extended from December 13, 2013. The postmark deadline to mail comments was November 8, 2013.

Due to difficulties finalizing the meeting agenda for the scheduled meeting of January 8, 2014, of the National Commission on the Structure of the Air Force the requirements of 41 CFR 102–3.150(a) were not met. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Background

The National Commission on the Structure of the Air Force was established by the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239). The Department of Defense sponsor for the Commission is the Director of Administration and Management, Mr. Michael L. Rhodes. The Commission is tasked to submit a report, containing a comprehensive study and recommendations, by February 1, 2014 to the President of the United States and the Congressional defense committees. The report will contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for such legislation and administrative actions it may consider appropriate in light of the results of the study. The comprehensive study of the structure of the U.S. Air Force will determine whether, and how, the structure should be modified to best fulfill current and anticipated mission requirements for the U.S. Air Force in a manner consistent with available resources.

The evaluation factors under consideration by the Commission are for a U.S. Air Force structure that—(a) meets current and anticipated requirements of the combatant commands; (b) achieves an appropriate balance between the regular and reserve components of the Air Force, taking advantage of the unique strengths and capabilities of each; (c) ensures that the regular and reserve components of the Air Force have the capacity needed to support current and anticipated homeland defense and disaster assistance missions in the United States; (d) provides for sufficient numbers of regular members of the Air Force to provide a base of trained personnel from which the personnel of the reserve components of the Air Force could be recruited; (e) maintains a peacetime rotation force to support operational tempo goals of 1:2 for regular members of the Air Forces and 1:5 for members of the reserve components of the Air Force; and (f) maximizes and appropriately balances affordability, efficiency, effectiveness, capability, and readiness.

Dated: December 23, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–31041 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the National Commission on the Structure of the Air Force

AGENCY: Director of Administration and Management, DoD.

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: The Department of Defense (DoD) announces that the following Federal advisory committee meeting of the National Commission on the Structure of the Air Force ("the Commission") will take place.

DATES: *Date of Open Meeting, including Hearing:* Thursday, January 9, 2014, from 11:30 a.m. to 5:00 p.m. Registration will begin at 11:00 a.m. Please also see instructions to register for oral public comments in advance.

ADDRESSES: 2521 South Clark Street Suite 200, Crystal City, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mrs. Marcia Moore, Designated Federal Officer, National Commission on the Structure of the Air Force, 1950 Defense Pentagon, Room 3A874, Washington, DC 20301–1950. Email: *dfoafstrucomm@osd.mil.* Desk (703) 545–9113. Facsimile (703) 692–5625.

SUPPLEMENTARY INFORMATION: Due to difficulties finalizing the meeting agenda for the scheduled meeting of January 9, 2014, of the National Commission on the Structure of the Air Force the requirements of 41 CFR 102–3.150(a) were not met. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of Meeting: The members of the Commission will hear testimony from Deborah Lee James, Secretary of the U.S. Air Force and oral comments from the public.

Agenda: Deborah Lee James, Secretary of the U.S. Air Force will testify from 11:30 a.m.—1:00 p.m. The public is invited to give oral comments to the Commission on the following topics that have been addressed in the Commission's draft report. The Chairman will introduce each topic and subtopic. Individual members of the public will then comment on the topic.

1:00 p.m.—The Uncertain Future Strategic Environment

1. The role of airpower in the post-Afghanistan national security situations likely to be encountered by the Air Force capabilities and Airmen and the implications for the structure of the Air Force.

2. Emerging demands on Air Force capabilities such as, intelligence, surveillance and reconnaissance, remotely piloted aircraft, space, cyberspace, special operations, and building partnership capacity. Further, implications for the structure of the Air Force from the growing threat involving simultaneous attacks on the Homeland.

3. Implications of rising demands and expectations for missions such as Homeland Defense, Homeland Security, and Defense Support to Civil Authorities.

4. Continuing growth of demand on traditional Air Force core functions including: Air Superiority, Air Mobility, Global Precision Attack, Nuclear Deterrence Operations, Command and Control, Personnel Recovery, Agile Combat Support, Training and Education, and other specific mission sets such as security forces, civil engineering and science and technology.

1:40 p.m.—The Inexorable Resource Trend

1. Projections and assumptions about future resource levels that will be available to organize, train and equip the Air Force; how the Budget Control Act and Sequestration legislation will affect Total Obligational Authority and associated planning, programming and budgeting flexibility.

2. Impact of strategic choices on Air Force capabilities and force structure options derived from the selection of national priorities among modernization, technology, recapitalization, readiness, capacity and force structure; various approaches on how to calculate and apply cost methods and data to questions of force structure.

2:30 p.m.—Enduring Roles of the Components

1. Address the root causes of legislative and bureaucratic development of the force structure issues that led to the creation of the Commission in 2013; how these issues are rooted in the American militia heritage and the arc of Air Force history since 1947.

2. Accounting for the socio-cultural dimensions of force structure issues ranging from the fundamental relationship of the American people to their military and to sub-cultures within the Air Force.

3:10 p.m.—Shaping and Sizing the Force

1. How to institutionalize the shift in the fundamental role of the reserve components from a strategic reserve to an operational reserve with associated expectations.

2. Force mix options to assess in terms of relative weight of force structure in each of the components.

3. Whether to recommend the Department of Defense invert the force sizing planning paradigm from sizing to meet the expected wartime surge to an approach that begins with the steady state requirement then resource the components to provide the nation with a meaningful surge capacity for the strategy.

4. Considerations for measuring and assessing active, reserve, and Air National Guard effectiveness, including both cost-effectiveness and mission effectiveness.

3:50 p.m.—Managing the Force

Weigh alternative approaches to how the nation should direct, control and guide the active, reserve, and Air National Guard to include:

1. Whether, and if so how, to simplify Title 10, Title 32 and other governing legislative authorities;

2. How to re-balance the current mix of Active, Reserve and Air National Guard components into and across any and all mission function;

3. Whether, and if so how, to reorganize the Air Force Active, Reserve and Air National Guard into less than 3 components;

4. Can the Air Force move to a periodic readiness schedule without creating a "hollow force";

5. Does component "ownership" of aircraft matter anymore and how can the Associate Unit paradigm be adapted to the future;

6. Approaching future force integration of new systems capabilities by means of a Concurrent Proportional resourcing method across the components to replace today's priority of equipping the Active Component first;

7. Accelerating the adoption of a "Continuum of Service" model to facilitate the ability of Airmen to move from any component into another at multiple points in their career path without prejudice:

a. Enhancing the total force through equalized opportunities across the components for professional and technical education and shared experiences;

b. Recognizing in promotion and selection processes differing but equivalent ends, ways, and means of professional development.

8. Fundamental shift in policy goals for "Deploy-to-Dwell," "Mobilization-to-Dwell," and associated metrics for the post-Afghanistan period, as well as how deployment credit will be accounted;

9. Reconsider the nation's needs for Overseas Basing and the capacity of CONUS infrastructure afforded by investments in Reserve and Guard basing capacities available to the Total Force.

Meeting Accessibility: The building is fully handicap accessible. Visitors must show a picture I.D. and complete a security screening. Public parking is available within walking distance. Media and other organizations who wish to use video or camera technology during the meeting must obtain permission prior to the meeting.

Written Comments: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, the public or interested organizations may submit written comments to the Commission in response to the stated agenda of the open meeting or the Commission's mission. The Designated Federal Officer (DFO) will review all submitted written statements. Written comments should be submitted to Mrs. Marcia Moore, DFO, via facsimile or electronic mail, the preferred modes of submission. Each page of the comment must include the author's name, title or affiliation, address, and daytime phone number. All contact information may be found in the **FOR FURTHER INFORMATION CONTACT** section. While written comments are forwarded to the Commissioners upon receipt, note that all written comments on the Commission's charge, as described in the Background section, must be received by 5:00 p.m. on January 6, 2014 to be considered by the Commissioners for the final report. This deadline for emailed and faxed comments has been extended from December 13, 2013. The postmark deadline to mail comments was November 8, 2013.

Oral Comments: Individuals who wish to make an oral comment during the meeting on January 9, 2014, on the specific topics described in this notice, are strongly encouraged to pre-register for the meeting by 5:00 p.m. on January 6, 2014. Walk-in registrations will be accepted by 11:30 a.m. on January 9, 2014. Oral commenters will be allotted no less than 5 minutes each for their presentations. The actual time allotment will be given on the day of the meeting. Registration for oral comments must include a summary of points to be made and the topic to be addressed on at least one of the following, as described in this notice:

1. The Uncertain Future Strategic Environment
2. The Inexorable Resource Trend

3. Enduring Roles of the Components
4. Shaping and Sizing the Force
5. Managing the Force

Registration: Individuals who wish to attend the public hearing and meeting on Thursday, January 9, 2014 are encouraged to register for the event in advance with the Designated Federal Officer, using the electronic mail and facsimile contact information found in the **FOR FURTHER INFORMATION CONTACT** section. The communication should include the registrant's full name, title, affiliation or employer, email address, and daytime phone number. If applicable, include written comments and/or a request to speak on one of the topics and a summary of your comments. Registrations and written comments must be typed.

Background: The National Commission on the Structure of the Air Force was established by the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239). The Department of Defense sponsor for the Commission is the Director of Administration and Management, Office of the Secretary of Defense. The Commission is tasked to submit a report, containing a comprehensive study and recommendations, by February 1, 2014 to the President of the United States and the Congressional defense committees. The report will contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for such legislation and administrative actions it may consider appropriate in light of the results of the study. The comprehensive study of the structure of the U.S. Air Force will determine whether, and how, the structure should be modified to best fulfill current and anticipated mission requirements for the U.S. Air Force in a manner consistent with available resources.

Dated: December 23, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–31003 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0234]

Privacy Act of 1974; System of Records

AGENCY: Office of the Inspector General, DoD.

ACTION: Notice to amend a System of Records.

SUMMARY: The Office of the Inspector General (OIG) is amending a system of records notice, CIG–21, Congressional Correspondence Tracking System, in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. This system maintains records of all Congressional inquiries and the OIG, DoD response, and to conduct the necessary research to provide information responsive to Congressional inquiries.

DATES: This proposed action will be effective on January 27, 2014 unless comments are received which result in a contrary determination. Comments will be accepted on or before January 27, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mark Dorgan, DoD IG FOIA/Privacy Office, Department of Defense, Inspector General, 4800 Mark Center Drive, Alexandria, VA 22350–1500 or telephone: (703) 699–5680.

SUPPLEMENTARY INFORMATION: The Office of the Inspector General systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at *http://dpclo.defense.gov/privacy/SORNs/component/oig/index.html.* The proposed changes to the record system being amended are set forth below. The proposed amendment is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: December 23, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

CIG–21

SYSTEM NAME:

Congressional Correspondence Tracking System (June 5, 2006, 71 FR 32312).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with "Assistant Inspector General for Office of Communications and Congressional Liaison, Office of the Inspector General of the Department of Defense, 4800 Mark Center Drive, Alexandria, VA 22350–1500."

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with "Assistant Inspector General for Office of Communications and Congressional Liaison, Office of the Inspector General of the Department of Defense, 4800 Mark Center Drive, Alexandria, VA 22350–1500."

NOTIFICATION PROCEDURE:

Delete entry and replace with "Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Freedom of Information Act Requester Service Center/Privacy Act Office, 4800 Mark Center Drive, Alexandria, VA 22350–1500.

Written requests should contain the individual's full name and work organization."

RECORD ACCESS PROCEDURES:

Delete entry and replace with "Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Freedom of Information Act Requester Service Center/Privacy Act Office, 4800 Mark Center Drive, Alexandria, VA 22350–1500.

Written requests should contain the individual's full name and work organization."

* * * * *

[FR Doc. 2013–30997 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2013–0039]

Proposed Collection; Comment Request

AGENCY: United States Air Force, DoD.

ACTION: Notice and request for comments.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, and as part of an effort to streamline the process to seek feedback from the public on service delivery, the Department of Defense announces a proposed generic information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 25, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Information Management Division, ATTN: Public Collections Team, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: United States Air Force Generic Clearance; OMB Control Number 0701–TBD.

Needs and Uses: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

Affected Public: Individuals or Households; Business or Other For-Profit; Not-For-Profit Institutions; Farms; Federal Government; State, Local, or Tribal Government.

Number Of Respondents: 50,000.

Average Annual Burden

Average Expected Annual Number of Activities: 4.

Average Number of Respondents per Activity: 4,167.

Annual Responses: 16,668.

Responses per Respondent: 1.

Average Time per Response: 15 minutes.

Annual Burden Hours: 4,167.

Three Year Burden

Average Expected Number of Activities: 12.

Total Respondents: 50,000.

Total Responses: 50,000.

Responses per Respondent: 1.

Average Time per Response: 15 minutes.

Total Burden Hours: 12,500.

Frequency: On occasion.

Dated: December 20, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–30925 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2013–0033]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by January 27, 2014.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Supplier Self-Services (SUS); OMB Control Number 0702–TBD.

Type of Request: New Collection

Number of Respondents: 1867

Responses per Respondent: 12

Annual Responses: 22,404

Average Burden per Response: 6 minutes

Annual Burden Hours: 2240

Needs and Uses: The information collection requirement via SUS is necessary to reduce the amount and complexity of required input by vendors that manually enter invoice data into Wide Area Workflow (WAWF) (not those utilizing Electronic Data Interchange (EDI). By pre-populating fields with accurate and up-to-date contract information, vendors are required to input significantly less data. Additionally, SUS simultaneously performs a front-end validation of submitted data, thus ensuring less manual intervention and fewer interest penalties incurred by the government.

Affected Public: Businesses (Federal Vendors)

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits

OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, Desk Officer

for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD Information Management Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: December 23, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–31007 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2013–0047]

Proposed Collection; Comment Request

AGENCY: United States Army, DoD.

ACTION: Notice and request for comments.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, and as part of an effort to streamline the process to seek feedback from the public on service delivery, the Department of Defense announces a proposed generic information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 25, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Information Management Division, ATTN: Public Collections Team, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: United States Army Generic Clearance; OMB Control Number 0702–TBD.

Needs and Uses: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions; farms; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 100,000.

Average Annual Burden

Average Expected Annual Number of Activities: 10.

Average Number of Respondents per Activity: 3,332.

Annual Responses: 33,320.

Responses per Respondent: 1.

Average Time per Response: 15 minutes.

Annual Burden Hours: 8,330 Hours.

Three Year Burden

Average Expected Number of Activities: 30.

Total Respondents: 100,000.

Total Responses: 100,000.

Responses per Respondent: 1.

Average Time per Response: 15 minutes.

Total Burden Hours: 25,000 Hours.

Frequency: On occasion.

Dated: December 20, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–30927 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare a Supplemental Environmental Impact Statement for the Route 460 Location Study From Prince George County to the City of Suffolk, VA

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent.

SUMMARY: The Federal Highway Administration (FHWA) and the United States Army Corps of Engineers (USACE), Norfolk District, as joint lead federal agencies, and in cooperation with the Virginia Department of Transportation (VDOT), will prepare a Supplemental Environmental Impact

Statement (SEIS) for the Route 460 Location Study Final Environmental Impact Statement (FEIS). The purpose of this SEIS is to evaluate new information regarding the aquatic resource impacts and alternatives described in the June 2008 FEIS and the September 2008 Record of Decision (ROD). In addition, FHWA is evaluating proposed changes to the termini of the selected alternative and the proposed interchange at Route 620, and proposed changes to the selected alignment to avoid and minimize aquatic resource impacts.

The USACE is preparing the document to produce a supplemented FEIS that fully evaluates the new information and to gather information that informs and supports the USACE's evaluation of the Department of the Army Individual Permit (IP) application submitted by U.S. Route 460 Mobility Partners (the Applicant) for the discharge of fill material into waters of the United States in conjunction with the construction of the Route 460 Corridor Improvements Project (Project). The USACE was a cooperating agency in the preparation of the June 2008 FEIS and will adopt that document as appropriate.

DATES: Submit comments on or before January 27, 2014.

ADDRESSES: Alice Allen-Grimes, U.S. Army Corps of Engineers, Regulatory Branch, 803 Front Street, Norfolk, VA 23510 or Ed Sundra, Division Administrator, Federal Highway Administration, 400 North 8th Street, Suite 750, Richmond, VA 23219.

FOR FURTHER INFORMATION CONTACT: Alice Allen-Grimes, email: *alice.w.allen-arimes@usace.army.mil;* (757) 201–7219. Ed Sundra, email: *ed.sundra@dot.gov;* (804) 775–3357.

SUPPLEMENTARY INFORMATION:

1. Description of the Proposed Action and Background: U.S. Route 460 Mobility Partners proposes to construct a limited access principle arterial tolled facility on new location for approximately 55 miles which would be located to the south and roughly parallel to the existing Route 460 corridor between Interstate 295 in Prince George County and Route 58 in the City of Suffolk, Virginia. The typical section consists of a four-lane, divided highway with two 12-foot lanes in each direction, a 40-foot median, and paved shoulders. Seven interchanges are proposed along the project at the secondary roads. The Applicant has entered into a design-build contract with VDOT to design and construct the Project. Upon determining that the submitted permit application is complete, the USACE will issue a public notice and continue processing the permit application.

An FEIS for the Route 460 Location Study was approved by FHWA in June 2008 and a ROD was issued by FHWA in September 2008. U.S. Route 460 Mobility Partners has entered into a contract with VDOT to obtain permits and construct the Preferred Alternative identified in the 2008 FEIS/ROD. In November 2012, based upon the information before them at the time, FHWA completed a National Environmental Policy Act (NEPA) Re-evaluation of the FEIS concluding that an SEIS was not needed. Based on new information bearing on the environmental impacts, including the aquatic impacts, it was later decided that an SEIS is required.

This SEIS will review information from the Route 460 Location Study FEIS/ROD, incorporate new information, update the alternatives and impacts analyses, and assess impacts not previously evaluated in the FEIS/ROD. To streamline federal processes, the SEIS will also include the USACE's NEPA evaluation.

2. Alternatives: Alternatives to be considered for the proposed project are the No-Build Alternative, the FHWA/VDOT preferred alternative (Preferred Alternative from the 2008 FEIS/ROD) and the FHWA/VDOT preferred alternative revised to include one or more of the following proposed changes: changes to the termini, the proposed interchange at Route 620, and alignment shifts to avoid and minimize impacts.

Additionally, so that the USACE may fulfill its required alternatives analysis responsibilities, consideration will also be given to the alternative from the DEIS to improve the existing Route 460 corridor (CBA–2), an alternative to provide a limited access tolled facility along the existing Route 460 corridor (CBA–2 Tolled), and potentially, other alternatives identified during the SEIS process.

The SEIS will also document the alternatives previously eliminated from consideration by FHWA. Actions available to the USACE for the proposed project are to issue the IP, issue the IP with special conditions, or deny the IP.

3. Scoping and Public Review Process: Throughout the development of the project, a variety of scoping and public involvement opportunities were provided to alert the public about the project, provide information and updates, and solicit feedback. These opportunities included but were not limited to a series of public hearings in the corridor when the DEIS was issued in 2005 and a series of public meetings in 2007 under Virginia's PPTA to evaluate conceptual proposals received from the private sector in response to the solicitation of proposals. Most recently, VDOT hosted public meetings in 2012 to update the public on the project and respond to public input.

To ensure that a full range of issues related to the Project are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments and suggestions concerning the range of issues to be evaluated under the SEIS should be submitted to FHWA and the Corps at (see **ADDRESSES**) within 30 days of the issuance of this notice to ensure timely consideration.

Based on the extensive public involvement to date on the proposed Project, no public input on the scope of the SEIS will be requested beyond the solicitation by this notice for comments on the range of issues to be evaluated. No formal scoping meetings will be held.

Notification of the availability of the draft SEIS for public and agency review will be made in the **Federal Register** and using other methods to be jointly determined by FHWA, USACE and VDOT. Those methods will identify where interested parties can go to review a copy of the draft SEIS.

For the draft SEIS, public meetings will be held and a minimum 45-day comment period will be provided. The public meetings will be conducted by VDOT and announced a minimum of 15 days in advance of the meetings. VDOT will provide information for the public meetings, including date, time and location through a variety of means including their Web site (*http://www.virginiadot.org/default_noflash.asp*) and by newspaper advertisement. In addition to the draft SEIS public involvement opportunities, the USACE will issue a public notice for a minimum 30-day comment period following receipt of a complete application.

4. Issues: Based on coordination between FHWA, USACE, and VDOT, the issues to be analyzed in the SEIS will include, but are not limited to, alternatives based on the updated effects to aquatic resources including wetland and stream impacts, threatened and endangered species, relocations, cultural resources, and cost.

5. Additional Review and Consultation: The SEIS will comply with other federal and state requirements including, but not limited to, the state water quality certification under Section 401 of the CWA; protection of water quality under the Virginia/National Pollutant Discharge Elimination System; consideration of

minority and low income populations under Executive Order 12898; protection of endangered and threatened species under Section 7 of the Endangered Species Act; and protection of cultural resources under Section 106 of the National Historic Preservation Act.

6. Availability of the Draft SEIS: The Draft SEIS is expected to be published and circulated during the Spring of 2014, and a public meeting will be held by VDOT after the publication of the Draft SEIS.

Dated: December 13, 2013.

Paul B. Olsen,

Colonel, U.S. Army, Commanding.

[FR Doc. 2013–30695 Filed 12–26–13; 8:45 am]

BILLING CODE 3720–36–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2013–0047]

Proposed Collection; Comment Request

AGENCY: United States Navy, DoD.

ACTION: Notice and request for comments.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, and as part of an effort to streamline the process to seek feedback from the public on service delivery, the Department of Defense announces a proposed generic information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 25, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Information Management Division, ATTN: Public Collections Team, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: United States Navy Generic Clearance; OMB Control Number 0703–TBD.

Needs and Uses: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

Affected Public: Individuals or Households; Business or Other For-Profit; Not-For-Profit Institutions; Farms; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 50,000.

Average Annual Burden

Average Expected Annual Number of Activities: 4.

Average Number of Respondents per Activity: 4,167.

Annual Responses: 16,668.

Responses per Respondent: 1.

Average Time per Response: 15 minutes.

Annual Burden Hours: 4,167.

Three Year Burden

Average Expected Number of Activities: 12.

Total Respondents: 50,000.

Total Responses: 50,000.

Responses per Respondent: 1.

Average Time per Response: 15 minutes.

Total Burden Hours: 12,500.

Frequency: On occasion.

Dated: December 20, 2013.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2013–30928 Filed 12–26–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2013–ICCD–0160]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application for Grants Under the Alaska Native and Native Hawaiian-Serving Institutions Program

AGENCY: Department of Education (ED), Office of Postsecondary Education (OPE).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement with change of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before January 27, 2014.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2013–ICCD–0160 or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments

submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For questions related to collection activities or burden, please call Kate Mullan, 202–401–0563 or electronically mail *ICDocketMgr@ed.gov*. Please do not send comments here. We will ONLY accept comments in this mailbox when the *regulations.gov* site is not available to the public for any reason.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for Grants Under the Alaska Native and Native Hawaiian-Serving Institutions Program.

OMB Control Number: 1840–0810.

Type of Review: A reinstatement with change of a previously approved information collection.

Respondents/Affected Public: Private Sector, State, Local, or Tribal Governments.

Total Estimated Number of Annual Responses: 46.

Total Estimated Number of Annual Burden Hours: 1,840.

Abstract: The overall purpose of this program is to provide grants to eligible Alaska Native and Native Hawaiian-Serving institutions of higher education to enable them to improve their academic quality, institutional management, and fiscal stability in order to increase their self-sufficiency and strengthen their capacity to make a substantial contribution to higher education resources of the nation. It is required that we collect this data in order to hold a program competition and award funds for program recipients.

Dated: December 23, 2013.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2013–31014 Filed 12–26–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2013–ICCD–0131]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Student Assistance General Provisions

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before January 27, 2014.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2013–ICCD–0131 or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 2E103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For questions related to collection activities or burden, please call Kate Mullan, 202–401–0563 or electronically mail *ICDocketMgr@ed.gov*. Please do not send comments here. We will ONLY accept comments in this mailbox when the regulations.gov site is not available to the public for any reason.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions.

OMB Control Number: 1845–0022.

Type of Review: Revision of an existing collection of information.

Respondents/Affected Public: State, Local, or Tribal Governments, Private Sector, Individuals or households.

Total Estimated Number of Annual Responses: 1,321,918.

Total Estimated Number of Annual Burden Hours: 2,138,320.

Abstract: The Department of Education is requesting a revision of the current burden hours in 1845–0022. Sections of the regulations in 34 CFR part 668-Student Assistance General Provisions establish the standards to participate in the student financial aid assistance programs authorized by Title IV of the Higher Education Act of 1965, as amended. Other sections of the regulations also establish required information that must be provided to students, the financial responsibility requirements of the institution, and the cohort default rates that apply to institutions. These regulations help to assure the Secretary that the integrity of the programs is protected from fraud

and misuse of program funds. ED is administratively transferring a small amount of burden from sections 34 CFR 668.23 and 668.24 that previously were included in OMB Collection Number 1845–0038 to correct an error that was made in the transfer of this information collection from the Office of Postsecondary Education (1840) to Federal Student Aid (1845). There have been no changes to the statutory or regulatory language since the prior information collection filing.

Dated: December 23, 2013.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2013–31013 Filed 12–26–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register.**

DATES: Thursday, January 16, 2014, 6:00 p.m.

ADDRESSES: Barkley Centre, 111 Memorial Drive, Paducah, Kentucky 42001.

FOR FURTHER INFORMATION CONTACT: Rachel Blumenfeld, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (270) 441–6806.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management and related activities.

Tentative Agenda:

- Call to Order, Introductions, Review of Agenda
- Administrative Issues
- Public Comments (15 minutes)
- Adjourn

Breaks Taken As Appropriate

Public Participation: The EM SSAB, Paducah, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Rachel Blumenfeld as soon as possible in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Rachel Blumenfeld at the telephone number listed above. Requests must be received as soon as possible prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments. The EM SSAB, Paducah, will hear public comments pertaining to its scope (clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities). Comments outside of the scope may be submitted via written statement as directed above.

Minutes: Minutes will be available by writing or calling Rachel Blumenfeld at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.pgdpcab.energy.gov/2013Meetings.html.*

Issued at Washington, DC, on December 20, 2013.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2013–31018 Filed 12–26–13; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0790; FRL–9904–56–OAR]

Access by EPA Contractors to Information Claimed as Confidential Business Information (CBI) Submitted under Title II of the Clean Air Act and Related to Code of Federal Regulation Parts and Subparts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA's Office of Transportation and Air Quality (OTAQ) plans to authorize various contractors to access information which will be submitted to EPA under Title II of the Clean Air Act that may be claimed as, or may be determined to be, confidential business information (CBI). Access to this information will begin on January 6, 2014.

DATES: EPA will accept comments on this Notice through January 2, 2014.

FOR FURTHER INFORMATION CONTACT: Jaimee Dong, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., MC 6405J; telephone number: 202–343–9672; fax number: 202–343–2802; email address: *dong.jaimee@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this notice apply to me?

This action is directed to the general public. However, this action may be of particular interest to parties who submit or have previously submitted information to EPA regarding the following programs: Fuel and fuel additive registration (40 CFR part 79); and various fuels programs including reformulated gasoline, anti-dumping, gasoline sulfur, ultra low sulfur diesel, benzene content, and the renewable fuel standard (40 CFR part 80). This action may also be of particular interest to parties such as suppliers of coal-based liquid fuels and suppliers of petroleum products, as described in 40 CFR part 98 subparts LL and MM, respectively. (40 CFR part 98, subpart A contains general provisions related to registration and reporting.) Parties who may be interested in this notice include refiners, importers, and exporters of these products.

This **Federal Register** notice may be of particular relevance to parties that have submitted data under the above-listed programs. Since other parties may also be interested, the Agency has not attempted to describe all the specific parties that may be affected by this action. If you have further questions regarding the applicability of this action to a particular party, please contact the person listed in **FOR FURTHER INFORMATION CONTACT.**

II. How can I get copies of this document and other related information?

A. Electronically

EPA has established a public docket for this **Federal Register** notice under Docket EPA–HQ–OAR–2013–0790.

All documents in the docket are identified in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, such as confidential business information (CBI) or other information for which disclosure is restricted by statute. Certain materials, such as copyrighted material, will only be available in hard copy at the EPA Docket Center.

B. EPA Docket Center

Materials listed under Docket EPA–HQ–OAR–2013–0790 will be available either electronically through *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20460. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

III. Description of Programs and Potential Disclosure of Information Claimed as Confidential Business Information (CBI) to Contractors

EPA's Office of Transportation and Air Quality (OTAQ) has responsibility for protecting public health and the environment by regulating air pollution from motor vehicles, engines, and the fuels used to operate them, and by encouraging travel choices that minimize emissions. In order to implement various Clean Air Act programs, and to permit regulated entities flexibility in meeting regulatory requirements (e.g., compliance on average), we collect compliance reports and other information from them. Occasionally, the information submitted is claimed to be confidential business information (CBI). Information submitted under such a claim is handled in accordance with EPA's regulations at 40 CFR part 2, subpart B and in accordance with EPA procedures, including comprehensive system security plans (SSPs) that are consistent with those regulations. When EPA has determined that disclosure of information claimed as CBI to contractors is necessary, the corresponding contract must address the appropriate use and handling of the information by the contractor and the contractor must require its personnel who require access to information claimed as CBI to sign written non-disclosure agreements before they are granted access to data.

In accordance with 40 CFR 2.301(h), we have determined that the contractors, subcontractors, and grantees (collectively referred to as "contractors") listed below, in addition to those listed in a previous **Federal Register** Notice (77 FR 217, November 8, 2012, pp. 66977–66978), require access to CBI submitted to us under the Clean Air Act and in connection with the Mandatory Greenhouse Gas (GHG) Reporting Rule [40 CFR part 98, subparts A (general registration and reporting provisions) LL, and MM], as well as various OTAQ programs related to fuels, vehicles, and engines (40 CFR parts 79 and 80) and we are providing notice and an opportunity to comment. OTAQ collects this data in order to monitor compliance with Clean Air Act programs and, in many cases, to permit regulated parties flexibility in meeting regulatory requirements. For example, data that may contain CBI is collected in order to register fuels and fuel additives prior to introduction into commerce and to certify engines. Certain programs are designed to permit regulated parties an opportunity to comply on average, or to engage in transactions using various types of credits. For example, OTAQ collects information about batches of gasoline that refiners produce in order to ensure compliance with reformulated gasoline standards. We are issuing this **Federal Register** notice to inform all affected submitters of information that we plan to grant access to material that may be claimed as CBI to the contractors identified below on a need-to-know basis.

Under Contract Number EP–C–11–007, SRA International, Inc., 4300 Fair Lakes Court, Fairfax, VA 22033, and its subcontractor, Ecco Select, 1301 Oak St #400, Kansas City, MO 64106, provide report processing, program support, technical support, and information technology services that involve access to information claimed as CBI related to 40 CFR part 79, 40 CFR part 80, and 40 CFR part 98 subparts A, LL, and MM. Access to data, including information claimed as CBI, will commence on January 6, 2014 and will continue until December 31, 2015.

If the contract is extended, this access will continue for the remainder of the contract without further notice.

Parties who wish further information about this **Federal Register** notice or about OTAQ's disclosure of information claimed as CBI to contactors may contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

List of Subjects

Environmental protection; confidential business information.

Dated: December 16, 2013.

Byron J. Bunker,

Director, Compliance Division, Office of Transportation & Air Quality, Office of Air and Radiation.

[FR Doc. 2013–30886 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–1158; FRL–9904–81–OAR]

Proposed Information Collection Request; Comment Request; Alternative Affirmative Defense Requirements for Ultra-Low Sulfur Diesel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), "Alternative Affirmative Defense Requirements for Ultra-low Sulfur Diesel" (EPA ICR No.2364.04, OMB Control No. 2060–0639 to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through March 31, 2014. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before February 25, 2014.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2007–1158, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Geanetta Heard, Fuels Compliance Center, 6406J, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–343–9017; fax number: 202–565–2085; email address: *heard.geanetta@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: With this ICR renewal, EPA is seeking permission to continue recordkeeping and reporting requirements under the ultra-low sulfur diesel (ULSD) fuel regulations. Where a violation of the 15 ppm sulfur standard is identified at a retail outlet, the retailer responsible for dispensing the noncompliant fuel is deemed liable, as well as the refiner(s), importer(s) and distributor(s) of such fuel. The highway diesel regulations further provide, however, that any person deemed liable can rebut this presumption by establishing an affirmative defense that includes, among other things, showing that it conducted a quality assurance sampling and testing program as prescribed by the regulations. This ICR covers burdens and costs associated with provisions that allow refiners and importers of ULSD an alternative means of meeting the affirmative defense requirements in the ULSD regulations by participating in a nationwide diesel fuel sampling and testing program. The reporting burden covered by this ICR renewal relates to reports that refiners, importers and distributors, have to submit in the event they have a non-complying sulfur test result.

Form Numbers: None.

Respondents/affected entities: 5.

Respondent's obligation to respond: mandatory.

Estimated number of respondents: 5 (total).

Frequency of response: On occasion.

Total estimated burden: 80 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $9,200 (per year), includes no annualized capital or operation & maintenance costs.

Changes in Estimates: There is no increase of hours in the total estimated respondent burden compared with the ICR currently approved by OMB. The respondent universe and responses decreased in this collection due to a higher than expected compliance rate. There was in increase in cost to the industry per response of $704 due to more accurate numbers used to calculate the industry burden and to account for inflation. There was a decrease in cost to the industry overall of $13,520 due to the reduction of expected responses from 20 to five.

Dated: December 20, 2013.

Byron Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc, 2013–31115 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2013–0652; FRL–9904–85–OW]

Extension of Comment Period for the Alaska Seafood Processing Effluent Limitation Guidelines Notice of Data Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability; Extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for the Alaska Seafood Processing Effluent Limitation Guidelines Notice of Data Availability. EPA is extending the comment period in response to stakeholder requests for an extension.

DATES: Comments must be received on or before March 7, 2014. The comment period was originally scheduled to end on January 6, 2014.

ADDRESSES: Submit your comments, identified by Docket identification (ID) No. EPA–HQ–OW–2013–0652, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Email: ow-docket@epa.gov*.
- *Mail:* Water Docket, U.S. Environmental Protection Agency, Mail code: 4203M, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Attention Docket ID No. EPA–HQ–OW–2013–0652. Please include three copies.
- *Hand Delivery:* Water Docket, EPA Docket Center, William Jefferson Clinton Building West Room 3334, 1301 Constitution Ave. NW., Washington, DC, Attention Docket ID No. EPA–HQ–OW–2013–0652. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information by calling 202–566–2426.
- *Instructions:* Direct your comments to Docket ID No. EPA–HQ–OW–2013–0652. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other

contact information in the body of your comment and with any disc you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available (e.g., CBI or other information whose disclosure is restricted by statute). Certain other materials, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Office of Water Docket Center, EPA/DC, William Jefferson Clinton Building West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744; the telephone number for the Office of Water Docket Center is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Lindsay Guzzo, Office of Water and Watersheds, NPDES Permit Unit (OWW–130), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101; (206) 553–0268, *guzzo.lindsay@epa.gov*, or Meghan Hessenauer, Engineering and Analysis Division (4303T), U.S. EPA, 1200 Pennsylvania Ave. NW., Washington, DC 20460; (202) 566–1040; *hessenauer.meghan@epa.gov.*

SUPPLEMENTARY INFORMATION: On November 7, 2013 the Environmental Protection Agency (EPA) published the Alaska Seafood Processing Effluent Limitations Guidelines Notice of Data Availability in the **Federal Register** (78 FR 66916). In the notice EPA made available for public review and comment additional data and information gathered recently by the EPA from seafood processing facilities in Alaska and other publicly available sources. These data relate to the applicability of and discharge requirements for the Alaskan seafood subcategories of the Canned and Preserved Seafood Processing effluent limitations guidelines. In the notice EPA provided preliminary results of analyses of the updated data and preliminary indications of how these results may be reflected in EPA's final response to petitions submitted in 1980 by certain members of the Alaskan seafood processing industry, and in amended effluent limitations guidelines applicable to certain Alaskan seafood processing discharges which EPA is considering whether to promulgate in final form (CFR part 408).

Dated: December 19, 2013.

Nancy K. Stoner,

Acting Assistant Administrator, Office of Water.

[FR Doc. 2013–31113 Filed 12–26–13; 8:45 am]

BILLING CODE 6550–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9012–7]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/*

Weekly receipt of Environmental Impact Statements filed 12/16/2013 through 12/20/2013 pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html*

EIS No. 20130375, Draft EIS, USN, PA, Disposal and Reuse of the Former Naval Air Station Joint Reserve Base (NAS JRB), Comment Period Ends: 02/10/2014, Contact: Gregory Preston 215–897–4909

EIS No. 20130376, Draft EIS, BLM, WY, Wyoming Greater Sage-Grouse Draft Land Use Plan Amendment, Comment Period Ends: 02/10/2014, Contact: Lisa Solberg Schwab 307–367–5340

EIS No. 20130377, Draft EIS, USFS, 00, Teckla-Osage-Rapid City 230 kV Transmission Line Project, Comment Period Ends: 02/10/2014, Contact: Ed Fischer 605–673–9207

EIS No. 20130378, Final EIS, FERC, 00, Toledo Bend Hydroelectric Relicensing Project No. 2305–036, Review Period Ends: 01/27/2014, Contact: Alan Mitchnick 202–502–6074

EIS No. 20130379, Final EIS, NRC, SC, William States Lee III Nuclear Station Units 1 and 2 Combined Licenses (COLs) Application, Review Period Ends: 01/27/2014, Contact: Patricia Vokoun 301–415–3470

EIS No. 20130380, Final EIS, USFS, AZ, Show Low South Land Exchange, Review Period Ends: 02/03/2014, Contact: Randall Chavez 928–328–2100

Amended Notices

EIS No. 20130246, Draft EIS, USFS, NV, Greater Sage Grouse Bi-State Distinct Population Segment Forest Plan Amendment, Comment Period Ends: 01/17/2014, Contact: James Winfrey 775–355–5308 Revision to FR Notice Published 08/23/2013; Extending Comment Period to 01/17/2014

EIS No. 20130370, Draft EIS, USFS, AZ, Coconino National Forest Land and Resource Management Plan, Comment Period Ends: 03/20/2014, Contact: Vernon Keller 928–527–3415 Revision to FR Notice Published 12/20/2013; Correct Status from Revised Draft to Draft

Dated: December 23, 2013.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2013–30992 Filed 12–26–13; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

[Public Notice: 2013–0060]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088412XX, AP088412XA and AP088412XB

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States ("Ex-Im Bank"), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction.

DATES: Comments must be received on or before January 21, 2014 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through Regulations.gov at

WWW.REGULATIONS.GOV. To submit a comment, enter EIB–2013–0060 under the heading "Enter Keyword or ID" and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2013–0060 on any attached document.

Reference: AP088412XX, AP088412XA and AP088412XB

Purpose and Use:

Brief description of the purpose of the transaction:

To support the export of U.S.-manufactured aircraft and engines.

Brief non-proprietary description of the anticipated use of the items being exported:

To provide commercial passenger air transportation services globally.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Supplier: Boeing and General Electric
Obligor: Kenya Airways
Guarantor(s): N/A

Description Of Items Being Exported: Boeing 787 and 777 aircraft and General Electric spare engines.

Information On Decision: Information on the final decision for this transaction will be available in the "Summary Minutes of Meetings of Board of Directors" on *http://exim.gov/newsandevents/boardmeetings/board/*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Cristopolis Dieguez,

Program Specialist, Office of the General Counsel.

[FR Doc. 2013–30858 Filed 12–26–13; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 012032–009.

Title: CMA CGM/MSC/Maersk Line North and Central China-US Pacific Coast Three-Loop Space Charter, Sailing and Cooperative Working Agreement.

Parties: A.P. Moller-Maersk A/S, CMA CGM S.A., and Mediterranean Shipping Company S.A.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100, Washington, DC 20006.

Synopsis: The Amendment provides for some additional slot sale arrangements among the parties and reflects the impact of these new arrangements on the overall slots allocations. The amendment also adds new language authorizing Maersk Line to charter space to CMA CGM on its TP6 service.

Agreement No.: 012238.

Title: HLAG/Maersk Line Gulf-Central America Slot Charter Agreement.

Parties: Hapag-Lloyd AG and A.P. Moller-Maersk A/S trading under the name Maersk Line.

Filing Party: Joshua P. Stein; Cozen O'Connor; 1627 I Street NW., Suite 1100, Washington, DC 20006.

Synopsis: The agreement authorizes HLAG to charter space to Maersk Line in the trade between Houston, TX and San Juan, PR, on the one hand, and ports in Mexico, the Dominican Republic, Colombia, Panama, Costa Rica, Guatemala, and Honduras on the other hand.

Agreement No.: 012239.

Title: LGL/SC Line Cooperative Working Agreement.

Parties: Liberty Global Logistics LLC and SC Line.

Filing Party: Brooke F. Shapiro; Winston & Strawn LLP; 200 Park Avenue, New York, NY 10166.

Synopsis: The agreement authorizes LGL and SC Line to discuss areas of potential cooperation and possibly engage in the purchasing of space on vessels operated by one another in the trade from the U.S. East and Gulf Coasts to ports in the Caribbean, South America, Central America, Mediterranean, and Middle East.

Agreement No.: 201212–001.

Title: Marine Terminal Lease and Operating Agreement Between Broward County and King Ocean Services Limited (Cayman Islands) Incorporated.

Parties: Broward County and King Ocean Services Limited (Cayman Islands) Incorporated.

Filing Party: Candace J. Running; Broward County Board of County Commissioners; Office of the County Attorney; 1850 Eller Drive, Suite 502, Fort Lauderdale, FL 33316.

Synopsis: The amendment updates the rent rate under the agreement.

Dated: December 20, 2013.

By Order of the Federal Maritime Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–30902 Filed 12–26–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov*.

3PL Logistics, Inc. (NVO), 1401 N. Wood Dale Road, Wood Dale, IL 60191, Officer: Hyung Tae Kim, President (QI), Application Type: New NVO License

A America Cargo International Logistics LLC (NVO & OFF), 5900 NW. 97th Avenue, Unit #1, Miami, FL 33178, Officers: Olga Aguirre, Manager (QI), Diana Renjifo, Manager/Member, Application Type: New NVO & OFF License

ADN Logistics Group, LLC (OFF), 12030 SW. 129th Court, #103, Miami, FL 33186, Officer: Lourdes P. Goderich, Member (QI), Application Type: New OFF License

Advantex Express Inc. (OFF), 4402 Theiss Road, Humble, TX 77338, Officers: Todd McKinnon, Assistant Secretary, FMC Compliance (QI), Steven Preston, CEO, Application Type: QI Change

Agility Logistics Corp. (OFF), 240 Commerce, Irvine, CA 96202, Officers: John Hubers, Vice President (QI),

Francese Casamitjana, President, Application Type: QI Change

Aya Logistics Inc. (NVO & OFF), 1260 Lunt Avenue, Elk Grove Village, IL 60007, Officers: Yanping Meng, Treasurer (QI), Xiqian (aka Steven) Wei, President, Application Type: New NVO & OFF License

Blue Ocean Logistics Corporation dba B.O Logistic Corp (NVO), 2461 W. 205th Street, B–105, Torrance, CA 90501, Officer: Bok Kun Yeom, President (QI), Application Type: New NVO License

Blue Wave Shipping LLC (NVO & OFF), 10 Millo Place, Little Ferry, NJ 07643, Officer: Mona A. Soliman, President (QI), Application Type: New NVO & OFF License

Cheryl G. Wilson dba JC Logistics (NVO & OFF), 28612 Redondo Beach Drive S, Des Moines, WA 98198, Officer: Cheryl G. Wilson, Sole Proprietor (QI), Application Type: Add OFF Service

Contamar Shipping Corporation (OFF), 27 Park Place, Suite 215, New York, NY 10007, Officers: Brian Castellana, Vice President (QI), Joseph Castellana, President (QI), Application Type: Add Trade Names CGC Line (for NVO) and CGC Logistics (for OFF)/QI Change

E-Cargoway Logistics USA, Inc. (NVO & OFF), 1515 Kona Drive, Compton, CA 90220, Officers: Won Rok (aka Steve) Choi, CFO (QI), Myeong H. Kim, CEO, Application Type: QI Change

Fago International, Inc. (NVO & OFF), 9682 Telstar Avenue, Suite 101, El Monte, CA 91731, Officers: Lynn H. Tran, Secretary (QI), Zheng Feng, CFO, Application Type: New NVO & OFF License

Flat Rate International, LLC (NVO & OFF), 27 Bruckner Blvd., Bronx, NY 10454, Officers: Israel Kessler, Executive Vice President (QI), Sharone Ben-Harosh, President, Application Type: QI Change

Freight Forwarding Network Corp. dba Costa Rica Carriers dba Freightnet (NVO), 12600 NW. 25th Street, Suite 107D, Miami, FL 33182, Officers: Sergio I. Lotero, President (QI), Stephen A. Blass, Secretary, Application Type: Change Trade Name to A&E Freight

Gabbro Global, LLC (NVO), 18353 US Highway 20, East Dubuque, IL 61025, Officers: Zheng Bin Ng, Director of Operations (QI), Todd Colin, CEO, Application Type: New NVO License

GAL GROUP INC. (NVO & OFF), 1667 Elmhurst Road, Elk Grove Village, IL 60007, Officers: Benny K. Clark, Vice President (QI), Pui L. Yu, President, Application Type: New NVO & OFF License

GLS Logistic Solutions, LLC (NVO), 3622 Riviera Ct., Coral Gables, FL 33134, Officers: Adelaida M. Echanique, Managing Member (QI), Patricio A. Barreiro, Managing Member, Application Type: New NVO License

Godspeed Transportation Inc (NVO & OFF), 743 El Mirador Drive, Fullerton, CA 92835, Officers: Yun S. Kang, President (QI), Shinhak Kang, Secretary, Application Type: New NVO & OFF License

Grandgood International, Inc. (NVO), 19254 E. Walnut Drive, City of Industry, CA 91745, Officers: Biyu Gao, President (QI), Ruxun Yang, Vice President, Application Type: New NVO License

HOC USA, INC. (NVO & OFF), 400 Riverwalk Parkway, Suite 200B, Tonawanda, NY 14150, Officers: Kim M. Host, Executive Vice President (QI), Stephen Cartwright, President, Application Type: New NVO & OFF License

Intransia LLC (NVO), 2701 NW. Boca Raton Blvd., Suite 218, Boca Raton, FL 33431, Officer: Nick Babus, Member (QI), Application Type: New NVO License

JSK Logistics LLC dba JSK Lines (NVO & OFF), 4 Wernik Place, Metuchen, NJ 08840, Officers: Jigar J. Choksi, Member (QI), Rumin H. Shah, Member, Application Type: QI Change

Kin Services, Inc. (NVO & OFF), 2027 Wainwright Court, Palatine, IL 60074, Officers: Majetete Balanganayi, President (QI), Ngalula Ivette Balanganayi, Secretary, Application Type: Add NVO Service

Linchpin Worldwide Logistics, Inc (NVO), 550 S. Serrano Avenue, Suite 311, Los Angeles, CA 90020, Officer: Sung Joon Kwak, President (QI), Application Type: New NVO License

Marine Bulk Freight Forwarding, S.A. De C.V. (NVO), Parque De Granada No. 71, Suite P.H. 504, Huixquilucan, Estado de Mexico 52785 Mexico, Officers: Moises S. Leon, President (QI), Moises S. Aviles, Secretary, Application Type: Add Trade Name Sea Marine Transport

Mass Parts, LLC dba ASG Cargo & Logistics (NVO & OFF), 5055 NW. 74th Avenue, Suite 7, Miami, FL 33166, Officers: Gabriel A. Garrido, Manager (QI), Albarosa Dugarte, Manager, Application Type: New NVO & OFF License

NVO Container Line Inc. dba Global Logistics USA (NVO & OFF), 1074 Broadway, Suite 102, West Long Branch, NJ 07764, Officers: Johannes Peet, Vice President (QI), Monika Sachdev, President, Application Type: QI Change

O.K. Cargo Corp. (NVO & OFF), 1720 NW. 94th Avenue, Miami, FL 33172, Officers: Jorge L. Garcia, President (QI), Nora V. Garcia, Vice President, Application Type: Add Trade Name GV USA Logistics

On Board International, Inc. (NVO & OFF), 2702 Temple Avenue, Long Beach, CA 90806, Officers: Evangeline A. Castano, Vice President (QI), Jose J. Castano, Sr., Application Type: Add NVO Service

Ontario Ltd. dba Qtrex International (NVO), 5185 Timberlea Blvd., Mississauga, Ontario, Canada, Officers: Hardutt Lachmansingh, President (QI), Tulsiedai Lachmansingh, Treasurer, Application Type: New NVO License

Oregon International Air Freight Co. dba OIA Global Logistics (NVO & OFF), 17230 NE. Sacramento Street, Portland, OR 97230, Officers: William D. Brady, Assistant Secretary (QI), Charles E. Hornecker, President, Application Type: Add Trade Name OIA Global

Overseas Moving Specialists, Inc. dba International Sea & Air Shipping (NVO), 115 Meacham Avenue, Elmont, NY 11003, Officers: Boaz Aviani, Vice President (QI), Ivy Aviani, President, Application Type: QI Change

Pass Trans, Inc. (NVO), 3530 Wilshire Blvd., Suite 1200, Los Angeles, CA 90010, Officers: Soon Bum An, CEO (QI), Seok Jun Choi, CFO, Application Type: New NVO License

Polmar Cargo, Inc. (NVO & OFF), 1225 NW. 93rd Court, Doral, FL 33172, Officers: Jesus A. Kauam, President (QI), Kenny Acosta, Secretary, Application Type: QI Change

Premier Van Lines International Inc. (NVO), 2509 S. Power Road, Suite 207, Mesa, AZ 85209, Officers: Heidi E. Lomax, Vice President (QI), James A. Haddow, President (QI), Application Type: QI Change

Priority RoRo Services, Inc. (NVO), Pier 15, Miraflores Avenue, San Juan, PR 00904, Officers: Wilmarie Rivera-Romero, Secretary (QI), Vinicio Mella, President, Application Type: New NVO License

Reza Rostami dba Pan World Trans (NVO & OFF), 5406 Juniper Court, Colleyville, TX 76034, Officer: Reza Rostami, President (QI), Application Type: Add NVO Service/Business Structure Change to Intercargo Management, Inc. dba Pan World Trans

Savitransport Inc. (NVO), 148–08 Guy R. Brewer Blvd., Jamaica, NY 11434, Officers: Kevin M. Kennedy, President

(QI), Filippo Occaso, Secretary, Application Type: New NVO License

Seahorse Container Lines, Inc. (NVO), 10731 Walker Street, Suite B, Cypress, CA 90630, Officers: Carlo DeAtouguia, Vice President Operations (QI), Michael Dugan, President (QI), Application Type: QI Change

Shiner Trading Company, LLC. (OFF), 391 Curtner Avenue, Suite #I, Palo Alto, CA 94306, Officer: Xin You, Member/Manager (QI), Application Type: New OFF License

Sky Freight Forward Inc. (NVO & OFF), 8545 NW 72nd Street, Miami, FL 33166, Officers: Becxi Z. Santos, Secretary (QI), Miguel Mayorga, President, Application Type: New NVO & OFF License

Sparx Logistics USA Limited (NVO & OFF), 7621 Little Avenue, Suite 113, Charlotte, NC 28226, Officers: John W. Dellinger, Jr., President (QI), Dan Zalomek, Secretary, Application Type: New NVO & OFF License

Sprint Cargo Corp. (NVO), 36–36 33rd Street, Suite 207, Astoria, NY 11106, Officers: Bini Gopal, President (QI), Pauljerry Koilparampil, Secretary, Application Type: QI Change

SSL Logistics Cargo, Inc. (OFF), 60 NW 37th Avenue, Suite 608, Miami, FL 33125, Officer: Luis A. LLedo, President (QI), Application Type: New OFF License

Suddath Global Logistics, LLC dba Suddath Global Logistics (NVO & OFF), 815 South Main Street, Jacksonville, FL 32207, Officers: Robert D. Gordon, Vice President (QI), Barry Vaughn, CEO, Application Type: QI Change

Super You Global (NVO), 391 Curtner Avenue, Suite #I, Palo Alto, CA 94306, Officer: Xin You, President (QI), Application Type: New NVO License

Top Logistics, Inc. (NVO & OFF), 1484 E. Valencia Drive, Fullerton, CA 92831, Officers: Yoon (aka Christina) Y. Yang, CFO (QI), Byung H. Jung, CEO, Application Type: New NVO & OFF License

By the Commission.

Dated: December 20, 2013.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–30903 Filed 12–26–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR Part 238), and Regulation MM (12 CFR Part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 4, 2014.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *AF Mutual Holding Company and Alamogordo Financial Corp.*, both in Alamogordo, New Mexico; to acquire Bank 1440, Phoenix, Arizona. Alamogordo Financial Corp., will conduct a minority stock issuance.

Board of Governors of the Federal Reserve System, December 23, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–30999 Filed 12–26–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–20694–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0162 scheduled to expire on January 31, 2014 Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before January 27, 2014.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0162 and document identifier HHS–OS–20694–30–D for reference.

Information Collection Request Title: State Medicaid Fraud Control Units' Reports.

OMB No.: 0990–0162.

Abstract: Office of Inspector General (OIG) is requesting an extension by Office of Management and Budget (OMB) approval for the collection of information to comply with the requirements in Title 19 of the Social Security Act at 1903(q), 42 CFR 1007.15, and 42 CFR § 1007.17, in accordance with the Paperwork Reduction Act. The information collected consists of fifty separate annual reports and fifty separate application requests for certification/recertification of State Medicaid Fraud Control Units (MFCU). The collection is required by the statute and submitted yearly to OIG by the fifty MFCUs. OIG uses the information collected to determine the MFCUs' compliance with Federal requirements and eligibility for continued Federal financial participation (FFP) under the Federal MFCU grant program.

Need and Proposed Use of the Information: Public Law 95–142, the Medicare-Medicaid Anti-Fraud and Abuse Amendments, was enacted in 1977 to strengthen the capabilities of Federal and State governments to combat and eliminate fraud and abuse

in Medicaid, through the establishment of the MFCUs. This law amended section 1903 of the Social Security Act to establish operating requirements for MFCUs and provide FFP to State governments for the cost of establishing MFCUs, training State personnel, and keeping the MFCUs operational.

Under section 1903(q)(7), each MFCU must annually submit to the Secretary of Health and Human Services (Secretary) an application and annual report containing information that the Secretary determines is necessary to certify the MFCU as meeting the requirements for FFP. FFP is available only for activities directly related to the investigation and prosecution of health care providers suspected of committing Medicaid fraud. The MFCUs also review complaints of alleged abuse or neglect of patients and the misuse of patients' personal funds in health care facilities. OIG reviews the information collected to ensure that Federal matching funds are expended by MFCUs only for allowable costs. In addition, OIG analyzes each MFCU's submission to determine whether there is a need for OIG technical assistance and to establish priorities for onsite reviews to further monitor program activities.

Likely Respondents: 50.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
MFCU	Annual Report	50	1	88	4,400
MFCU, estimating a "medium" [1] level of State participation in data mining activities.	Annual Report, data mining reporting only.	13	1	1	13
MFCU	Recertification Application	50	1	5	250
Total		50	2	94	4,663

[1] For medium participation, we estimate 25 percent of the 50 MFCUs participating, or 13 Units.

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2013–30988 Filed 12–26–13; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records Notice

AGENCY: National Disaster Medical System (NDMS), Office of Emergency Management (OEM), Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice to revise an existing system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended (5 U.S.C. 552a), HHS is altering an existing system of records, "National Disaster Medical System (NDMS) Patient Treatment and Tracking," system number 09–90–0040. The system of records was originally published June 26, 2007 (see 72 FR 35052) and previously revised March 27, 2008 (see 73 FR 16307). The alterations include: (1) Changing the system name to "National Disaster Medical System (NDMS) Disaster Medical Information Suite (DMIS);" (2) revising the categories of individuals to reflect that patients may include disaster workers and others who are provided medical countermeasures; (3) dividing the records into three categories (patient treatment, patient tracking, and veterinarian treatment) instead of two (patient treatment and veterinarian treatment); (4) adding, as a purpose for which information from this system is used, that the system provides HHS' NDMS claims processing system with records needed to reimburse NDMS providers for their services; (5) revising the first routine use to include these additional disclosure recipients: state and city governmental agencies, Non-Governmental Organizations (NGOs; e.g., American Red Cross), and hospitals that provide care to NDMS patients; and (6) adding one new routine use, pertaining to security breach response.

DATES: *Effective Dates:* Effective 30 days after publication. Written comments should be submitted on or before the effective date. HHS/ASPR/OEM/NDMS may publish an amended System of Records Notice (SORN) in light of any comments received.

ADDRESSES: The public should address written comments to: NDMS Director, National Disaster Medical System, 200 C Street SW., Washington, DC 20024. To review comments in person, please contact the Director NDMS, 200 C Street SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: CDR Sumner Bossler, NDMS Disaster Medical Information Suite (DMIS), IT Program Manager, ASPR/OEM/NDMS, 200 C Street SW., C1L07, Washington, DC 20024. *sumner.bossler@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. National Disaster Medical System (NDMS) Disaster Medical Information Suite (DMIS)

This system was established pursuant to Section 2812 of the Public Health Service (PHS) Act (42 U.S.C. 300hh–11), as amended, and resides in HHS/ASPR/OEM. Under section 2801 of the PHS Act, the HHS Secretary leads all Federal public health and medical response to public health emergencies and incidents covered by the National Response Framework, or any successor plan. The Secretary delegates to ASPR the leadership role for all health and medical services support functions in a health emergency or public health event, including National Special Security Events. In such events, ASPR

may deploy this system, Field Medical Station assets, and other HHS employees under the control of the Secretary and provide operational oversight over officers of the U.S. Public Health Service Commissioned Corps and other Federal public health and medical personnel. Under the National Response Framework, HHS is the lead agency for Emergency Support Function 8, *Public Health and Medical*. HHS uses this system to collect medical records and share them with the other Federal agencies and departments that share ESF 8 responsibilities with HHS. The ESF 8 agencies have shared statutory authority to collect and use medical information as needed to coordinate the following three key functions with Federal, state, local and private partners, to augment public health and medical activities of State and local governments in disaster or public health emergency situations:

- *Medical response*—this function involves activation and deployment of Federal response teams comprised of medical and logistical personnel, to assess the health and medical needs of disaster victims and to provide physical and mental health care during a public health emergency, including National Special Security Events.
- *Patient evacuation*—this function involves establishment of communications, transportation, patient tracking, and a medical regulating system to evacuate and move patients from a staging center near a disaster site to patient reception sites known as Federal Coordinating Centers (FCCs). The Department of Defense (DOD) and Veterans Administration (VA) have the prime responsibility for activating and managing the FCCs. In turn, upon receiving the patients, the FCCs have the authority to arrange for necessary referrals and admissions of evacuated patients.

The information collected by the NDMS–DMIS system and the purposes for which the information is used and disclosed by HHS are described in more detail in the revised SORN that follows below. Because some of the revisions constitute significant changes, HHS provided adequate advance notice of the altered SORN to the Office of Management and Budget (OMB) and Congress as required by the Privacy Act at 5 U.S.C. 552a(r).

II. The Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the U.S. Government collects, maintains, and uses information about individuals in a system of records. A "system of records" is a group of any records under the control of a Federal agency from which information about an individual is retrieved by the individual's name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a system of records notice (SORN) identifying and describing each system of records the agency maintains, including the purposes for which the agency uses information about individuals in the system, the routine uses for which the agency discloses such information outside the agency, and how individual record subjects can exercise their rights under the Privacy Act (e.g., to determine if the system contains information about them).

SYSTEM NUMBER:

09–90–0040

SYSTEM NAME:

National Disaster Medical System (NDMS) Disaster Medical Information Suite (DMIS).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Paper records are stored at NDMS headquarters, 200 C. Street SW., Washington, DC 20024. The electronic database and server where information is entered and stored is maintained at the MAHC data center in Reston, Virginia.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records in this system pertain to:

- patients who are treated and evacuated by Federal public health and medical personnel, including NDMS and PHS teams, that are activated to respond to an emergency or other situation; and
- owners of animals that are treated and evacuated by NDMS and PHS teams.

Patients may include disaster workers/responders and others who are provided medical countermeasures; however, this SORN excludes patient treatment records for federal employee-workers to the extent such records are covered under the Office of Personnel Management (OPM) SORN titled "Employee Medical File System Records" (OPM/GOVT–10). Patient records may include information about patients' family members and non-medical attendants, but only the patients—not their family members and non-medical attendants—are considered record subjects.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system includes the following categories of records containing personally identifiable information about patients or owners of animals:

CATEGORY A:

Completed Patient Treatment Record that includes

1. Team/personnel identification record, for patients who are disaster workers/responders on NDMS teams or other Federal public health and medical teams.
2. Patient treatment record.
   a. Chart Number.
   b. Time and Date Patient seeks treatment.
   c. Triage Category and health status.
   d. Location where Patient is seen and transferred.
   e. Patient Identification: Name, Address, City, State, Zip, Date of Birth, Phone Number, Employment, Weight, Next of Kin.
   f. Complaints/Symptoms.
   g. Patient Acuity, health status, Vital Signs/Treatment Recommended and/or Prescribed, laboratory tests
   h. Reported Medications and allergies
   i. History of present illness and reported past medical history
   j. Digital Images of patient and non-medical attendant for Identification
   k. Digital images, audio or video used for medical assessment
   l. Discharge—Time, Date, Disposition, Recommendations.
3. Patient Authorization—Requires Patient Signature in Front of Witness and Witness Verification through Signature.
4. Any potential attachments such as X-rays and laboratory reports showing test results.

CATEGORY B:

Completed Patient Tracking Record that includes

1. Patient Tracking Record.
   a. Patient Identification: Name, gender, and Address, City, State, Zip, Date of Birth, Phone Number, Employment, Weight, Next of Kin, unique ID.
   b. Attendant Identification: Name, gender, Address, City, State, Zip, Date of Birth, Phone Number, Next of Kin, email address, unique ID
   c. Triage Category and health status.
   d. Location where Patient is seen and transferred.
   e. Patient Acuity, health status
   f. Digital Images of patient and non-medical attendant for Identification
   g. Discharge: Time, Date, Disposition

CATEGORY C:

Veterinarian Treatment Records on animals

1. Privacy Act Data such as the name, address and telephone contact

information of owners of animals will be maintained to be associated with the animal patient. However, animal treatment records themselves are not subject to the Privacy Act protections.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The PHS Act, primarily section 2812 (42 U.S.C. 300hh–11); Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.); and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794).

PURPOSE(S):

NDMS staff and other relevant HHS personnel use personally identifiable information from this system, on a need to know basis, for the following purposes:

- To document medical treatment rendered to patients, e.g., for use if questions of liability arise about the treatment or the subsequent condition of the patient while under the care of NDMS.
- To conduct medical quality assurance reviews and establish a quality improvement process (QIP), by reviewing medical treatment on a specific deployment, spotting best practices and developing process improvements for future deployments.
- For research projects related to the prevention of disease or disability as a result of a disaster and for situational awareness required for ASPR operations during disasters.
- To provide HHS' NDMS claims processing system with records needed to reimburse NDMS providers for their services.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a (b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to parties outside HHS as follows:

1. To Federal agencies that are ESF 8 partners, including but not limited to DHS, DoD, and the VA, or that participate in National Special Security Events; state and city governmental agencies; Non-Governmental Organizations such as the American Red Cross; and hospitals providing care to NDMS patients; which share responsibility with HHS for the medical treatment and movement of patients (including responders), decedents, and animals, for the purpose of discharging those responsibilities, including ensuring that patients treated receive the maximum level of health care possible. The medical and demographic information collected during the treatment of a patient is shared with relevant partners to ensure that patients treated through NDMS–DMIS receive the appropriate level of health care. The health information disclosed among the partners is limited to what is needed for continuity of health care operations.

2. To a member of Congress or a Congressional staff member in response to an inquiry from the Congressional office made at the written request of the constituent about whom the record is maintained.

3. To the Department of Justice (DOJ), a court, or an adjudicatory body when the following situations arise:

a. The agency or any component thereof, or

b. Any employee of the agency whether in his/her official or individual capacity, where DOJ has agreed to represent the employee, or

c. The United States government, is a party to litigation or has an interest in such litigation and, after careful review, the agency deems that the records requested are relevant and necessary to the litigation and that the use of such records by DOJ, the court or the adjudicatory body is compliant with the purposes for which the agency collected the records.

4. To contractors, consultants, grantees, or volunteers that have been engaged by HHS to assist in the performance of a service related to this collection and who have a need to have access to the records in order to perform the activity.

5. To assist another federal or state agency, or its fiscal agent:

a. To establish the benefit entitlement of the patient.

b. To establish the relationship between the existing state benefit and the benefit funded in whole or part with federal funds, such as the one associated with the NDMS definitive care.

c. To collaborate with the state and state agencies on behalf of family members regarding the current location and placement of their evacuated family member or patient population.

6. To family members of a patient, to provide them with information about the location or the status of the patient. Disclosure of a patient's location or status is not permitted when there is a reasonable belief that disclosing such information could endanger the life, safety, health, or well-being of the patient.

7. To appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting HHS's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, provided the information disclosed is relevant and necessary for that assistance.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM—

STORAGE:

Records are stored in paper files kept at NDMS headquarters and in an electronic database housed in Reston, Virginia.

RETRIEVABILITY:

Records are organized by event, location, and date of treatment. Data are retrieved by name and other demographic information provided by the patient (or for veterinary records, by animal owner), as well as by location of treatment, diagnosis, and other data fields within the database.

SAFEGUARDS:

Information in this system is safeguarded in accordance with applicable laws, rules and policies, including the HHS Information Technology Security Program Handbook, all pertinent National Institutes of Standards and Technology publications and OMB Circular A–130, Management of Federal Resources. Records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include restricting access to authorized personnel who have need-to-know, using physical locks in the office environment, and the process of authentication using user IDs and passwords function as identification protection features. HHS file areas are locked after normal duty hours and the facilities are protected from the outside by security personnel. Personnel with authorized access to the system have been trained in the Privacy Act and information security requirements for both paper copies and electronically stored information.

RETENTION AND DISPOSAL:

Records are retained in accordance with records disposition schedule N1–468–07–1, approved by the National Archives and Records Administration (NARA) for the Office of Public Health and Emergency Preparedness (OPHEP); the Pandemic and All Hazards Preparedness Act (Pub. L. 109–417) established the ASPR to serve in a similar capacity as OPHEP for medical disaster response. Schedule N1–486–08–1 covers Patient Care Forms or other Medical Records regulated under the Health Insurance Portability and

Accountability Act (HIPAA), created by the Federal Medical Station(s) or by any component of HHS/ASPR during a response to an event while caring for victims of that event, and provides the following disposition authority:

Cutoff is at the end of the response activity by the Federal Medical Station(s) for a particular event. Retire to the Washington National Records Center 2 years after cutoff. Destroy 75 years after cutoff.

Cutoff refers to breaking, or ending files at regular intervals, usually at the close of a fiscal or calendar year, to permit their disposal or transfer in complete blocks and, in this case, cutoff is at the end of the response activity. The cutoff date marks the beginning of the records retention period. Veterinarian treatment records pertaining to animals and their owners are not included in the above schedule, and cannot be destroyed until NARA approves a disposition schedule for them.

SYSTEM MANAGER AND ADDRESS:

NDMS Director, 200 C. Street SW., Washington, DC 20024.

NOTIFICATION PROCEDURE:

Individuals seeking to know if this system contains records about them must submit a written request to the System Manager at the above mailing address, clearly marked as a "Privacy Act Request" on the envelope and letter (see, generally, HHS Privacy Act regulations found at 45 CFR Part 5b). Requests pertaining to patients should include the full name of the patient, appropriate verification of identity, current address of the patient, and the name of the requester, appropriate verification of identity, current address of the requester, and the nature of the record sought, as required by HHS Privacy Act regulations at 45 CFR 5b.5. Requests pertaining to owners of animals should include the full name of the owner and the animal, appropriate verification of identity, current address of the requester, and the nature of the record sought, as required by HHS Privacy Act regulations at 45 CFR 5b.5

RECORD ACCESS PROCEDURES:

Same as the notification procedure above.

CONTESTING RECORD PROCEDURES:

Same as the notification procedure above; the request should also clearly and concisely describe the information contested, the reasons for contesting it, and the proposed amendment sought, pursuant to HHS Privacy Act regulations at 45 CFR 5b.7.

RECORD SOURCE CATEGORIES:

Information in patient treatment and tracking records is obtained directly from the patients and from medical or clinical personnel treating or evacuating the patients or accessing their personal health records (PHR). In the case of minors or other patients who are unable to explain symptoms, information may be obtained from a parent or guardian, or other family members or individuals attending. Information in veterinarian treatment records about owners of animals is obtained from NDMS veterinary personnel and/or the owners or caretakers of the animals.

SYSTEM EXEMPTED FROM CERTAIN PROVISION OF THE PRIVACY ACT:

None.

Dated: December 6, 2013.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2013–31118 Filed 12–26–13; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

[CDC–2013–0025, Docket Number NIOSH–266]

Criteria for a Recommended Standard; Occupational Exposure to Heat and Hot Environments; Draft Criteria Document Availability

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft document for public comment and public meeting.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of a draft Criteria Document entitled Criteria for a Recommended Standard: Occupational Exposure to Heat and Hot Environments for public comment. To view the notice and related materials, visit *http://www.regulations.gov* and enter CDC–2013–0025 in the search field and click "Search." Comments may be provided to the NIOSH docket, as well as given orally at the meeting.

DATES: *Public comment period:* Comments must be received by February 25, 2014.

Public Meeting Time and Date: February 13, 2014, 9 a.m.–4 p.m., Eastern Time. Please note that public comments may end before the time indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend the meeting at the start time listed.

Place: Robert A. Taft Laboratories, 4676 Columbia Pkwy., Cincinnati, OH 45226. Room: Taft Auditorium.

Status: The meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 100 people. In addition, there will be an audio teleconference line for those who cannot attend in-person. There is no registration fee to attend this public meeting. However, those wishing to attend are encouraged to register by February 5, 2014 with the NIOSH Docket Office at 513/533–8611 or email *nioshdocket@cdc.gov,*

Security Considerations: Due to mandatory security clearance procedures at the Robert A. Taft Laboratories, in-person attendees must present valid government-issued picture identification to security personnel upon entering the building and go through an airport-type security check.

Non-U.S. Citizens: Because of CDC Security Regulations, any non-U.S. citizen wishing to attend this meeting must provide the following information in writing to the NIOSH Docket Officer at the address below no later than January 13, 2014 to allow time for mandatory CDC facility security clearance procedures to be completed.

1. Name:
2. Gender:
3. Date of Birth:
4. Place of Birth (city, province, state, country):
5. Citizenship:
6. Passport Number:
7. Date of Passport Issue:
8. Date of Passport Expiration:
9. Type of Visa:
10. U.S. Naturalization Number (if a naturalized citizen):
11. U.S. Naturalization Date (if a naturalized citizen):
12. Visitor's Organization:
13. Organization Address:
14. Organization Telephone Number:
15. Visitor's Position/Title within the Organization:

This information will be transmitted to the CDC Security Office for approval. Visitors will be notified as soon as approval has been obtained. Non-U.S. citizens are encouraged to participate in the audio conferencing due to the extra clearance involved with in-person attendance.

Attendee and Speaker Registration: Attendees are encouraged to sign up by

February 5, 2014 with the NIOSH Docket Office. Individuals wishing to speak during the meeting may sign up when registering with the NIOSH Docket Office no later than February 5, 2014, at 513/533–8611 or by email at *nioshdocket@cdc.gov*. Those who have not signed up to present in advance may be allowed to present at the meeting if time allows.

Persons wanting to provide oral comments will be permitted up to 20 minutes. If additional time becomes available, presenters will be notified. Oral comments given at the meeting must also be submitted to the docket in writing in order to be considered by the Agency.

Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come basis. Unreserved walk-in attendees will not be admitted due to security clearance requirements.

Purpose of the Meeting: To discuss and obtain comments on the draft document, "Criteria for a Recommended Standard: Occupational Exposure to Heat and Hot Environments". Special emphasis will be placed on discussion of the following:

Overall Questions

(1) Is worker acclimatization clearly explained and presented?

(2) Are there any additional recommendations that should be made?

(3) Is there any additional information on hydration that should be considered?

(4) Are there any additional risk factors for heat-related illnesses that should be discussed?

(5) Are there any additional examples of auxiliary body cooling and protective clothing that should be included?

(6) Are there any additional research needs that should be mentioned?

(7) Are there any additional references that should be included?

Written comments will be accepted at the meeting. Written comments may also be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C–34, Cincinnati, Ohio 45226.

All material submitted to the Agency should reference the agency name and docket number (CDC–2013–0025; NIOSH–266). All electronic comments should be formatted as Microsoft Word. Please make reference to CDC–2013–0025 and Docket Number NIOSH–266.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 109, 4676 Columbia Parkway, Cincinnati, Ohio, 45226.

Background: Workers who are exposed to extreme heat or work in hot environments may be at risk of heat stress. Exposure to extreme heat can result in occupational illnesses and injuries. Heat stress can result in heat-related illnesses such as heat stroke, heat exhaustion, heat cramps, or heat rashes. Heat can also increase the risk of injuries in workers as it may result in sweaty palms, fogged-up safety glasses, and dizziness. Burns may also occur as a result of accidental contact with hot surfaces or steam. Workers at risk of heat stress include outdoor workers and workers in hot environments such as firefighters, bakery workers, farmers, construction workers, miners, boiler room workers, factory workers, and others.

In 1986, NIOSH published a Criteria Document on hot environments [DHHS (NIOSH) Publication No. 86–113] *http://www.cdc.gov/niosh/docs/86-113/86-113.pdf* which identified many of the effects of heat, provided information on appropriate measuring techniques, and made recommendations for occupational standards, prevention and control. In recent years, including during the oil spill response of 2010, questions were raised regarding whether this document needed to be updated with additional research and findings. Recent literature was reviewed to determine areas that needed updating and revision.

FOR FURTHER INFORMATION CONTACT: Brenda Jacklitsch, Phone: (513) 533–8369, Email: *GWE6@CDC.GOV*, NIOSH, MS–C32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, OH 45226.

Dated: December 20, 2013.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2013–31066 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2013–0001, NIOSH 134–B]

Issuance of Final Guidance Publication.

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of final guidance publication.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), announces the availability of the following publication: "Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan 2013–2016" [NIOSH 2014–106].

ADDRESSES: This document may be obtained at: *http://www.cdc.gov/niosh/docs/2014-106/*.

FOR FURTHER INFORMATION CONTACT: Charles Geraci, NIOSH Nanotechnology Research Center, Education and Information Division, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513)533–8339.

Dated: December 20, 2013.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2013–31063 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee on Procedures Review, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned subcommittee:

Time and Date: 11:00 a.m.–5:00 p.m. Eastern Time, February 13, 2014.

Place: Audio Conference Call via FTS Conferencing. The USA toll-free, dial-in number is 1–866–659–0537 and the pass code is 9933701.

Status: Open to the public, without a verbal public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-

free, dial-in number, 1–866–659–0537 and the passcode is 9933701.

Background: The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the ABRWH include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the ABRWH to HHS, which subsequently delegated this authority to CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: The ABRWH is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is a reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures Review was established to aid the ABRWH in carrying out its duty to advise the Secretary, HHS, on dose reconstructions. The Subcommittee on Procedures Review is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

Matters To Be Discussed: The agenda for the Subcommittee meeting includes discussion of the following ORAU and DCAS procedures: ORAU Team Technical Information Bulletin (OTIB) 0034 ("Internal Dose Coworker Data for X–10"), OTIB 0054 ("Fission and Activation Product Assignment for Internal Dose-Related Gross Beta and Gross Gamma Analyses"), OTIB 0083 (Dissolution Models for Insoluble Plutonium 238"), Program Evaluation Report (PER) 011 ("K–25 TBD and TIB Revisions"), PER 014 ("Construction Trades Workers"), PER 020 ("Blockson TBD Revision"), PER 25 ("Huntington Pilot Plant TBD Revision"), PER 031 ("Y–12 TBD Revisions"), PER 033 ("Reduction Pilot Plant TBD Revision"), PER 038 ("Hooker Electrochemical TBD Revisions"); Update on Review of ORAU Team Report 0053 ("Stratified Co-Worker Sets); estimating radiation doses associated with localized skin exposures to uranium at Atomic Weapons Employer facilities; and a continuation of the comment-resolution process for other dose reconstruction procedures under review by the Subcommittee.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email *dcas@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30930 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns The Cooperative Re-Engagement Controlled Trial (CoRECT), Funding Opportunity Announcement (FOA) PS14–001, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 12:00 p.m.–5:00 p.m., March 7, 2014 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "The Cooperative Re-Engagement Controlled Trial (CoRECT), FOA PS14–001".

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30909 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Time and Date: 10:00 a.m.–5:00 p.m. Eastern Time, February 6, 2014.

Place: Audio Conference Call via FTS Conferencing.

Status: Open to the public, without a verbal public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1–866–659–0537 and the passcode is 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC.

NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy (DOE) facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Discussed: The agenda for the Subcommittee meeting includes the following dose reconstruction program quality management and assurance activities: Discussion of current findings from NIOSH internal dose reconstruction blind reviews; discussion of dose reconstruction cases under review (set 9, and cases involving Portsmouth, Hanford, Oak Ridge National Laboratory, Y–12, K–25, and other DOE and Atomic Weapons Employer sites from sets 10–13); and preparation of the Advisory Board's next report to the Secretary, HHS, summarizing the results of completed dose reconstruction reviews.

The agenda is subject to change as priorities dictate.

Contact Person For More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email ocas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30907 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee on Procedures Review, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned subcommittee:

Time and Date: 11:00 a.m.–5:00 p.m. Eastern Time, February 13, 2014.

Place: Audio Conference Call via FTS Conferencing. The USA toll-free, dial-in number is 1–866–659–0537 and the pass code is 9933701.

Status: Open to the public, without a verbal public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1–866–659–0537 and the passcode is 9933701.

Background: The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the ABRWH include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the ABRWH to HHS, which subsequently delegated this authority to CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: The ABRWH is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is a reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures Review was established to aid the ABRWH in carrying out its duty to advise the Secretary, HHS, on dose reconstructions. The Subcommittee on Procedures Review is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

Matters To Be Discussed: The agenda for the Subcommittee meeting includes discussion of the following ORAU and DCAS procedures: ORAU Team Technical Information Bulletin (OTIB) 0034 ("Internal Dose Coworker Data for X–10"), OTIB 0054 ("Fission and Activation Product Assignment for Internal Dose-Related Gross Beta and Gross Gamma Analyses"), OTIB 0083 (Dissolution Models for Insoluble Plutonium 238"), Program Evaluation Report (PER) 011 ("K–25 TBD and TIB Revisions"), PER 014 ("Construction Trades Workers"), PER 020 ("Blockson TBD Revision"), PER 25 ("Huntington Pilot Plant TBD Revision"), PER 031 ("Y–12 TBD Revisions"), PER 033 ("Reduction Pilot Plant TBD Revision"), PER 038 ("Hooker Electrochemical TBD Revisions"); Update on Review of ORAU Team Report 0053 ("Stratified Co-Worker Sets); estimating radiation doses associated with localized skin exposures to uranium at Atomic Weapons Employer facilities; and a continuation of the comment-resolution process for other dose reconstruction procedures under review by the Subcommittee.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email *dcas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30908 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the following meeting of the aforementioned committee:

Times and Dates: 11:00 a.m.–5:30 p.m., January 27, 2014; 8:30 a.m.–1:00 p.m., January 28, 2014.

Place: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

Status: This meeting is open to the public; however, visitors must be processed in accordance with established federal policies and procedures. For foreign nationals or non-US citizens, pre-approval is required (please contact Gwen Mustaf, 301–458–4500, *glm4@cdc.gov* or Virginia Cain, *vcain@cdc.gov* at least 10 days in advance for requirements). All visitors are required to present a valid form of picture identification issued by a state, federal or international government. As required by the Federal Property Management Regulations, Title 41, Code of Federal Regulation, Subpart 101–20.301, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters To Be Discussed: The agenda will include welcome remarks and update by the Director, NCHS; discussion of vital statistics; future program reviews; National Health Interview Survey 2017 redesign, long-term care report.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by January 13, 2014.

The agenda items are subject to change as priorities dictate.

Contact Person For More Information: Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, telephone (301) 458–4500, fax (301) 458–4020

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30904 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Epidemiology, Prevention, and Treatment of Influenza and Other Respiratory Infections in a Malaria-Endemic Area of Malawi with High HIV Prevalence, Funding Opportunity Announcement (FOA) IP14–002, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1:00 p.m.–3:00 p.m., February 25, 2014 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Epidemiology, Prevention, and Treatment of Influenza and Other Respiratory Infections in a Malaria-Endemic Area of Malawi with High HIV Prevalence, FOA IP14–002".

Contact Person For More Information: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30906 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Capacity Building Assistance for High Impact HIV Prevention, Funding Opportunity Announcement (FOA) PS14–1403, Initial Review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned SEP:

Times and Dates: 8:00 a.m.–8:00 p.m., January 22, 2014 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Capacity Building Assistance for High Impact HIV Prevention", FOA PS14–1403.

Contact Person for More Information: Harriette A. Lynch, Public Health Analyst, CDC, 1600 Clifton Road NE., Mailstop E07, Atlanta, Georgia 30333, Telephone: (404) 718–8837.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30910 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Interagency Committee on Smoking and Health, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

The CDC is soliciting nominations for possible membership on the Interagency Committee on Smoking and Health (ICSH), Office on Smoking and Health (OSH).

The ICSH consists of five experts in the field related to smoking and health appointed by the Secretary from physicians and scientists who represent private entities involved in informing the public about the health effects of smoking. The members are selected by the Secretary, HHS. The committee provides advice and guidance to the Secretary, HHS, and the Director, CDC regarding (a) coordination of all research and education programs and other activities within the Department and with other Federal, State, local and private agencies and (b) establishment and maintenance of liaison with appropriate private entities, federal agencies, and State and local public health agencies with respect to smoking and health activities.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishment of the committee's objectives. More information is available on the ICSH, OSH Web site: *http://www.cdc.gov/tobacco/ICSH/index.htm.*

Nominees will be selected based on expertise in the field of tobacco control and multi-disciplinary expertise in public health. Additionally, desirable qualifications include: (1) Knowledge of emerging tobacco control policies and experience in analyzing, evaluating, and interpreting Federal, State and/or local health or regulatory policy; or (2) knowledge of emerging tobacco products and the evolving environment of tobacco control and expertise in developing or contributing to the development of policies and/or programs; or (3) familiarity of rapid and emerging surveillance systems that will allow for the timely evaluation of tobacco product regulation and/or the impact of tobacco control interventions.

Federal employees will not be considered for membership. Members may be invited to serve for terms of up to four years. The U.S. Department of Health and Human Services policy stipulates that committee membership shall be balanced in terms of professional training and background, points of view represented, and the committee's function. In addition to an extensive range of expertise, consideration is given to a broad representation of geographic areas within the U.S., with diverse representation of both genders, ethnic and racial minorities, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government.

Candidates should submit the following items:

- Current *curriculum vitae,* including complete contact information (name, affiliation, mailing address, telephone number, email address)
- A letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services
- A statement indicating the nominee's willingness to serve as a potential member of the Committee.

Nominations should be submitted electronically or in writing, and must be postmarked by January 17, 2014 and sent to: Ms. Monica Swann, NCCDPHP, CDC, 395 E Street SW., Room 9167, MS P06, Washington, DC 20024. (Email address: *zqe0@cdc.gov*). Telephone and facsimile submissions cannot be accepted.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–30929 Filed 12–26–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10215]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *February 25, 2014:*

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10215 Medicaid Payment for Prescription Drugs—Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Payment for Prescription Drugs—Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs; *Use:* In accordance with the Deficit Act of 2005, states are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive federal financial participation for these drugs. Physicians, serving as respondents to states, submit National Drug Code numbers and utilization information for "J" code physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars; *Form Number:* CMS–10215 (OCN: 0938–1026); *Frequency:* Weekly; *Affected Public:* Private sector—business or other for-profits and not-for-profit institutions; *Number of Respondents:* 20,000; *Total Annual Responses:* 3,910,000; *Total Annual Hours:* 16,227. (For policy questions regarding this collection contact Bernadette Leeds at 410–786–9463).

Dated: December 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–31016 Filed 12–26–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10379 and CMS–724]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 25, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10379 Rate Increase Disclosure and Review Reporting Requirements

CMS–724 Medicare/Medicaid Psychiatric Hospital Survey Data

Under the Paperwork Reduction Act (PRA)(44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved information collection; *Title of Information Collection:* Rate Increase Disclosure and Review Reporting Requirements; *Use:* Section 1003 of the Affordable Care Act adds a new section 2794 of the PHS Act which directs the Secretary of the Department of Health and Human Services (the Secretary), in conjunction with the states, to establish a process for the annual review of "unreasonable increases in premiums for health insurance coverage." The statute provides that health insurance issuers must submit to the Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 also specifies that beginning with plan years beginning in 2014, the Secretary, in conjunction with the states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 2794 directs the Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. The regulation therefore develops a process to ensure the public disclosure of all such information and justification. Section 2794 requires that health insurance issuers submit justification for an unreasonable rate increase to both us and the relevant state prior to its implementation. Additionally, section 2794 requires that rate increases effective in 2014 (submitted for review in 2013) be monitored by the Secretary, in conjunction with the states. To those ends the regulation establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined by a state or CMS to be unreasonable, and a notification requirement for unreasonable rate increases which the issuer will not implement.

On November 14, 2013, we issued a letter to State Insurance Commissioners outlining transitional policy for non-grandfathered coverage in the small group and individual health insurance markets. If permitted by applicable State authorities, health insurance issuers may choose to continue coverage that would otherwise be terminated or cancelled, and affected individuals and small businesses may choose to re-enroll in such coverage. Under this transitional policy, non-grandfathered health insurance coverage in the individual or small group market that is renewed for a policy year starting between January 1, 2014, and October 1, 2014, will not be considered to be out of compliance with certain market reforms if certain specific conditions are met. These transitional plans continue to be subject to the requirements of section 2794, but are not subject to 2701 (market rating rules), 2702 (guaranteed availability), 2704 (prohibition on health status rating), 2705 (prohibition on health status discrimination) and 2707 (requirements of essential health benefits) and the because the single risk pool (1311(e)) is dependent on all of the aforementioned sections (2701, 2702, 2704, 2705 and 2707), the transitional plans are also exempt from the single risk pool The Unified Rate Review Template and system are exclusively designed for use with the single risk pool plan, and any attempt to include non-single risk pool plans in the Unified Rate Review template or system will create errors, inaccuracies and limitations on submissions that would prevent the effectiveness of reviews of both sets of non-grandfathered plans (single risk pool and transitional). For these many reasons, we are requiring issuers with transitional plans that experience rate increases subject to review to use the Rate Review Justification system and templates which were required and utilized prior to April 1, 2013. *Form Number:* CMS–10379 (OCN: 0938–1141); *Frequency:* Annual; *Affected Public:* Private Sector, State Governments; *Number of Respondents:* 81; *Number of Responses:* 359; *Total Annual Hours:* 1,880. (For policy questions regarding this collection, contact Doug Pennington at 410–786–1553.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare/Medicaid Psychiatric Hospital Survey Data; *Use:* The CMS–724 form is used to collect data that is not collected elsewhere and assists us in program planning and evaluation and in maintaining an accurate database on providers participating in the psychiatric hospital program. *Form Number:* CMS–724 (OCN: 0938–0378); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 500; Total *Annual Responses:* 150; *Total Annual Hours:* 75. (For policy questions regarding this collection contact Donald Howard at 410–786–6764.)

Dated: December 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–30994 Filed 12–26–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10500 and CMS–10515]

Agency information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *January 27, 2014.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of

Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new control number); *Title of Information Collection:* Outpatient and Ambulatory Surgery Experience of Care Survey; *Use:* We will use the information collected through the field test to inform the development of a larger national survey effort, including development of the final survey instrument and data collection procedures. Looking toward the survey development specifically, the data collected in this survey effort will be used to conduct a rigorous psychometric analysis of the survey content. The goal of such an analysis is to assess the measurement properties of the proposed instrument and sub-domain composites created from item subsets, to assure the information reported from any future administrations of the survey is well-defined. Such careful definition will prevent data distortion or misinformation if they are publicly reported. Data collection procedures will also be fine-tuned during this field test. The 30-day PRA package has been revised since the publication of the 60-day **Federal Register** notice on October 4, 2013 (78 FR 61848). (*Form Number:* CMS–10500 (OCN: 0938-New); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 2,304; *Total Annual Responses:* 2,304; *Total Annual Hours:* 384. (For policy questions regarding this collection contact Caren Ginsberg at 410–786–0713.)

2. *Type of Information Collection Request:* New collection (request for a new OMB control number); *Title of Information Collection:* Payment Collections Operations Contingency Plan; *Use:* Under sections 1401, 1411, and 1412 of the Affordable Care Act and 45 CFR part 155 subpart D, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in QHP coverage through the Exchange and seek financial assistance. Using information available at the time of enrollment, the Exchange determines whether the individual meets the income and other requirements for advance payments and the amount of the advance payments that can be used to pay premiums. Advance payments are made periodically under section 1412 of the Affordable Care Act to the issuer of the QHP in which the individual enrolls. Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the Affordable Care Act provides for the advance payment of these reductions to issuers. The statute directs issuers to reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 400 percent of the Federal poverty level (FPL) who are enrolled in a silver level QHP through an individual market Exchange and are eligible for advance payments of the premium tax credit. The data collection will be used by HHS to make payments or collect charges from issuers under the following programs: advance payments of the premium tax credit, advanced cost-sharing reductions, and Marketplace user fees. The template will be used to make payments in January 2014 and for a number of months thereafter, as may be required based on HHS's operational progress. *Form Number:* CMS–10515 (OCN 0938–NEW). *Frequency:* Monthly. *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 575. *Total Annual Responses:* 7,475. *Total Annual Hours:* 51,175. (For policy questions regarding this collection contact Jaya Ghildiyal at 301–492–5149.)

Dated: December 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–31015 Filed 12–26–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10510]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB); Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice; correction.

SUMMARY: This document corrects a date in the December 23, 2013, **Federal Register** notice (document identifier: CMS–10510) entitled "Basic Health Program Report for Health Insurance Exchange Premium."

FOR FURTHER INFORMATION CONTACT: Jessica Schubel at 410–786–3032.

SUPPLEMENTARY INFORMATION:

I. Background

On December 23, 2013 (78 FR 77469), we published an emergency Paperwork Reduction Act (PRA) notice for the information collection request entitled "Basic Health Program Report for Health Insurance Exchange Premium."

While the date requested for OMB approval (January 6, 2014) is correct in the associated PRA package, the date in the December 23, 2013, **Federal Register** notice incorrectly reads "December 23, 2013." This notice corrects that error as follows.

II. Correction

In the **Federal Register** of December 23, 2013, in FR Doc. 2013–30434, on page 77469, in the third column, in the third paragraph, correct the first sentence to read:

We are requesting OMB review and approval of this collection by January 6, 2014, with a 180-day approval period.

Dated: December 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–30989 Filed 12–26–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0179]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 27, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0520. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285 (OMB Control Number 0910–0520)—Revision.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that we receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of our regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting our review after we have refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(l) of the FD&C Act; and § 1.285(i) (21 CFR 1.285(i)) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, "any country to which the article has been refused entry." In the **Federal Register** of May 5, 2011 (76 FR 25542), we issued an interim final rule (IFR) entitled "Information Required in Prior Notice of Imported Food" (2011 IFR) that implemented section 304 of FSMA and requested public comments. OMB approved the collection of information requirements of the 2011 IFR under OMB control number 0910–0683. On May 30, 2013 (78 FR 32359), we published a final rule that adopts, without change, the regulatory requirements established in the 2011 IFR, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country that has refused entry of that product. In this request for extension of OMB approval under the PRA, we are combining the burden hours associated with OMB control number 0910–0683 (collection entitled "Information Required in Prior Notice of Imported Food") with the burden hours approved under OMB control number 0910–0520 (collection entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002").

Advance notice of imported food allows us, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain additional information that indicates prior refusals by any country and also identifies the country or countries, we may better identify imported food shipments that may pose safety and security risks to U.S. consumers. This additional knowledge can further help us to make better informed decisions in managing the potential risks of imported food shipments into the United States.

Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

Our regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at *http://www.access.fda.gov/*. Information we collect in the prior notice submission includes: The submitter and transmitter (if different from the submitter); entry type and CBP identifier; the article of food including complete FDA product code; the manufacturer, for an article of food no longer in its natural state; the grower, if known, for an article of food that is in its natural state; the FDA Country of Production; the name of any country that has refused entry of the article of food; the shipper, except for food imported by international mail; the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; the carrier and mode of transportation, except for food imported by international mail; and planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for our importer's entry notice, which has been approved under OMB control number 0910–0046. The information in an importer's entry notice is collected electronically via CBP's ABI/ACS at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in

table 1 of this document reflects our estimate of the reduced burden for prior notice submitted through ABI/ACS in the column labeled "Hours per Response."

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information to us if information changes after we have confirmed a prior notice submission for review (e.g., if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after we have confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to 1.282(a)(1)(iii)). In the event that we refuse admission to an article of food under section 801(m)(1) or we place it under hold under section 801(l) of the (FD&C Act), §§ 1.283(d) and 1.285(j) set forth the procedure for requesting our review and the information required in a request for review. In the event that we place an article of food under hold under section 801(l) of the (FD&C Act), § 1.285(i) sets forth the procedure for, and the information to be included in, a post-hold submission.

In the **Federal Register** of November 1, 2013 (78 FR 65670) FDA published a 60-day notice requesting public comment on the proposed collection of information; no comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section No.	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions						
Prior Notice Submitted Through ABI/ACS						
1.280–1.281	None	15,000	608	9,120,000	0.167	1,523,040 [2]
Prior Notice Submitted Through PNSI						
1.280–1.281	FDA 3540 [3]	26,667	58	1,546,686	0.384	593,927
New Prior Notice Submissions Subtotal						2,116,967
Prior Notice Cancellations						
Prior Notice Cancelled Through ABI/ACS						
1.282	FDA 3540	4,098	1	4,098	0.25	1,025
Prior Notice Cancelled Through PNSI						
1.282, 1.283(a)(5).	FDA 3540	33,096	1	33,096	0.25	8,274
Prior Notice Cancellations Subtotal						9,299
Prior Notice Requests for Review and Post-Hold Submissions						
1.283(d), 1.285(j).	None	1	1	1	8	8
1.285(i)	None	1	1	1	1	1
Prior Notice Requests for Review and Post-hold Submissions Subtotal						9
Total Hours Annually						2,126,275

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] To avoid double-counting, an estimated 396,416 burden hours already accounted for in the Importer's Entry Notice information collection approved under OMB Control No. 0910–0046 are not included in this total.

[3] The term "Form FDA 3540" refers to the electronic submission system known as the Prior Notice System Interface (PNSI), which is available at *http://www.access.fda.gov.*

This estimate is based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years.

As previously discussed, on May 30, 2013, we published a final rule that adopts, without change, the regulatory requirements established in the 2011 IFR, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country that has refused entry of that product. We estimate that it would take on average about one additional minute (0.016 hours) per entry for each respondent to submit prior notice with this additional piece of information. Accordingly, we have increased our estimate of the hours per response for prior notices received through ABI/ACS from 9 minutes, or 0.15 hours, per notice, to 10 minutes, or 0.167 hours, per notice. We have also increased our estimate of the hours per response for prior notices received through PNSI from 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice, to 23 minutes, or 0.384 hours, per notice.

We received 8,570,504 prior notices through ABI/ACS during 2010; 9,054,187 during 2011; and 9,716,147 during 2012. Based on this experience, we estimate that approximately 15,000 users of ABI/ACS will submit an average of 608 prior notices annually, for a total of 9,120,000 prior notices received annually through ABI/ACS. FDA estimates the reporting burden for a prior notice submitted through ABI/

ACS to be 10 minutes, or 0.167 hours, per notice, for a total burden of 1,523,040 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for our importer's entry notice, as previously discussed in this document.

We received 1,566,029 prior notices through PNSI during 2010; 1,498,609 during 2011; and 1,524,901 during 2012. Based on this experience, we estimate that approximately 26,667 registered users of PNSI will submit an average of 58 prior notices annually, for a total of 1,546,686 prior notices received annually. We estimate the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hours, per notice, for a total burden of 593,927 hours.

We received 4,488 cancellations of prior notices through ABI/ACS during 2010; 3,993 during 2011; and 3,812 during 2012. Based on this experience, we estimate that approximately 4,098 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 4,098 cancellations received annually through ABI/ACS. We estimate the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 1,024.5 hours, rounded to 1,025 hours.

We received 33,353 cancellations of prior notices through PNSI during 2010; 33,343 during 2011; and 32,592 during 2012. Based on this experience, we estimate that approximately 33,096 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 33,096 cancellations received annually. We estimate the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 8,274 hours.

We have not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (2010, 2011, and 2012); therefore, we estimate that one or fewer requests for review will be submitted annually. We estimate that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, we have estimated a total reporting burden of 8 hours.

We have not received any post-hold submissions under § 1.285(i) in the last 3 years (2010, 2011, and 2012); therefore, we estimate that one or fewer post-hold submissions will be submitted annually. We estimate that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, we have estimated a total reporting burden of 1 hour.

Dated: December 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30996 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1147]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 27, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0541. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (OMB Control Number 0910–0541)—Extension

As an integral part of its decisionmaking process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, we amended our regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, we no longer routinely require submission of information about the manufacturing and production of our regulated articles. We also have eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, we have provided guidance that contains sample formats to help the industry submit a claim of categorical exclusion or an EA to the Center for Food Safety and Applied Nutrition (CFSAN). The guidance document entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion, (2) what must a claim of categorical exclusion include by regulation, (3) what is an EA, (4) when is an EA required by regulation and what format should be used, (5) what are extraordinary circumstances, and (6) what suggestions does CFSAN have for preparing an EA? CFSAN encourages the industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the

efficiency of the review process. Although alternative approaches may be used, if these approaches satisfy the requirements of the applicable statutes and regulations. We are requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of October 28, 2013 (78 FR 64218), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. However, the comment was beyond the scope of the collection of information's four topics that are being solicited. Therefore, it will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part 25; Environmental impact considerations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 25.32(i)	42	1	42	1	42
§ 25.32(o)	1	1	1	1	1
§ 25.32(q)	2	1	2	1	2
Total					45

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the Agency has received in the past 3 years. Please note that in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested for each of these three categorical exclusions in this guidance is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30998 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1558]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information request regarding the guidance for industry and FDA staff entitled "Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products."

DATES: Submit either electronic or written comments on the collection of information by February 25, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the

validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information Request Regarding Guidance for Industry and FDA Staff on Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (OMB Control Number 0910–0673—Extension)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) authorizes FDA to establish the form for the submission of information related to substantial equivalence. In a Level 1 guidance document issued under the Good Guidances Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act sections	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
905(j)(1)(A)(i) and 910(a)	1,000	1	1,000	360	360,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA's expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j) and 910(a) of the FD&C Act (21 U.S.C. 387j(a)). FDA estimates that it will receive 1,000 section 905(j) reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 360,000 hours.

Dated: December 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30880 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Publication of a Draft of the Revised Guidebook for the National Practitioner Data Bank

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Publication of a Draft of the Revised Guidebook for the National Practitioner Data Bank.

SUMMARY: The National Practitioner Data Bank (NPDB) announces the release of a draft of the revised user Guidebook. The public is able to request a copy of the draft of the revised Guidebook and submit comments to the NPDB by the deadline below. The revised Guidebook includes expanded and improved reporting and querying examples; useful tables explaining Data Bank policies; and live links to statutes, regulations, and the Web site.

The NPDB is a confidential information clearinghouse created by Congress intended to facilitate a comprehensive review of the professional credentials of health care practitioners, health care entities, providers, and suppliers. The Guidebook is a policy manual that serves as an essential reference for Data Bank users to clarify legislative and regulatory requirements through the use of reporting and querying examples, explanations, definitions, and frequently asked questions (FAQs). The new Guidebook incorporates legislative and regulatory changes adopted since its last edition, including the merger of the NPDB with the Healthcare Integrity and Protection Data Bank. Once the comments have been reviewed, a final version of the revised Guidebook will be made available and will replace previous Guidebooks. For information on how to request a PDF copy of the draft Guidebook and instructions on how to submit comments, visit the NPDB Web site at: *http://www.npdb.hrsa.gov/news/news.jsp.*

DATES: Comments may be submitted through January 10, 2014. The comment period may be extended if needed. Information on any extensions of the review period will be posted on the Web site here: *http://www.npdb.hrsa.gov/news/news.jsp.*

FOR FURTHER INFORMATION CONTACT: Ernia P. Hughes, MBA, Acting Director of the Division of Practitioner Data Banks at: *NPDBPolicy@hrsa.gov* or 301–443–2300.

SUPPLEMENTARY INFORMATION: When submitting remarks, the NPDB requests that commenters:

- Reference the page number(s) each comment addresses; and
- Ensure comments are specific and relate to the clarity of the NPDB Guidebook's content, as regulatory or statutory concerns are beyond the scope of this comment process. Comments should be limited to content-based feedback that seeks to improve the examples and FAQs, clarify definitions, and eliminate ambiguity in the text. Comments that are not specific to content clarity and found beyond the scope of this review will not be addressed in this process.

Dated: December 19, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–31119 Filed 12–26–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program Part C Early Intervention Services Grant Under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of Ryan White HIV/AIDS Program Part C Early Intervention Services One-Time Noncompetitive Award To Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for persons living with HIV/AIDS, HRSA will provide a one-time noncompetitive Ryan White HIV/AIDS Program Part C award to Our Lady of the Lake Regional Medical Center, Inc. (OLOL), Baton Rouge, Louisiana.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is $348,111.

Authority: Section 2651 of the Public Health Service (PHS) Act, 42 U.S.C. 300ff–51. CFDA Number: 93.918.

Project period: The period of support for this award is 13 months, explained below in further detail.

Justification for the Exception to Competition: The Louisiana State University Health Sciences Center—Earl K. Long Medical Center (Grant Number: H76HA00591) announced the relinquishment of their Part C grant effective April 15, 2013. To prevent a lapse in HIV medical care, grant funds of $348,111 are to be awarded to OLOL to provide interim HIV medical care. The $348,111 represents the balance of the fiscal year 2013 award to cover HIV primary medical care services until April 30, 2014. The service area will be competed under HRSA–14–059 with a program start date of May 1, 2014.

FOR FURTHER INFORMATION CONTACT: John Fanning, Senior Policy Advisor, Division of Community HIV/AIDS Programs/HAB, HRSA, 5600 Fishers Lane, Rockville, MD 20857, by email at *jfanning@hrsa.gov*, or by phone at (301) 443–8367.

Dated: December 23, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–31120 Filed 12–26–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indian Health Professions Preparatory, Indian Health Professions Pre-graduate and Indian Health Professions Scholarship Programs

Announcement Type: Initial.

CFDA Numbers: 93.971, 93.123, AND 93.972

Key Dates

Application Deadline: February 28, 2014, for continuing students.

Application Deadline: March 28, 2014, for new students.

Application Review: May 5–16, 2014.

Continuation Award Notification Deadline: June 6, 2014.

New Award Notification Deadline: July 3, 2014.

Award Start Date: August 1, 2014.

Acceptance/Decline of Awards Deadline: August 1, 2014.

I. Funding Opportunity Description

The Indian Health Service (IHS) is committed to encouraging American Indians and Alaska Natives to enter the health professions and to assuring the availability of Indian health professionals to serve Indians. The IHS is committed to the recruitment of students for the following programs:

- The Indian Health Professions Preparatory Scholarship authorized by Section 103 of the Indian Health Care Improvement Act, Public Law 94–437 (1976), as amended (IHCIA), codified at 25 U.S.C. 1613(b)(1).
- The Indian Health Professions Pre-graduate Scholarship authorized by Section 103 of the IHCIA, codified at 25 U.S.C. 1613(b)(2).
- The Indian Health Professions Scholarship authorized by Section 104 of the IHCIA, codified at 25 U.S.C. 1613a.

Full-time and part-time scholarships will be funded for each of the three scholarship programs.

The scholarship award selections and funding are subject to availability of funds appropriated for the Scholarship Program.

II. Award Information

Type of Award

Scholarship.

Estimated Funds Available

An estimated $13.2 million will be available for Fiscal Year (FY) 2014 awards. The IHS Scholarship Program (IHSSP) anticipates, but cannot guarantee, due to possible funding changes, student scholarship selections from any or all of the following disciplines in the Preparatory, Pre-graduate or Health Professions Scholarship Programs for the Scholarship Period 2014–2015. Due to the rising cost of education and the decreasing number of scholars who can be funded by the IHSSP, the IHSSP has changed the funding policy for Preparatory and Pre-graduate scholarship awards and reallocated a greater percentage of its funding in an effort to increase the number of Health Professions scholarships, and inherently the number of service-obligated scholars, to better meet the health care needs of the IHS and its Tribal and Urban Indian health care system partners.

Anticipated Number of Awards

Approximately 45 awards will be made under the Health Professions Preparatory and Pre-graduate Scholarship Programs for Indians. The awards are for ten months in duration, with an additional two months for approved summer school requests, and will cover both tuition and fees and Other Related Costs (ORC). The average award to a full-time student is approximately $34,490.60. An estimated 276 awards will be made under the Indian Health Professions Scholarship Program. The awards are for 12 months in duration and will cover both tuition and fees and ORC. The average award to a full-time student is approximately $42,432.70. In FY 2014, an estimated $11,700,000 is available for Health Professions awards, and an estimated $1,500,000 is available for Preparatory and Pre-graduate awards.

Project Period

The project period for the IHS Health Professions Preparatory Scholarship support, tuition, fees and ORC is limited to two years for full-time students and the part-time equivalent of two years, not to exceed four years for part-time students. The project period for the Health Professions Pre-graduate Scholarship support, tuition, fees and ORC is limited to four years for full-time students and the part-time equivalent of four years, not to exceed eight years for part-time students. The IHS Indian Health Professions Scholarship provides support for tuition, fees, and ORC and is limited to four years for full-time students and the part-time equivalent of four years, not to exceed eight years for part-time students.

III. Eligibility Information

This is a limited competition announcement. New and Continuation

scholarship awards are limited to "Indians" as defined at 25 U.S.C. Section 1603(13). **Note:** The definition of "Indians" for Section 103 Preparatory and Pre-graduate scholarships is broader than the definition of "Indians" for the Section 104 Health Professions scholarship, as specified below. Continuation awards are non-competitive.

1. Eligibility

The Health Professions Preparatory Scholarship awards are made to American Indians. (Federally recognized Tribal members, including those from Tribes terminated since 1940, first and second degree descendants of Federally recognized Tribal members. State recognized Tribal members and first and second degree descendants of State recognized Tribal members), or Eskimo, Aleut and other Alaska Natives who:

- Have successfully completed high school education or high school equivalency; and
- Have been accepted for enrollment in a compensatory, pre-professional general education course or curriculum

The Health Pre-graduate Scholarship awards are made to American Indians (Federally recognized Tribal members, including those from Tribes terminated since 1940, first and second degree descendants of Tribal members, and State recognized Tribal members, first and second degree descendants of Tribal members), or Eskimo, Aleut and other Alaska Natives who:

- Have successfully completed high school education or high school equivalency; and
- Have been accepted for enrollment or are enrolled in an accredited pre-graduate program leading to a baccalaureate degree in pre-medicine, pre-dentistry, pre-optometry or pre-podiatry.

The Indian Health Professions Scholarship may be awarded only to an individual who is a member of a Federally recognized Indian Tribe, Eskimo, Aleut or other Alaska Native as provided by Section 1603(13) of the IHCIA. Membership in a Tribe recognized only by a State does not meet this statutory requirement. To receive an Indian Health Professions Scholarship, an otherwise eligible individual must be enrolled in an appropriately accredited school and pursuing a course of study in a health profession as defined by Section 1603(10) of the IHCIA.

2. Cost Sharing/Matching

The Scholarship Program does not require matching funds or cost sharing to participate in the competitive grant process.

3. Benefits from State, Local, Tribal and Other Federal Sources

Awardees of the Health Professions Preparatory scholarship, Health Professions Pre- Graduate scholarship, or Health Professions scholarship, who accept outside funding from other scholarship, grant and fee waiver programs, will have these monies applied to their student account tuition and fees charges at the college or university they are attending, before the IHS Scholarship Program will pay any of the remaining balance, unless said outside scholarship, grant or fee waiver award letter specifically excludes use for tuition and fees. These outside funding sources must be reported on the student's invoicing documents submitted by the college or university they are attending. Student loans and Veterans Administration (VA)/GI Bill Benefits accepted by Health Professions scholarship recipients will have no effect on the IHSSP payment made to their college or university.

IV. Application Submission Information

1. Electronic Application System and Application Handbook Instructions and Forms

Applicants must go online to *www.ihs.gov/scholarship* to apply for an IHS scholarship and access the Application Handbook instructions and forms for submitting a properly completed application for review and funding consideration. Applicants are strongly encouraged to seek consultation from their Area Scholarship Coordinator (ASC) in preparing their scholarship application for award consideration. ASC's are listed on the IHS Web site at: *http://www.scholarship.ihs.gov/area_coordinators.cfm.*

This information is listed below. Please review the following list to identify the appropriate IHS Area Scholarship Coordinator for your State.

IHS area office and states/locality served	Scholarship coordinator address
Aberdeen Area IHS	
Nebraska	IHS Area Scholarship Coordinator, Ms. Kim Annis, Aberdeen Area IHS, 115 4th Avenue SE., Aberdeen, SD 57401, Tele: (605) 226–7466.
Iowa.	
North Dakota.	
South Dakota.	
Alaska Native Tribal Health Consortium	
Alaska	Ms. Sandy Stearns, IHS Area Scholarship Coordinator, Alaska Native Tribal Consortium, 4000 Ambassador Drive, Anchorage, AK 99508, Tele: (907) 729–3035, 1–800–684–8361 (toll free). Ms. Tasha Hotch, Alaska Native Tribal Consortium, 4000 Ambassador Drive, Anchorage, AK 99508, Tele: (907) 729–1913, 1–800–684–8361 (toll free).
Albuquerque Area IHS	
Colorado	Ms. Cora Boone, IHS Area Scholarship Coordinator, Albuquerque Area IHS, 5300 Homestead Road NE., Albuquerque, NM 87110, Tele: (505) 248–4418, 1–800–382–3027 (toll free).
New Mexico.	
Bemidji Area IHS	
Illinois	Mr. Tony Buckanaga, IHS Area Scholarship Coordinator, Bemidji Area IHS, 522 Minnesota Avenue NW., Room 209, Bemidji, MN 56601, Tele: (218) 444–0486, 1–800–892–3079 (toll free).
Indiana.	
Michigan.	
Minnesota.	
Wisconsin.	
Billings Area IHS	

IHS area office and states/locality served	Scholarship coordinator address
Montana	Mr. Delon Rock Above, Alternate: Ms. Bernice Hugs, IHS Area Scholarship Coordinator, Billings Area IHS, Area Personnel Office, P.O. Box 36600, 2900 4th Avenue, North, Suite 400, Billings, MT 59103, Tele: (406) 247–7215.
Wyoming.	
California Area IHS	
California	Ms. Mona Celli, IHS Area Scholarship Coordinator, California Area IHS, 650 Capitol Mall, Suite 7–100, Sacramento, CA 95814, Tele: (505) 248–4418.
Nashville Area IHS	
Alabama	Ms. Marla Jones, IHS Area Scholarship Coordinator, Nashville Area IHS, 711 Stewarts Ferry Pike, Nashville, TN 37214, Tele: (615) 467–1576.
Arkansas.	
Connecticut.	
Delaware.	
Florida.	
Georgia.	
Kentucky.	
Louisiana.	
Maine.	
Maryland.	
Massachusetts.	
Mississippi.	
New Hampshire.	
New Jersey.	
New York.	
North Carolina.	
Ohio.	
Pennsylvania.	
Rhode Island.	
South Carolina.	
Tennessee.	
Vermont.	
Virginia.	
West Virginia.	
District of Columbia.	
Navajo Area IHS	
Arizona	Ms. Aletha John, IHS Area Scholarship Coordinator, Navajo Area IHS, P.O. Box 9020, Window Rock, AZ 86515, Tele: (928) 871–1360.
New Mexico.	
Utah.	
Oklahoma City Area IHS	
Kansas	Mr. Keith Bohanan, IHS Area Scholarship Coordinator, Oklahoma City Area IHS, 701 Market Drive, Oklahoma City, OK 73114, Tele: (405) 951–3789, 1–800–722–3357 (toll free).
Missouri.	
Oklahoma.	
Phoenix Area IHS	
Arizona	Ms. Trudy Begay, IHS Area Scholarship Coordinator, Phoenix Area IHS, Suite 510, 40 North Central Avenue, Phoenix, AZ 85004, Tele: (602) 364–5256.
Nevada.	
Utah.	
Portland Area IHS	
Idaho	Mr. Wayne Teeias, IHS Area Scholarship Coordinator, Portland Area IHS, 1414 NW Northrup Street, Suite 800, Portland, OR 97209, Tele: (503) 414–5546.
Oregon.	
Washington.	
Tucson Area IHS	
Arizona	Ms. Trudy Begay, (See Phoenix Area).
Texas.	

2. Content and Form Submission

Each applicant will be responsible for entering their basic applicant account information online, in addition to submitting a completed, original signature hard copy and one copy set of application documents, in accordance with the IHS Scholarship Program Application Handbook instructions, to the: IHS Scholarship Program Branch Office, 801 Thompson Avenue, TMP 450A, Rockville, MD 20852. Applicants must initiate an application through the on-line portal or their applications will be considered incomplete. For more information on how to use the on-line portal, go to *www.ihs.gov/scholarship*. The portal will be open on December 1, 2013. The application will be considered complete if the following documents (original and one copy) are included:

- Completed and signed online Application Checklist.
- Completed, printed, and signed IHSSP online application form for new or continuation student.
- Current Letter of Acceptance from College/University or Proof of Application to a College/University or Health Professions Program.
- One set of Official transcripts for all colleges/universities attended (or high school transcripts or Certificate of

Completion of Home School Program or General Education Diploma (G.E.D.) for applicants who have not taken college courses).

• Cumulative Grade Point Average (GPA): Calculated by the applicant.

• Applicant's Documents for Indian Eligibility.

A. If you are a member of a Federally recognized Tribe or Alaska Native (recognized by the Secretary of the Interior), provide evidence of membership such as:

(1) Certification of Tribal enrollment by the Secretary of the Interior, acting through the Bureau of Indian Affairs (BIA) Certification: Form 4432—Category A or D, whichever is applicable); or

(2) In the absence of BIA certification, documentation that you meet requirements of Tribal membership as prescribed by the charter, articles of incorporation or other legal instrument of the Tribe and have been officially designated as a Tribal member as evidenced by an accompanying document signed by an authorized Tribal official, i.e., Tribal enrollment card showing enrollment number; or

(3) Other evidence of Tribal membership satisfactory to the Secretary of the Interior.

Note: If you meet the criteria of B or C, you are eligible only for the Preparatory or Pre-graduate Scholarships.

B. For Preparatory or Pre-graduate Scholarships, only: If you are a member of a Tribe terminated since 1940 or a State recognized Tribe and first or second degree descendant, provide official documentation that you meet the requirements of Tribal membership as prescribed by the charter, articles of incorporation or other legal instrument of the Tribe and have been officially designated as a Tribal member as evidenced by an accompanying document signed by an authorized Tribal official; or other evidence, satisfactory to the Secretary of the Interior, that you are a member of the Tribe. In addition, if the terminated or state recognized Tribe of which you are a member is not on a list of such Tribes published by the Secretary of the Interior in the Federal Register, you must submit an official signed document that the Tribe has been terminated since 1940 or is recognized by the state in which the Tribe is located in accordance with the law of that state.

C. For Preparatory or Pre-graduate Scholarships, only: If you are not a Tribal member, but are a natural child or grandchild of a Tribal member you must submit: (1) evidence of that fact, e.g., your birth certificate and/or your parent's/grandparent's birth/death certificate showing the name of the Tribal member; and (2) evidence of your parent's or grandparent's Tribal membership in accordance with paragraphs A and B. The relationship to the Tribal member must be clearly documented. Failure to submit the required documentation will result in the application not being accepted for review.

• Two Faculty/Employer Evaluations with original signature.

• Online Narratives—Reasons for Requesting the Scholarship.

• Delinquent Debt Form.

• Course Curriculum Verification with original signature.

• Curriculum for Major.

3. Submission Dates

Application Receipt Date: The online Continuation Application submission deadline for *Continuation* applicants is Friday, February 28, 2014. Required application support documents will be accepted through Friday, March 28, 2014.

Application Receipt Date: New applicants must print and sign their online application and Checklist and submit it with their supporting documents by the postal deadline of Friday, March 28, 2014. No supporting documents will be accepted after this date, except final Letters of Acceptance, which must be submitted no later than Friday, May 30, 2014.

Applications and supporting documents (original and one copy) shall be considered as meeting the deadline if they are received by the IHSSP Branch Office, postmarked on or before the deadline date. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing and will not be considered for funding.

New and Continuation applicants may check the status of their application receipt and processing by logging into their online account at www.ihs.gov/scholarship. Applications received with postmarks after the announced deadline date will not be considered for funding.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

No more than 5% of available funds will be used for part-time scholarships this fiscal year. Students are considered part-time if they are enrolled for a minimum of six hours of instruction and are not considered in full-time status by their college/university. Documentation must be received from part-time applicants that their school and course curriculum allows less than full-time status. Both part-time and full-time scholarship awards will be made in accordance with 42 CFR Subpart J, Subdivisions J–3, J–4, and J–8 and this information will be published in all IHSSP Application and Student Handbooks as they pertain to the IHSSP.

6. Other Submissions Requirements

New and Continuation applicants are responsible for using the online application system. See section 3. Submission Dates for application deadlines.

V. Application Review Information

1. Criteria

Applications will be reviewed and scored with the following criteria.

• Academic Performance (40 Points)

Applicants are rated according to their academic performance as evidenced by transcripts and faculty evaluations. In cases where a particular applicant's school has a policy not to rank students academically, faculty members are asked to provide a personal judgment of the applicant's achievement. Preparatory, Pre-graduate and Health Professions applicants with a cumulative GPA below 2.0 are not eligible for award.

• Faculty/Employer Recommendations (30 Points)

Applicants are rated according to evaluations by faculty members, current and/or former employers and Tribal officials regarding the applicant's potential in the chosen health related professions.

• Stated Reasons for Asking for the Scholarship and Stated Career Goals Related to the Needs of the IHS (30 Points)

Applicants must provide a brief written explanation of reasons for asking for the scholarship and of their career goals. Applicants are considered for scholarship awards based on their desired career goals and how these goals relate to current Indian health personnel needs.

The applicant's narrative will be judged on how well it is written and its content.

Applications for each health career category are reviewed and ranked separately.

• Applicants who are closest to graduation or completion of training are awarded first. For example, senior and junior applicants under the Health Professions Pre-graduate Scholarship receive funding before freshmen and sophomores.

• Priority Categories

The following is a list of health professions that will be considered for funding in each scholarship program in FY 2014.

○ Indian Health Professions Preparatory Scholarships

A. Pre-Clinical Psychology (Jr. and Sr. undergraduate years only).
B. Pre-Nursing.
C. Pre-Pharmacy.
D. Pre-Social Work (Jr. and Sr. preparing for an MS in social work).

○ Indian Health Professions Pre-Graduate Scholarships

A. Pre-Dentistry.
B. Pre-Medicine.
C. Pre-Optometry.
D. Pre-Podiatry.

○ Indian Health Professionals Scholarship

A. Bio Medical Engineering—BS. (Jr. and Sr. undergraduate years only).
B. Bio Medical Technology—AAS.
C. Chemical Dependency Counseling—Master's Degrees.
D. Clinical Psychology—Ph.D. or Psy.D.
E. Coding Specialist—AAS degree.
F. Dentistry: DDS or DMD degrees.
G. Diagnostic Radiology Technology: Associates and B.S.
H. Environmental Health/Sanitarian: B.S. (Jr. and Sr. undergraduate years only).
I. Health Records Administration: R.H.I.T. (A.A.S.) and R.H.I.A (B.S.).
J. Medical Technology: B.S. (Jr. and Sr. undergraduate years only).
K. Medicine: Allopathic and Osteopathic.
L. Nurse: Associate and Bachelor Degrees and advanced degrees in Psychiatry, Geriatric, Women's Health, Pediatric Nursing, Midwifery, Nurse Anesthetist, and Nurse Practitioner. (Priority consideration will be given to Registered Nurses employed by the IHS; in a program conducted under a contract or compact entered into under the Indian Self-Determination Act and Education Assistance Act (Pub. L. 93–638) and its amendments; or in a program assisted under Title V of the IHCIA).
M. Optometry: O.D.
N. Pharmacy: Pharm.D.
O. Physician Assistant: PA–C.
P. Physical Therapy: M.S. and D.P.T.
Q. Podiatry: D.P.M.
R. Public Health Nutritionist: M.S.
S. Respiratory Therapy: B.S. Degree.
T. Social Work: Masters Level only (Direct Practice and Clinical concentrations).
U. Ultrasonography (Prerequisite: Diagnostic Radiology Technology degree/certificate).

2. Review and Selection Process

The applications will be reviewed and scored by the IHS Scholarship Program's Application Review Committee appointed by the IHS. Reviewers will not be allowed to review an application from his/her Area or his/her own Tribe. Each application will be reviewed by three reviewers. The average score of the three reviews provides the final Ranking Score for each applicant. To determine the ranking of each applicant, these scores are sorted from the highest to the lowest within each scholarship health discipline by date of graduation and score. If several students have the same date of graduation and score within the same discipline, computer ranking list will randomly sort and will not be sorted by alphabetical name. Selections are then made from the top of each ranking list to the extent that funds allocated by the IHS among the three scholarships are available for obligation.

VI. Award Administration Information

1. Award Notices

It is anticipated that recipients applying for extension of their scholarship funding will be notified in writing during the first week of June 2014 and new applicants will be notified in writing during the first week of July 2014. An Award Letter will be issued to successful applicants. Unsuccessful applicants will be notified in writing, which will include a brief explanation of the reason(s) the application was not successful and provide the name of the IHS official to contact if more information is desired.

2. Administrative and National Policy Requirements

Regulations at 42 CFR § 136.304 provide that the IHS shall, from time to time, publish a list of allied health professions eligible for consideration for the award of IHS Indian Health Professions Preparatory and Pre-graduate Scholarships and IHS Health Professions Scholarship. Section 104(b)(1) of the IHCIA, 25 U.S.C. 1613a(b)(1), authorizes the IHS to determine the distribution of scholarships among the health professions.

Awards for the Indian Health Professions Scholarships will be made in accordance 42 CFR 136.330–136.334. Awardees shall incur a service obligation prescribed under the IHCIA, Section 1613a(b), which shall be met by service, through full-time clinical practice:

(1) In the IHS;

(2) In a program conducted under a contract or compact entered into under the Indian Self-Determination Act and Education Assistance Act (Pub. L. 93–638) and its amendments;

(3) In a program assisted under Title V of the Indian Health Care Improvement Act (Pub. L. 94–437) and its amendments; or

(4) In a private practice option of his or her profession if the practice (a) is situated in a health professional shortage area, designated in regulations promulgated by the Secretary of Health and Human Services (Secretary) and (b) addresses the health care needs of a substantial number (75% of the total served) of Indians as determined by the Secretary in accordance with guidelines of the Service.

Pursuant to the IHCIA Section 1613a(b)(3)(C), an awardee of an IHS Health Professions Scholarship may, at the election of the awardee, meet his/her service obligation prescribed under IHCIA Section 1613a(b) by a program specified in options (1)–(4) above that:

(i) Is located on the reservation of the Tribe in which the awardee is enrolled; or

(ii) Serves the Tribe in which the awardee is enrolled, if there is an open vacancy available in the discipline for which the awardee was funded under the IHS Health Professions Scholarship during the required 90-day placement period.

In summary, all awardees of the Indian Health Professions Scholarship are reminded that acceptance of this scholarship will result in a service obligation required by both statute and contract, which must be performed, through full-time clinical practice, at an approved service payback facility. The Acting Director reserves the right to make final decisions regarding assignment of scholarship recipients to fulfill their service obligation.

Moreover, the Acting Director, IHS, has the authority to make the final determination, designating a facility, whether managed and operated by IHS, or one of its Tribal or Urban Indian partners, consistent with IHCIA, as approved for scholar obligated service payback.

3. Reporting

Scholarship Program Minimum Academic Requirements

It is the policy of the IHS that a scholarship awardee funded under the Health Professions Scholarship Program of the Indian Health Care Improvement Act must maintain a 2.0 cumulative GPA, remain in good academic standing each semester/trimester/quarter, maintain full-time student status (Institutional definition of 'minimum hours' constituting full-time enrollment applies) or part-time student status (Institutional definition of 'minimum and maximum' hours constituting part-time enrollment applies) for the entire academic year, as indicated on the scholarship application submitted for that academic year. The Health Professions awardee may not change his or her enrollment status between terms of enrollment, during the same academic year. New recipients may not request a Leave of Absence during the first year of their funding. In addition to these requirements, a Health Professions Scholarship awardee must be enrolled in an approved/accredited school for a Health Professions degree.

An awardee of a scholarship under the IHS Health Professions Preparatory and Health Professions Pre-Graduate Scholarship authority must maintain a minimum 2.0 cumulative GPA, remain in good standing each semester/trimester/quarter and be a full-time student (Institutional definition of 'minimum hours' constituting full-time enrollment applies, typically 12 credit hours per semester) or a part-time student (Institutional definition of 'minimum and maximum' hours constituting part-time enrollment applies, typically 6–11 credit hours). The Preparatory and Pre-graduate awardee may not change from part-time status to full-time status or vice versa in the same academic year. New recipients may not request a Leave of Absence during the first year of their funding.

The following reports must be sent to the IHSSP at the identified time frame. Each scholarship awardee will have access to an online Recipient Handbook and required program forms and instructions on when, how, and to whom these must be submitted, by logging into the IHSSP Web site at *www.ihs.gov/scholarship*. If a scholarship awardee fails to submit these forms and reports as required, they will be ineligible for continuation of scholarship support and scholarship award payments will be discontinued.

A. Recipient's Enrollment and Initial Progress Report

Within thirty (30) days from the beginning of each semester/trimester/quarter, scholarship awardees must submit a Recipient's Enrollment and Initial Progress Report (Form IHS–856–8; page 69 of the Student Handbook).

B. Transcripts

Within thirty (30) days from the end of each academic period, i.e., semester/trimester/quarter, or summer session, scholarship awardees must submit an Official Transcript showing the results of the classes taken during that period.

C. Notification of Academic Problem/Change

If at any time during the semester/trimester/quarter, scholarship awardees are advised to reduce the number of credit hours for which they are enrolled below the minimum of the 12 (or the number of hours considered by their school as full-time) for a full-time student or at least six hours for part-time students; or if they experience academic problems, they must submit this report (Form IHS–856–9, page 71 of the Student Handbook).

D. Change of Status

- Change of Academic Status

Scholarship awardees must immediately notify their Scholarship Program Analyst if they are placed on academic probation, dismissed from school, or voluntarily withdraw for any reason (personal or medical).

- Change of Health Discipline

Scholarship awardees may not change from the approved IHSSP health discipline during the school year. If an unapproved change is made, scholarship payments will be discontinued.

- Change in Graduation Date

Any time that a change occurs in a scholarship awardee's expected graduation date, they must notify their Scholarship Program Analyst immediately in writing. Justification must be attached from the school advisor.

VII. Agency Contacts

1. Questions on the application process may be directed to the appropriate IHS Area Scholarship Coordinator.

2. Questions on other programmatic matters may be addressed to: Dr. Dawn A. Kelly, Chief, Scholarship Program, 801 Thompson Avenue, TMP 450A, Rockville, Maryland 20852, Telephone: (301) 443–6197 (This is not a toll-free number).

3. Questions on payment information may be directed to: Mr. Craig Boswell, Grants Scholarship Coordinator, Division of Grants Management, Indian Health Service, 801 Thompson Avenue, TMP 360, Rockville, Maryland 20852, Telephone: (301) 443–0243 (This is not a toll-free number).

VIII. Other Information

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2020*, a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Education and Community-Based Programs. Potential applicants may download a copy of *Healthy People 2020* from *http://www.healthypeople.gov*.

Interested individuals are reminded that the list of eligible health and allied professions is effective for applicants for the 2014–2015 academic year. These priorities will remain in effect until superseded. Applicants who apply for health career categories not listed as priorities during the current scholarship cycle will not be considered for a scholarship award.

Dated: December 13, 2013.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2013–31076 Filed 12–26–13; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Overflow: Virology B.

Date: December 20, 2013.

Time: 2:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: John C Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 23, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–31051 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the NCI-Frederick Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: NCI-Frederick Advisory Committee.
Date: February 4, 2014.
Time: 9:00 a.m. to 12:00 p.m.
Agenda: Ongoing and New Activities at the Frederick National Laboratory for Cancer Research.
Place: National Institutes of Health, 45 Center Drive, Natcher Building; Conference Room E1/E2, Bethesda, MD 20892.
Contact Person: Thomas M. Vollberg, Sr., Ph.D., Executive Secretary, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 7W–102, Bethesda, MD 20892, 240–276–6341, *vollbert@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/fac/fac.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–30890 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, December 11, 2013, 08:30 a.m., National Institutes of Health, Two Democracy Plaza, Suite 951, 6707 Democracy Boulevard, Bethesda, MD 20892, which was published in the **Federal Register** on August 29, 2013, 78 FR 64506.

The meeting notice is amended to change the date and time from December 11, 2013, 08:30 a.m.–05:00 p.m., to January 9, 2014, 08:00 a.m.–08:00 p.m. The meeting is closed to the public.

Dated: December 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–30892 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the AIDS Research Advisory Committee, NIAID.

The meetings will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: AIDS Research Advisory Committee, NIAID.
Date: *January 27, 2014.
Time: 1:00 p.m. to 5:00 p.m.
Agenda: Reports from the Division Director and other staff.
Place: National Institutes of Health, Natcher Building, Conference Rooms E1/E2, 45 Center Drive, Bethesda, MD 20892.
Contact Person: Mark A. Mueller, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, Bethesda, MD 20892. 301–402–2308, *mark.mueller@nih.gov*.

Name of Committee: AIDS Research Advisory Committee, NIAID.
Date: June 2 2014.
Time: 1:00 p.m. to 5:00 p.m.
Agenda: Reports from the Division Director and other staff.
Place: National Institutes of Health, Natcher Building, Conference Rooms E1/E2, 45 Center Drive, Bethesda, MD 20892.
Contact Person: Mark A. Mueller, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, Bethesda, MD 20892. 301–402–2308, *mark.mueller@nih.gov*.

Name of Committee: AIDS Research Advisory Committee, NIAID.
Date: September 15, 2014.
Time: 1:00 p.m. to 5:00 p.m.
Agenda: Reports from the Division Director and other staff.
Place: National Institutes of Health, Natcher Building, Conference Rooms E1/E2, 45 Center Drive, Bethesda, MD 20892.
Contact Person: Mark A. Mueller, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, Bethesda, MD 20892. 301–402–2308, *mark.mueller@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance

onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and ransplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–31048 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bacterial Transcription and Regulation.

Date: January 3, 2014.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Dominique Lorang-Leins, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5108, MSC 7766, Bethesda, MD 20892, 301.326.9721, *Lorangd@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–30891 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NINDS Clinical Trial Methods Course.

Date: January 9, 2014.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ernest W Lyons, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS, NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, *lyonse@ninds.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: December 23, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–31052 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Council of Councils.

Open: January 31, 2014.

Time: 9:45 a.m. to 12:00 p.m.

Agenda: Council Business Matters and Updates; NIH Update.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Closed: January 31, 2014.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Open: January 31, 2014.

Time: 1:00 p.m. to 4:40 p.m.

Agenda: Updates on Phase 2 Common Fund Planning. Report from Common Fund Science of Behavior Change Program. Update on Common Fund Planning and Management Working Group.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Contact Person: Franziska Grieder, DVM, Ph.D., Executive Secretary, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, 301–435–0744.

Any interested person may file written comments with the committee by forwarding

the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda will be posted before the meeting date

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: December 23, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–31053 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34) and Clinical Trial Implementation Cooperative Agreement (U01).

Date: January 14, 2014.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications

Place: National Institutes of Health, 6700–B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Quirijn Vos, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–451–2666, *qvos@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–31049 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS and AIDS Related Research.

Date: January 6, 2014.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Cellular Neurosciences.

Date: January 6, 2014.

Time: 3:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter B Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS and AIDS Related Research.

Date: January 7–8, 2014.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS and AIDS Related Research.

Date: January 8–9, 2014.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Cell Biology.

Date: January 14, 2014.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rass M Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 23, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–31050 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR: Genetic and Genomic Analysis of Xenopus (R01).

Date: January 8, 2014.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Genetics and Genomics.

Date: January 24, 2014.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group Psychosocial Risk and Disease Prevention Study Section.

Date: January 30–31, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Stacey FitzSimmons, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, 301–451–9956, *fitzsimmonss@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group Social Sciences and Population Studies A Study Section.

Date: January 30, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Long Beach, 500 East First Street, Long Beach, CA 90802.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group Molecular Genetics B Study Section.

Date: January 30–31, 2014.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Richard A Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–31047 Filed 12–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Access to Recovery (ATR) Program (OMB No. 0930–0266)—Extension

The Center for Substance Abuse Treatment (CSAT) is charged with the Access to Recovery (ATR) program which will allow grantees (States, Territories, the District of Columbia and Tribal Organizations) a means to implement voucher programs for substance abuse clinical treatment and recovery support services. The ATR program is part of a Presidential initiative to: (1) Provide client choice among substance abuse clinical treatment and recovery support service providers, (2) expand access to a comprehensive array of clinical treatment and recovery support options (including faith-based programmatic options), and (3) increase substance abuse treatment capacity. Monitoring outcomes, tracking costs, and preventing waste, fraud and abuse to ensure accountability and effectiveness in the use of Federal funds are also important elements of the ATR program. Grantees, as a contingency of their

award, are responsible for collecting Voucher Information (VI) and Voucher Transaction (VT) data from their clients.

The primary purpose of this data collection activity is to meet the reporting requirements of the Government Performance and Results Act (GPRA) by allowing SAMHSA to quantify the effects and accomplishments of SAMHSA programs. The following table is an estimated annual response burden for this effort.

ESTIMATES OF ANNUALIZED HOUR BURDEN [1]

Center/form/respondent type	Number of respondent	Responses per respondent	Total responses	Hours per response	Total hour burden	Total wage cost	Total hour Cost/respondent [1]
Voucher information and transaction	53,333	1.5	80,000	.03	2,400	$18.40	$44,160

[1] This table represents the maximum additional burden if adult respondents for ATR provide responses/data at an estimated hourly wage (from 2010 Bureau of Labor Statistics).

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received by February 25, 2014.

Summer King,

Statistician.

[FR Doc. 2013–30990 Filed 12–26–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Voluntary Customer Satisfaction Surveys to Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0197)—Extension

Executive Order 12862 directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and Web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of Respondents	Responses/ Respondent	Hours/ Response	Total hours
Focus groups	250	1	2.50	625
Self-administered, mail, telephone and e-mail surveys	89,750	1	.250	22,438
Total	90,000			23,063

Written comments and recommendations concerning the proposed information collection should be sent by January 27, 2014 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–7285.

Summer King,

Statistician.

[FR Doc. 2013–30983 Filed 12–26–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: New or modified Base (1% annual-chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard

Area (SFHA) boundaries or zone designations, and/or the regulatory floodway (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard determinations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

These new or modified flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

These new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Alabama: Jefferson, (FEMA Docket No.:, B–1328).	City of Leeds, (12–04–8094P).	The Honorable David Miller, Mayor, City of Leeds, 1040 Park Drive, Leeds, AL 35094.	City Hall, 100 9th Street, Southeast, Leeds, AL 35094.	August 5, 2013	010125
Arizona:					
Maricopa, (FEMA Docket No.:, B–1328).	City of Glendale, (12–09–3189P).	The Honorable Jerry Weiers, Mayor, City of Glendale, 5850 West Glendale Avenue, Glendale, AZ 85301.	City Hall, 5850 West Glendale Avenue, Glendale, AZ 85301.	August 2, 2013	040045
Maricopa, (FEMA Docket No.:, B–1328).	City of Glendale, (13–09–0598P).	The Honorable Jerry Weiers, Mayor, City of Glendale, 5850 West Glendale Avenue, Glendale, AZ 85301.	City Hall, 5850 West Glendale Avenue, Glendale, AZ 85301.	August 9, 2013	040045
Maricopa, (FEMA Docket No.:, B–1328).	City of Peoria, (12–09–2079P).	The Honorable Bob Barrett, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345.	City Hall, 8401 West Monroe Street, Peoria, AZ 85345.	July 12, 2013	040050
Maricopa, (FEMA Docket No.:, B–1328).	City of Phoenix, (13–09–0598P).	The Honorable Greg Stanton, Mayor, City of Phoenix, 200 West Washington Street, 11th Floor, Phoenix, AZ 85003.	Street Transportation Department, 200 West Washington Street, 5th Floor, Phoenix, AZ 85003.	August 9, 2013	040051
Maricopa, (FEMA Docket No.:, B–1328).	Unincorporated areas of Maricopa County, (12–09–3189P).	The Honorable Andy Kunasek, Chairman, Maricopa County Board of Supervisors, 301 West Jefferson, 10th Floor, Phoenix, AZ 85003.	Maricopa County Flood Control District, 2801 West Durango Street, Phoenix, AZ 85009.	August 2, 2013	040037
Maricopa, (FEMA Docket No.:, B–1328).	Unincorporated areas of Maricopa County, (13–09–0598P).	The Honorable Andy Kunasek, Chairman, Maricopa County Board of Supervisors, 301 West Jefferson, 10th Floor, Phoenix, AZ 85003.	Maricopa County Flood Control District, 2801 West Durango Street, Phoenix, AZ 85009.	August 9, 2013	040037
Yavapai, (FEMA Docket No.:, B–1335).	Town of Chino Valley, (13–09–1088P).	The Honorable Chris Marley, Mayor, Town of Chino Valley, P.O. Box 406, Chino Valley, AZ 86323.	Development Services Department, 1982 Voss Drive, Chino Valley, AZ 86323.	September 20, 2013	040094
Yuma, (FEMA Docket No.:, B–1328).	Unincorporated areas of Yuma County, (12–09–2329P).	The Honorable Gregory S. Ferguson, Chairman, Yuma County Board of Supervisors, 198 South Main Street, Yuma, AZ 85364.	Department of Development Services, 2351 West 26th Street, Yuma, AZ 85364.	August 9, 2013	040099
California:					
Los Angeles, (FEMA Docket No.:, B–1328).	City of Santa Clarita, (12–09–2819P).	The Honorable Bob Kellar, Mayor, City of Santa Clarita, 23920 Valencia Boulevard, Santa Clarita, CA 91355.	City Hall, Planning Department, 23920 Valencia Boulevard, Santa Clarita, CA 91355.	August 9, 2013	060729
Los Angeles, (FEMA Docket No.:, B–1320).	City of Santa Clarita, (13–09–0273P).	The Honorable Bob Kellar, Mayor, City of Santa Clarita, 23920 Valencia Boulevard, Santa Clarita, CA 91355.	City Hall, Planning Department, 23920 Valencia Boulevard, Santa Clarita, CA 91355.	July 12, 2013	060729

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
San Bernardino, (FEMA Docket No.:, B–1335).	City of Ontario, (13–09–0673P).	The Honorable Paul S. Leon, Mayor, City of Ontario, 303 East B Street, Ontario, CA 91764.	City Hall, Engineering Department, Public Counter, 303 East B Street, Ontario, CA 91764.	September 20, 2013	060278
San Bernardino, (FEMA Docket No.:, B–1320).	City of Rancho Cucamonga, (13–09–0388P).	The Honorable L. Dennis Michael, Mayor, City of Rancho Cucamonga, 10500 Civic Center Drive, Rancho Cucamonga, CA 91730.	Engineering Department, 10500 Civic Center Drive, Rancho Cucamonga, CA 91730.	July 15, 2013	060671
San Bernardino, (FEMA Docket No.:, B–1328).	City of Redlands, (12–09–0729P).	The Honorable Pete Aguilar, Mayor, City of Redlands, P.O. Box 3005, Redlands, CA 92373.	City Hall, 35 Cajon Street, Redlands, CA 92373.	August 2, 2013	060279
San Bernardino, (FEMA Docket No.:, B–1328).	City of San Bernardino, (12–09–0729P).	The Honorable Patrick J. Morris, Mayor, City of San Bernardino, 300 North D Street, 6th Floor, San Bernardino, CA 92418.	Water Department, 399 Chandler Place, San Bernardino, CA 92408.	August 2, 2013	060281
Sierra, (FEMA Docket No.:, B–1328).	Unincorporated areas of Sierra County, (13–09–0454P).	The Honorable Scott A. Schlefstein, Chairman, Sierra County Board of Supervisors, P.O. Drawer D, Downieville, CA 95936.	Sierra County Department of Planning, Sierra County Courthouse Annex, 101 Courthouse Square, Downieville, CA 95936.	August 16, 2013	060630
Ventura, (FEMA Docket No.:, B–1328).	City of Simi Valley, (13–09–1538P).	The Honorable Bob Huber, Mayor, City of Simi Valley, 2929 Tapo Canyon Road, Simi Valley, CA 93063.	City Hall, 2929 Tapo Canyon Road, Simi Valley, CA 93063.	August 16, 2013	060421
Colorado:					
Adams, (FEMA Docket No.:, B–1328).	City of Thornton, (13–08–0065P).	The Honorable Heidi Williams, Mayor, City of Thornton, 9500 Civic Center Drive, Thornton, CO 80229.	City Hall, 12450 Washington Street, Thornton, CO 80241.	July 26, 2013	080007
Boulder, (FEMA Docket No.:, B–1320).	City of Boulder, (13–08–0187P).	The Honorable Matthew Appelbaum, Mayor, City of Boulder, P.O. Box 791, Boulder, CO 80306.	Municipal Building Plaza, 1777 Broadway Street, Boulder, CO 80302.	July 12, 2013	080024
Boulder, (FEMA Docket No.:, B–1328).	Unincorporated areas of Boulder County, (13–08–0273P).	The Honorable Cindy Domenico, Chair, Boulder County Board of Commissioners, P.O. Box 471, Boulder, CO 80306.	Boulder County Transportation Department, 2525 13th Street, Suite 203, Boulder, CO 80306.	August 2, 2013	080023
Denver, (FEMA Docket No.:, B–1328).	City and County of Denver, (13–08–0098P).	The Honorable Michael B. Hancock, Mayor, City and County of Denver, 1437 Bannock Street, Suite 350, Denver, CO 80202.	Public Works Department, 201 West Colfax Avenue, Denver, CO 80202.	August 9, 2013	080046
Douglas, (FEMA Docket No.:, B–1328).	Unincorporated areas of Douglas County, (13–08–0136P).	The Honorable Jill Repella, Chair, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Douglas County Department of Public Works, Engineering Division, 100 3rd Street, Castle Rock, CO 80104.	August 9, 2013	080049
Douglas, (FEMA Docket No.:, B–1320).	Unincorporated areas of Douglas County, (13–08–0255P).	The Honorable Jill Repella, Chair, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Douglas County Public Works Department, Engineering Division, 100 3rd Street, Castle Rock, CO 80104.	July 12, 2013	080049
El Paso, (FEMA Docket No.:, B–1320).	City of Colorado Springs, (12–08–0531P).	The Honorable Steve Bach, Mayor, City of Colorado Springs, 30 South Nevada Avenue, Colorado Springs, CO 80903.	Planning Commission, 30 South Nevada Avenue, Colorado Springs, CO 80903.	July 12, 2013	080060
El Paso, (FEMA Docket No.:, B–1320).	Unincorporated areas of El Paso County, (12–08–0659P).	The Honorable Dennis Hisey, Chairman, El Paso County Board of Commissioners, 200 South Cascade Avenue, Suite 100, Colorado Springs, CO 80903.	Development Services Department, 2880 International Circle, Suite 110, Colorado Springs, CO 80910.	July 12, 2013	080059
Jefferson, (FEMA Docket No.:, B–1314).	Unincorporated areas Jefferson County, (13–08–0089P).	The Honorable Donald Rosier, Chairman, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Golden, CO 80419.	Jefferson County Department of Planning and Zoning, 100 Jefferson County Parkway, Golden, CO 80419.	May 31, 2013	080087
Jefferson, (FEMA Docket No.:, B–1320).	Unincorporated areas of Jefferson County, (13–08–0255P).	The Honorable Donald Rosier, Chairman, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Golden, CO 80419.	Jefferson County Department of Planning and Zoning, 100 Jefferson County Parkway, Golden, CO 80419.	July 12, 2013	080087
Summit, (FEMA Docket No.:, B–1320).	Town of Silverthorne, (13–08–0262P).	The Honorable Dave Koop, Mayor, Town of Silverthorne, P.O. Box 1309, Silverthorne, CO 80498.	Planning Commission, 601 Center Circle, Silverthorne, CO 80498.	July 22, 2013	080201
Summit, (FEMA Docket No.:, B–1320).	Unincorporated areas of Summit County, (13–08–0262P).	The Honorable Thomas C. Davidson, Chairman, Summit County Board of Commissioners, P.O. Box 68, Breckenridge, CO 80424.	Summit County Planning Department, 0037 Peak One Drive, Frisco, CO 80443.	July 22, 2013	080290
Florida:					
Lee, (FEMA Docket No.:, B–1328).	Unincorporated areas of Lee County, (12–04–4132P).	The Honorable Cecil L. Pendergrass, Chairman, Lee County Board of Commissioners, P.O. Box 398, Fort Myers, FL 33902.	Lee County Community Development Department, 1500 Monroe Street, 2nd Floor, Fort Myers, FL 33901.	August 16, 2013	125124
Miami-Dade, (FEMA Docket No.:, B–1320).	Unincorporated areas of Miami-Dade County, (12–04–5035P).	The Honorable Carlos A. Gimenez, Mayor, Miami-Dade County, Stephen P. Clark Center, 111 Northwest 1st Street, Miami, FL 33128.	Miami-Dade County Public Works and Waste Management Division, 701 Northwest 1st Court, Miami, FL 33136.	July 26, 2013	120635
Orange, (FEMA Docket No.:, B–1328).	City of Orlando, (13–04–0940P).	The Honorable Buddy Dyer, Mayor, City of Orlando, P.O. Box 4990, Orlando, FL 32808.	One City Commons, 400 South Orange Avenue, Orlando, FL 32801.	August 2, 2013	120186

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Sarasota, (FEMA Docket No.:, B–1328).	Unincorporated areas of Sarasota County, (13–04–1684P).	The Honorable Carolyn Mason, Chair, Sarasota County Commission, 1660 Ringling Boulevard, Sarasota, FL 34236.	Sarasota County Operations Center, 1001 Sarasota Center Boulevard, Sarasota, FL 34236.	August 9, 2013	125144
Sarasota, (FEMA Docket No.:, B–1328).	Unincorporated areas of Sarasota County, (13–04–1985P).	The Honorable Carolyn Mason, Chair, Sarasota County Commission, 1660 Ringling Boulevard, Sarasota, FL 34236.	Sarasota County Operations Center, 1001 Sarasota Center Boulevard, Sarasota, FL 34236.	August 23, 2013	125144
Georgia:					
Chatham, (FEMA Docket No.:, B–1320).	City of Pooler, (12–04–3344P).	The Honorable Mike Lamb, Mayor, City of Pooler, 100 Southwest Highway 80, Pooler, GA 31322.	Public Works Department, 1095 South Rogers Street, Pooler, GA 31322.	July 12, 2013	130261
Chatham, (FEMA Docket No.:, B–1320).	Unincorporated areas of Chatham County, (12–04–3344P).	The Honorable Albert J. Scott, Chairman, Chatham County Board of Commissioners, P.O. Box 8161, Savannah, GA 31412.	Chatham County Emergency Management Agency, 124 Bull Street, Suite 200, Savannah, GA 31401.	July 12, 2013	130030
Columbia, (FEMA Docket No.:, B–1335).	Unincorporated areas of Columbia County, (13–04–3711P).	The Honorable Ron C. Cross, Chairman, Columbia County Board of Commissioners, P.O. Box 498, Evans, GA 30809.	Columbia County Development Services Division, 630 Ronald Reagan Drive, Building A, Evans, GA 30809.	September 19, 2013	130059
Kentucky: Kenton, (FEMA Docket No.:, B–1320).	City of Fort Wright, (12–04–6732P).	The Honorable Joe Nienaber, Jr., Mayor, City of Fort Wright, 409 Kyles Lane, Fort Wright, KY 41011.	Planning Division, 409 Kyles Lane, Fort Wright, KY 41011.	July 15, 2013	210249
Nevada: Washoe, (FEMA Docket No.:, B–1328).	Unincorporated areas of Washoe County, (13–09–0552P).	The Honorable David Humke, Chairman, Washoe County Board of Commissioners, P.O. Box 11130, Reno, NV 89520.	Washoe County Administration Building, Department of Public Works, 1001 East 9th Street, Reno, NV 89512.	August 23, 2013	320019
North Carolina: Cabarrus, (FEMA Docket No.:, B–1320).	City of Kannapolis, (11–04–5137P).	The Honorable Robert Misenheimer, Mayor, City of Kannapolis, 246 Oak Avenue, Kannapolis, NC 28081.	City Hall, 246 Oak Avenue, Kannapolis, NC 28081.	July 25, 2013	370469
South Carolina:					
Charleston, (FEMA Docket No.:, B–1328).	City of Folly Beach, (12–04–6719P).	The Honorable Tim Goodwin, Mayor, City of Folly Beach, P.O. Box 1692, Folly Beach, SC 29439.	City Hall, 21 Center Street, Folly Beach, SC 29439.	July 26, 2013	455415
Charleston, (FEMA Docket No.:, B–1320).	Town of Mount Pleasant, (13–04–1093P).	The Honorable Billy Swails, Mayor, Town of Mount Pleasant, 100 Ann Edwards Lane, Mount Pleasant, SC 29464.	Legal Department, 100 Ann Edwards Lane, Mount Pleasant, SC 29464.	July 12, 2013	455417
Georgetown, (FEMA Docket No.:, B–1328).	Unincorporated areas of Georgetown County, (12–04–7938P).	The Honorable Johnny Morant, Chairman, Georgetown County Council, P.O. Drawer 437, Georgetown, SC 29442.	Georgetown County Courthouse, 129 Screven Street, Georgetown, SC 29440.	August 12, 2013	450085
Tennessee: Sumner, (FEMA Docket No.:, B–1320).	City of Gallatin, (12–04–4835P).	The Honorable Jo Ann Graves, Mayor, City of Gallatin, 132 West Main Street, Gallatin, TN 37066.	City Hall, 132 West Main Street, Gallatin, TN 37066.	July 18, 2013	470185
Utah:					
Davis, (FEMA Docket No.:, B–1328).	City of Kaysville, (13–08–0218P).	The Honorable Steve A. Hiatt, Mayor, City of Kaysville, 697 North 240 East, Kaysville, UT 84037.	City Hall, 3 East Center, Kaysville, UT 84037.	August 2, 2013	490046
San Juan, (FEMA Docket No.:, B–1320).	City of Monticello, (12–08–0884P).	The Honorable Douglas L. Allen, Mayor, City of Monticello, 17 North 100 East, Monticello, UT 84535.	Public Works Department, 17 North 100 East, Monticello, UT 84535.	July 18, 2013	490212

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: November 20, 2013.

Roy Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–31020 Filed 12–26–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: New or modified Base (1% annual-chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or the regulatory floodway (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering

Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard determinations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

These new or modified flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

These new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

State and county	Location and case no.	Chief executive officer of community	Community map repository	Effective date of modification	Community no.
Arkansas: Garland, (FEMA Docket No.: B–1318).	City of Hot Springs, (13–06–1387P).	The Honorable Ruth Carney, Mayor, City of Hot Springs, 133 Convention Boulevard, Hot Springs National Park, AR 71901.	City Hall Annex, 111 Opera Street, Hot Springs National Park, AR 71901.	September 23, 2013	050084
New Mexico					
Bernalillo, (FEMA Docket No.: B–1324).	City of Albuquerque, (12–06–3488P).	The Honorable Richard J. Berry, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103.	Planning Department, 600 2nd Street Northwest, Albuquerque, NM 87102.	August 12, 2013	350002
Otero, (FEMA Docket No.: B–1338).	City of Alamogordo, (13–06–0956P).	The Honorable Susie Galea, Mayor, City of Alamogordo, 1376 East 9th Street, Alamogordo, NM 88310.	1376 East 9th Street, Alamogordo, NM 88310.	September 23, 2013	350045
Otero, (FEMA Docket No.: B–1338).	Unincorporated areas of Otero County, (13–06–0956P).	Ms. Pamela Heltner, County Manager, Otero County, 1101 New York Avenue, Room 106, Alamogordo, NM 88310.	Otero County, 1101 New York Avenue, Room 106, Alamogordo, NM 88310.	September 23, 2013	350044
Oklahoma:					
Oklahoma, (FEMA Docket No.: B–1324).	City of Oklahoma City, (12–06–4147P).	The Honorable Mick Cornett, Mayor, City of Oklahoma City, 200 North Walker Avenue, 3rd Floor, Oklahoma City, OK 73102.	420 West Main Street, Suite 700, Oklahoma City, OK 73102.	August 12, 2013	405378
Woods, (FEMA Docket No.: B–1324).	Unincorporated areas of Woods County, (12–06–2877P).	The Honorable Clint Strawn, Chairman, Woods County Board of Commissioners, P.O. Box 386, Alva, OK 73717.	Woods County Courthouse, 407 Government Street, Alva, OK 73717.	August 12, 2013	400481
Pennsylvania:					
Chester, (FEMA Docket No.: B–1338).	Township of East Whiteland, (12–03–2075P).	The Honorable Virginia McMichael, Chairman, East Whiteland Township Board of Supervisors, 209 Conestoga Road, Frazer, PA 19355.	East Whiteland Township Building, 209 Conestoga Road, Frazer, PA 19355.	September 19, 2013	420279
Chester, (FEMA Docket No.: B–1338).	Township of Tredyffrin, (12–03–2075P).	The Honorable Michelle H. Kichline, Chairman, Tredyffrin Township Board of Supervisors, 1100 Duportail Road, Berwyn, PA 19312.	Tredyffrin Municipal Building, 1100 Duportail Road, Berwyn, PA 19312.	September 19, 2013	420291
Montgomery, (FEMA Docket No.: B–1341).	Township of Whitpain, (12–03–1849P).	The Honorable Joseph J. Palmer, Chairman, Township of Whitpain Board of Supervisors, 960 Wentz Road, Blue Bell, PA 19422.	Whitpain Township Building, 960 Wentz Road, Blue Bell, PA 19422.	August 12, 2013	420713
Texas:					
Bell, (FEMA Docket No.: B–1341).	City of Killeen, (13–06–0268P).	The Honorable Daniel A. Corbin, Mayor, City of Killeen, P.O. Box 1329, Killeen, TX 76540.	City Hall, 101 North College Street, Killeen, TX 76541.	September 9, 2013	480031
Bell, (FEMA Docket No.: B–1341).	City of Killeen, (13–06–2244P).	The Honorable Daniel A. Corbin, Mayor, City of Killeen, P.O. Box 1329, Killeen, TX 76540.	City Hall, 101 North College Street, Killeen, TX 76541.	October 7, 2013	480031
Bexar, (FEMA Docket No.: B–1338).	City of San Antonio, (13–06–0089P).	The Honorable Julian Castro, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Department of Public Works, Storm Water Engineering, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	September 3, 2013	480045

State and county	Location and case no.	Chief executive officer of community	Community map repository	Effective date of modification	Community no.
Bexar, (FEMA Docket No.: B–1338).	City of San Antonio, (13–06–1508P).	The Honorable Julian Castro, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Department of Public Works, Storm Water Engineering, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	September 25, 2013	480045
Bexar, (FEMA Docket No.: B–1341).	City of San Antonio, (13–06–0967P).	The Honorable Julian Castro, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Department of Public Works, Storm Water Engineering, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	October 7, 2013	480045
Bexar, (FEMA Docket No.: B–1349).	City of San Antonio, (13–06–1131P).	The Honorable Julian Castro, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Department of Public Works, Storm Water Engineering, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	October 21, 2013	480045
Bexar, (FEMA Docket No.: B–1338).	Unincorporated areas of Bexar County, (13–06–0089P).	The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	September 3, 2013	480035
Bexar, (FEMA Docket No.: B–1341).	Unincorporated areas of Bexar County, (13–06–2069P).	The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	October 7, 2013	480035
Bexar, (FEMA Docket No.: B–1349).	Unincorporated areas of Bexar County, (13–06–1809P).	The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	October 10, 2013	480035
Brazoria, (FEMA Docket No.: B–1338).	City of West Columbia, (12–06–1432P).	The Honorable Laurie B. Kincannon, Mayor, City of West Columbia, P.O. Box 487, West Columbia, TX 77486.	512 East Brazos Avenue, West Columbia, TX 77486.	August 29, 2013	480081
Brazoria, (FEMA Docket No.: B–1338).	Unincorporated areas of Brazoria County, (12–06–1432P).	The Honorable Joe King, Brazoria County Judge, 111 East Locust Street, Suite 102, Angleton, TX 77515.	Brazoria County, 451 North Velasco Street, Suite 210, Angleton, TX 77515.	August 29, 2013	485458
Brazos, (FEMA Docket No.: B–1324).	City of Bryan, (12–06–2987P).	The Honorable Jason Bienski, Mayor, City of Bryan, 300 South Texas Avenue, Bryan, TX 77803.	City Hall, 300 South Texas Avenue, Bryan, TX 77803.	August 12, 2013	480082
Collin, (FEMA Docket No.: B–1338).	City of Plano, (12–06–4168P).	The Honorable Phil Dyer, Mayor, City of Plano, P.O. Box 860358, Plano, TX 75086.	City Hall, 1520 Avenue K, Plano, TX 75074.	September 20, 2013	480140
Collin, (FEMA Docket No.: B–1349).	Unincorporated areas of Collin County, (13–06–1085P).	The Honorable Keith Self, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Department of Public Works, 210 South McDonald Street, McKinney, TX 75069.	October 24, 2013	480130
Dallas, (FEMA Docket No.: B–1338).	City of Coppell, (13–06–0810P).	The Honorable Karen Hunt, Mayor, City of Coppell, P.O. Box 9478, Coppell, TX 75019.	City Engineering Department, 255 Parkway Boulevard, Coppell, TX 75019.	September 9, 2013	480170
Dallas, (FEMA Docket No.: B–1341).	City of Garland, (13–06–0314P).	The Honorable Douglas Athas, Mayor, City of Garland, 200 North 5th Street, Garland, TX 75040.	800 Main Street, Garland, TX 75040.	October 7, 2013	485471
Dallas, (FEMA Docket No.: B–1338).	City of Grand Prairie, (13–06–1633P).	The Honorable Charles England, Mayor, City of Grand Prairie, P.O. Box 534045, Grand Prairie, TX 75053.	City Development Center, 206 West Church Street, Grand Prairie, TX 75050.	September 9, 2013	485472
Dallas, (FEMA Docket No.: B–1341).	City of Sachse, (13–06–0314P).	The Honorable Mike Felix, Mayor, City of Sachse, 3815 Sachse Road, Building B, Sachse, TX 75048.	Community Development Department, 5560 Highway 78, Sachse, TX 75048.	October 7, 2013	480186
Denton, (FEMA Docket No.: B–1324).	City of Frisco, (12–06–4054P).	The Honorable Maher Maso, Mayor, City of Frisco, 6101 Frisco Square Boulevard, Frisco, TX 75034.	City Hall, 6101 Frisco Square Boulevard, Frisco, TX 75034.	August 19, 2013	480134
Denton, (FEMA Docket No.: B–1331).	City of Frisco, (12–06–3923P).	The Honorable Maher Maso, Mayor, City of Frisco, 6101 Frisco Square Boulevard, Frisco, TX 75034.	City Hall, 6101 Frisco Square Boulevard, Frisco, TX 75034.	September 3, 2013	480134
Denton, (FEMA Docket No.: B–1324).	Town of Little Elm, (12–06–4054P).	The Honorable David Hillock, Mayor, Town of Little Elm, 100 West Eldorado Parkway, Little Elm, TX 75068.	Town Hall, 100 West Eldorado Parkway, Little Elm, TX 75068.	August 19, 2013	481152
Fort Bend, (FEMA Docket No.: B–1324).	City of Katy, (12–06–1798P).	The Honorable Don Elder, Jr., Mayor, City of Katy, P.O. Box 617, Katy, TX 77493.	Public Works Department, 910 Avenue C, Katy, TX 77493.	August 2, 2013	480301
Harris, (FEMA Docket No.: B–1331).	City of Pasadena, (13–06–0356P).	The Honorable John Isbell, Mayor, City of Pasadena, 1211 Southmore Avenue, Pasadena, TX 77502.	1201 Jeff Ginn Memorial Drive, Pasadena, TX 77502.	August 30, 2013	480307
Hays, (FEMA Docket No.: B–1324).	City of Niederwald, (12–06–3911P).	The Honorable Reynell Smith, Mayor, City of Niederwald, 13851 Camino Real, Niederwald, TX 78640.	City Office, 13851 Camino Real, Niederwald, TX 78640.	August 15, 2013	481670
Hays, (FEMA Docket No.: B–1324).	Unincorporated areas of Hays County, (12–06–3911P).	The Honorable Bert Cobb, M.D., Hays County Judge, 111 East San Antonio Street, Suite 300, San Marcos, TX 78666.	Hays County Environmental Health Department, 1251 Civic Center Loop, San Marcos, TX 78666.	August 15, 2013	480321

State and county	Location and case no.	Chief executive officer of community	Community map repository	Effective date of modification	Community no.
Johnson, (FEMA Docket No.: B–1331).	City of Burleson, (12–06–3813P).	The Honorable Ken D. Shetter, Mayor, City of Burleson, 141 West Renfro Street, Burleson, TX 76028.	City Hall, 141 West Renfro Street, Burleson, TX 76028.	August 29, 2013	485459
Johnson, (FEMA Docket No.: B–1341).	City of Burleson, (12–06–1425P).	The Honorable Ken D. Shetter, Mayor, City of Burleson, 141 West Renfro Street, Burleson, TX 76028.	City Hall, 141 West Renfro Street, Burleson, TX 76028.	October 3, 2013	485459
Montgomery, (FEMA Docket No.: B–1338).	Unincorporated areas of Montgomery County, (13–06–1567P).	The Honorable Alan B. Sadler, Montgomery County Judge, 501 North Thompson Street, Suite 401, Conroe, TX 77301.	Montgomery County Permitting Department, 501 North Thompson Street, Suite 100, Conroe, TX 77301.	September 26, 2013	480483
Tarrant, (FEMA Docket No.: B–1338).	City of Fort Worth, (13–06–1283P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, 1000 Throckmorton Street, Fort Worth, TX 76102.	September 5, 2013	480596
Tarrant, (FEMA Docket No.: B–1341).	City of Keller, (13–06–0279P).	The Honorable Pat McGrail, Mayor, City of Keller, 1100 Bear Creek Parkway, Keller, TX 76248.	City Hall, 1100 Bear Creek Parkway, Keller, TX 76248.	August 12, 2013	480602
Travis, (FEMA Docket No.: B–1324).	City of Austin, (13–06–0132P).	The Honorable Lee Leffingwell, Mayor, City of Austin, P.O. Box 1088, Austin, TX 78767.	Stormwater Management Division, 505 Barton Springs Road, Suite 908, Austin, TX 78704.	August 8, 2013	480624
Travis, (FEMA Docket No.: B–1331).	Unincorporated areas of Travis County, (13–06–0775P).	The Honorable Samuel T. Biscoe, Travis County Judge, P.O. Box 1748, Austin, TX 78767.	Travis County Administration Building, Transportation and Natural Resources Department, 700 Lavaca Street,, 5th Floor, Austin, TX 78701.	August 26, 2013	481026
Virginia: Loudoun, (FEMA Docket No.: B–1338).	Unincorporated areas of Loudoun County, (12–03–1164P).	The Honorable Scott K. York, Chairman-at-Large, Loudoun County Board of Supervisors, 1 Harrison Street Southeast, 5th Floor, Mailstop 1, Leesburg, VA 20175.	Loudoun County Building and Development Department, 1 Harrison Street Southeast, Leesburg, VA 20175.	September 19, 2013	510090
West Virginia: Kanawha, (FEMA Docket No.: B–1324).	Unincorporated areas of Kanawha County, (13–03–0645P).	The Honorable W. Kent Carper, President, Kanawha County Commission, 407 Virginia Street East, Charleston, WV 25301.	Kanawha County Courthouse, Planning and Development Department, 407 Virginia Street East, Charleston, WV 25301.	August 12, 2013	540070

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: November 20, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–30944 Filed 12–26–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3354–EM; Docket ID FEMA–2013–0001]

New Jersey; Amendment No. 5 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for State of New Jersey (FEMA–3354–EM), dated October 28, 2012, and related determinations.

DATES: Effective December 13, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William L. Vogel, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Gracia B. Szczech as Federal Coordinating Officer for this emergency.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant,

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–31001 Filed 12–26–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–B–1301]

Proposed Flood Hazard Determinations for Plaquemines Parish, Louisiana and Incorporated Areas, and St. Charles Parish, Louisiana and Incorporated Areas

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its proposed notice concerning proposed flood hazard determinations, which may include the addition or modification of any Base Flood Elevation, base flood depth, Special Flood Hazard Area boundary or

zone designation, or regulatory floodway on the Flood Insurance Rate Maps, and where applicable, in the supporting Flood Insurance Study reports for Plaquemines Parish, Louisiana, and Incorporated Areas, and St. Charles Parish, Louisiana, and Incorporated Areas.

DATES: This withdrawal is effective December 27, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FEMA–B–1301, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*.

SUPPLEMENTARY INFORMATION: On April 4, 2013, FEMA published proposed notices at 78 FR 20340 and 78 FR 20341 proposing flood hazard determinations in Plaquemines Parish, and St. Charles Parish, Louisiana, respectively. FEMA is withdrawing both of the proposed notices.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Dated: November 22, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–30950 Filed 12–26–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4111–DR; Docket ID FEMA–2013–0001]

New York; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of New York (FEMA–4111–DR), dated April 23, 2013, and related determinations.

DATES: *Effective Date:* December 17, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, John Long, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Willie G. Nunn as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–30961 Filed 12–26–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4086–DR; Docket ID FEMA–2013–0001]

New Jersey; Amendment No. 10 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of New Jersey (FEMA–4086–DR), dated October 30, 2012, and related determinations.

DATES: Effective December 13, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William L. Vogel, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Gracia B. Szczech as Federal Coordinating Officer for this disaster.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–31000 Filed 12–26–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–B–1239]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; correction.

SUMMARY: On March 28, 2012, FEMA published in the **Federal Register** a proposed flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table, to be used in lieu of the information published. The table provided here represents the proposed flood hazard determinations and communities affected for Cowlitz County, Washington, and Incorporated Areas.

DATES: Comments are to be submitted on or before March 27, 2014.

ADDRESSES: The Preliminary Flood Insurance Rate Map (FIRM), and where applicable, the Flood Insurance Study (FIS) report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1239, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed in the table below, in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the table below. Any request for reconsideration of the revised flood hazard determinations shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations will also be considered before the FIRM and FIS report are made final.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP may only be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The communities affected are listed in the table below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Correction

In the proposed flood hazard determination notice published at 77 FR 18844 in the March 28, 2012, issue of the **Federal Register**, FEMA published a table titled "Cowlitz County, Washington, and Incorporated Areas." The table contained inaccurate information as to the online location for the Preliminary FIRM and FIS report and the building name for the Community Map Repository address for the City of Woodland. In addition, revisions to the Preliminary FIRM have since been made and posted to the online location published as part of this notice. In this notice, FEMA is publishing a table containing the accurate information. The information provided below should be used in lieu of that previously published.

Community	Community map repository address
Cowlitz County, Washington, and Incorporated Areas	
Maps Available for Inspection Online at: *www.fema.gov/preliminaryfloodhazarddata*	
City of Castle Rock	City Hall, 141 A Street Southwest, Castle Rock, WA 98611.
City of Kalama	City Hall, 320 North 1st Street, Kalama, WA 98625.
City of Kelso	City Hall, 203 South Pacific Avenue, Kelso, WA 98626.
City of Longview	City Hall, 1525 Broadway Street, Longview, WA 98632.
City of Woodland	City Hall, 230 Davidson Avenue, Woodland, WA 98674.
Unincorporated Areas of Cowlitz County	Cowlitz County Administration Building, 207 4th Avenue North, Kelso, WA 98626.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: September 30, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–30942 Filed 12–26–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–B–1348]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before March 27, 2014.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1348, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm7/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Community	Community Map Repository Address
Fayette County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Connersville	Fayette County Area Plan Commission, Courthouse Annex, 111 West Fourth Street, Connersville, IN 47331.
Unincorporated Areas of Fayette County	Fayette County Area Plan Commission, Courthouse Annex, 111 West Fourth Street, Connersville, IN 47331.
Henry County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	

Community	Community Map Repository Address
City of New Castle	City Hall, 227 North Main Street, New Castle, IN 47362.
Town of Dunreith	Henry County Planning Commission, 101 South Main Street, New Castle, IN 47362.
Town of Greensboro	Town Hall, 130 North 525, Greensboro, IN 47344.
Town of Kennard	Kennard Town Hall, 100 North Main Street, Kennard, IN 47351.
Town of Lewisville	Henry County Planning Commission, 101 South Main Street, New Castle, IN 47362.
Town of Middletown	Henry County Planning Commission, 101 South Main Street, New Castle, IN 47362.
Town of Mooreland	Henry County Planning Commission, 101 South Main Street, New Castle, IN 47362.
Unincorporated Areas of Henry County	Henry County Planning Commission, 101 South Main Street, New Castle, IN 47362.
Howard County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Kokomo	Kokomo Planning Commision, 120 East Mulberry Street, Suite 114, Kokomo, IN 46901.
Town of Greentown	Town Hall, 112 North Meridian Street, Greentown, IN 46936.
Town of Russiaville	Town Hall, 250 North Union Street, Russiaville, IN 46979.
Unincorporated Areas of Howard County	Kokomo Planning Commission, 120 East Mulberry Street, Suite 114, Kokomo, IN 46901.
Jefferson County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Madison	City Hall, Plan Commission Office, 101 West Main Street, Madison, IN 47250.
Town of Brooksburg	County Courthouse, Room 204, 300 East Main Street, Madison, IN 47250.
Town of Hanover	Town Hall, 11 North Madison Avenue, Hanover, IN 47243.
Unincorporated Areas of Jefferson County	County Courthouse, Room 204, 300 East Main Street, Madison, IN 47250.
Jennings County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of North Vernon	Jennings County Area Plan Commission, 200 East Brown Street, Vernon, IN 47282.
Town of Vernon	Jennings County Area Plan Commission, 200 East Brown Street, Vernon, IN 47282.
Unincorporated Areas of Jennings County	Jennings County Area Plan Commission, 200 East Brown Street, Vernon, IN 47282.
Noble County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Kendallville	City Hall, 234 South Main Street, Kendallville, IN 46755.
City of Ligonier	City Hall, 301 South Cavin Street, Suite 2, Ligonier, IN 46767.
Town of Albion	Municipal Building, 211 East Park Drive, Albion, IN 46701.
Town of Avilla	Town Hall, 108 South Main Street, Avilla, IN 46710.
Town of Rome City	Town Hall, 402 Kelly Street, Rome City, IN 46784.
Unincorporated Areas of Noble County	Noble County South Complex, 2090 North State Road 9, Suite A, Albion, IN 46701.
Porter County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Portage	Building Department, 6070 Central Avenue, Portage, IN 46368.
City of Valparaiso	Building Department, 166 West Lincolnway, Valparaiso, IN 46383.
Town of Beverly Shores	Town Hall, 500 South Broadway, Beverly Shores, IN 46301.
Town of Burns Harbor	Building Department, 1240 North Boo Road, Burns Harbor, IN 46304.
Town of Chesterton	Building Department, 726 Broadway, Chesterton, IN 46304.
Town of Dune Acres	Building Department, 1 East Road, Dune Acres, IN 46304.
Town of Hebron	Building Department, 106 East Sigler Street, Hebron, IN 46341.
Town of Ogden Dunes	Building Department, 115 Hillcrest Road, Ogden Dunes, IN 46368.
Town of Porter	Building Department, 303 Franklin Street, 2nd Floor, Porter, IN 46304.

Community	Community Map Repository Address
Unincorporated Areas of Porter County	Porter County Plan Commission, 155 Indiana Avenue, Valparaiso, IN 46383.
Wayne County, Indiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Richmond	City Hall, 50 North 5th Street, Richmond, IN 47374.
Town of Cambridge City	Town Hall, 127 North Foote Street, Cambridge City, IN 47327.
Town of Centerville	Municipal Building, 204 East Main Street, Centerville, IN 47330.
Town of Fountain City	Town Hall, 312 West Main Street, Fountain City, IN 47341.
Town of Greens Fork	Town Hall, 12 South Water Street, Greens Fork, IN 47345.
Town of Hagerstown	Town Hall, 49 East College Street, Hagerstown, IN 47346.
Town of Milton	Town Hall, 113 East Main Street, Milton, IN 47357.
Town of Mount Auburn	Town Hall, 1113 National Road, Mount Auburn, IN 47327.
Town of Spring Grove	Town Hall, 3 Sunset Drive, Richmond, IN 47374.
Unincorporated Areas of Wayne County	Office of Planning and Zoning, Wayne County Annex Building, 401 East Main Street, Richmond, IN 47374.
Ionia County, Michigan (All Jurisdictions)	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Belding	City Hall, 120 South Pleasant Street, Belding, MI 48809.
City of Ionia	City Hall, 114 North Kidd Street, Ionia, MI 48846.
City of Portland	City Hall, 259 Kent Street, Portland, MI 48875.
Township of Berlin	Township of Berlin, 4947 Harwood Road, Ionia, MI 48846.
Township of Boston	Township Hall, 30 North Center Street, Saranac, MI 48881.
Township of Campbell	Township Hall, 331 South Main Street, Clarksville, MI 48815.
Township of Danby	Township Hall, 13122 Charlotte Highway, Sunfield, MI 48890.
Township of Easton	Township of Easton, 3960 Potters Road, Ionia, MI 48846.
Township of Ionia	Township Hall, 1042 East Washington Street, Ionia, MI 48846.
Township of Keene	Township Hall, 8505 Potters Road, Saranac, MI 48881.
Township of Lyons	Township Hall, 108 Prairie Street, Lyons, MI 48851.
Township of North Plains	Hubbardston Fire Station, 126 North Washington Street, Hubbardston, MI 48845.
Township of Odessa	Township Hall, 3862 Laurel Drive, Lake Odessa, MI 48849.
Township of Otisco	Township Hall, 9663 West Button Road, Belding, MI 48809.
Township of Portland	Township Hall, 773 East Grand River Avenue, Portland, MI 48875.
Village of Hubbardston	Village Hall, 305 Russell Street, Hubbardston, MI 48845.
Village of Lake Odessa	Page Memorial Building, 839 Fourth Avenue, Lake Odessa, MI 48849.
Village of Lyons	Village of Lyons Office, 212 Water Street, Lyons, MI 48851.
Village of Muir	Village Hall, 122 Superior Street, Muir, MI 48860.
Village of Saranac	Village Hall, 27 North Bridge Street, Saranac, MI 48881.
Mecosta County, Michigan (All Jurisdictions)	
Maps Available for Inspection Online at: *www.fema.gov/preliminaryfloodhazarddata*	
Charter Township of Green	Green Charter Township, 21431 Northland Drive, Paris, MI 49338.
City of Big Rapids	City Hall, 226 North Michigan Avenue, Big Rapids, MI 49307.
Township of Aetna	Aetna Township Hall, 196 North Cass Street, Morley, MI 49336.
Township of Austin	Austin Township Hall, 14132 Pierce Road, Stanwood, MI 49346.
Township of Big Rapids	Township Hall, 14212 Northland Drive, Big Rapids, MI 49307.
Township of Colfax	Colfax Township Hall, 14428 157th Avenue, Big Rapids, MI 49307.
Township of Deerfield	Deerfield Township Hall, 396 East Fourth Street, Morley, MI 49336.
Township of Fork	Fork Township Hall, 147 Northern Avenue, Barryton, MI 49305.
Township of Grant	Grant Township Hall, 21 Mile Road and 150th Avenue, Big Rapids, MI 49307.
Township of Mecosta	Mecosta Township Hall, 19729 11 Mile Road, Big Rapids, MI 49307.
Township of Morton	Morton Township Hall, 290 West Main Street, Mecosta, MI 49332.
Village of Barryton	Village Hall, 94 Angel, Barryton, MI 49305.
Village of Mecosta	Village Office, 115 West Main Street, Mecosta, MI 49332.
Village of Morley	Village Hall, 189 South Cass Street, Morley, MI 49336.
Newaygo County, Michigan (All Jurisdictions)	
Maps Available for Inspection Online at: *www.fema.gov/preliminaryfloodhazarddata*	
Charter Township of Sheridan	Township Hall, 6360 West Township Parkway, Fremont, MI 49412.
City of Fremont	City Hall, 101 East Main Street, Fremont, MI 49412.
City of Newaygo	City Hall, 28 North State Road, Newaygo, MI 49337.
City of White Cloud	City Hall, 12 North Charles Street, White Cloud, MI 49349.
Township of Ashland	Township Hall, 2019 West 120th Street, Grant, MI 49327.
Township of Bridgeton	Township Hall, 11830 South Warner Avenue, Grant, MI 49327.

Community	Community Map Repository Address
Township of Brooks	Township Hall, 490 Quarterline Road, Newaygo, MI 49337.
Township of Croton	Township Hall, 5833 East Division Street, Newaygo, MI 49337.
Township of Dayton	Township Hall, 3215 South Stone Road, Fremont, MI 49412.
Township of Everett	Township Hall, 1516 East 8th Street, White Cloud, MI 49349.
Township of Garfield	Township Hall, 7910 South Bingham Avenue, Newaygo, MI 49337.
Township of Lilley	Multi Purpose Building, 10767 Prospect Avenue, Bitely, MI 49309.
Township of Lincoln	Township Hall, 1988 North Wisner Avenue, White Cloud, MI 49349.
Township of Merrill	Township Hall, 1585 West 11 Mile Road, Bitely, MI 49309.
Township of Sherman	Township Hall, 2168 South Wisner Avenue, Fremont, MI 49412.
Township of Wilcox	Township Hall, 1795 North Evergreen Drive, White Cloud, MI 49349.
Anoka County, Minnesota, and Incorporated Areas	
Maps Available for Inspection Online at: *www.fema.gov/preliminaryfloodhazarddata*	
City of Andover	City Hall, 1685 Crosstown Boulevard Northwest, Andover, MN 55304.
City of Anoka	City Hall, 2015 First Avenue North, Anoka, MN 55303.
City of Bethel	City Hall, 23820 Dewey Street, Bethel, MN 55005.
City of Blaine	City Hall Offices, 10801 Town Square Drive Northeast, Blaine, MN 55449.
City of Centerville	City Hall, 1880 Main Street, Centerville, MN 55038.
City of Circle Pines	City Hall, 200 Civic Heights Circle, Circle Pines, MN 55014.
City of Columbia Heights	City Hall, 590 40th Avenue Northeast, Columbia Heights, MN 55421.
City of Columbus	City Hall, 16319 Kettle River Boulevard, Columbus, MN 55025.
City of Coon Rapids	City Hall, 11155 Robinson Drive, Coon Rapids, MN 55433.
City of East Bethel	City Hall, 2241 221st Avenue Northeast, East Bethel, MN 55011.
City of Fridley	City Hall, 6431 University Avenue Northeast, Fridley, MN 55432.
City of Ham Lake	City Hall, 15544 Central Avenue Northeast, Ham Lake, MN 55304.
City of Lexington	City Hall, 9180 Lexington Avenue, Lexington, MN 55014.
City of Lino Lakes	City Hall, 600 Town Center Parkway, Lino Lakes, MN 55014.
City of Nowthen	City Offices, 8188 199th Avenue Northwest, Elk River, MN 55330.
City of Oak Grove	City Hall, 19900 Nightingale Street Northwest, Cedar, MN 55011.
City of Ramsey	Municipal Center, 7550 Sunwood Drive Northwest, Ramsey, MN 55303.
City of Spring Lake Park	City Hall, 1301 81st Avenue Northeast, Spring Lake Park, MN 55432.
City of St. Francis	City Hall, 23340 Cree Street Northwest, St. Francis, MN 55070.
Unincorporated Areas of Anoka County	Government Center, 2100 Third Avenue, 7th Floor, Anoka, MN 55303.
Wilkin County, Minnesota, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Breckenridge	City Hall, 420 Nebraska Avenue, Breckenridge, MN 56520.
City of Campbell	Post Office, 510 5th Street, Campbell, MN 56522.
City of Doran	City Hall, 1106 4th Street, Doran, MN 56522.
City of Foxhome	City Hall, 303 Main Street, Foxhome, MN 56543.
City of Kent	City Hall, 204 Main Street, Kent, MN 56553.
City of Nashua	Fur House, 217 County Road 19, Nashua, MN 56565.
City of Wolverton	City Hall, 301 King of Trails Parkway, Wolverton, MN 56594.
Unincorporated Areas of Wilkin County	Wilkin County Courthouse, 300 5th Street South, Breckenridge, MN 56520.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: November 20, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–31012 Filed 12–26–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5684–N–08]

60-Day Notice of Proposed Information Collection: HUD Environmental Review Online System (HEROS)

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* February 25, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400

(this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Danielle Schopp, Director, Office of Environment and Energy, Department of Housing and Urban Development, 451 7th Street SW., Room 7250, Washington, DC 20410–7000. For telephone and email communication, contact Elizabeth Zepeda, Environmental Planning Division, (202) 402–3988 or email: *elizabeth.g.zepeda@hud.gov*. This phone number is not toll-free. Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: HUD Environmental Review Online System (HEROS).

OMB Approval Number: 2506-New.

Type of Request: New.

Description of the need for the information and proposed use: 224 CFR Part 58, "Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities" requires units of general local government receiving HUD assistance to maintain a written environmental review record for all projects receiving HUD funding documenting compliance with the National Environmental Policy Act (NEPA), the regulations of the Council on Environmental Quality, related federal environmental laws, executive orders, and authorities, and Part 58 procedure. Various laws that authorize this procedure are listed in 24 CFR 58.1(b).

In the past, HUD recipients were allowed to prepare their environmental review records using HUD recommended formats or equivalent formats. Now, HUD is developing a new online tool called the HUD Environmental Review Online System (HEROS), which will allow users to complete, store, and submit their environmental review records online. HUD's intention is HEROS will improve HUD's environmental reviews in a number of ways. First, it will replace HUD's many environmental review forms and requirements with one single format housed online with guidance integrated throughout to simplify the process and assist new employees in the preparation of their reviews. Second, HUD plans to increase transparency and overall compliance with NEPA by posting many environmental review records online for public review through HEROS. Finally, storing recipients' records in HEROS will allow HUD to collect data on environmental compliance for the first time. Once completed, HUD intends to make HEROS the only permitted format in most cases.

24 CFR Part 50, "Protection and Enhancement of Environmental Quality," implements procedures for HUD to perform environmental reviews for projects where Part 58 is not permitted by law. Under Part 50, HUD staff complete the environmental review records, but they may use any information supplied by an applicant or contractor, provided HUD independently evaluates the information and is responsible for its accuracy and prepares the environmental finding. There is no current format for applicants and contractors to submit required information, but HEROS would allow these parties to submit environmental information to HUD staff through the system as well. HUD staff will then use HEROS to complete the environmental review record.

Respondents (i.e. affected public): The respondents are state and local governments receiving HUD funding who are required to complete environmental reviews.

Estimation of the total number of hours to prepare the information collection including number of respondents, frequency of response and hours of response:

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Total	2,500	5	12,500	1	12,500	30	$375,000

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: December 19, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs Program.

[FR Doc. 2013–31037 Filed 12–26–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5690–N–19]

60-Day Notice of Proposed Information Collection: Consolidated Public Housing Certification of Completion

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice

is to allow for 60 days of public comment.

DATES: *Comments Due Date:* February 25, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW., (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Consolidated Public Housing Certification of Completion.

OMB Approval Number: 2577–0021.

Type of Request: extension of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: Public Housing Agencies (PHAs) certify to HUD that contract requirements and standards have been satisfied in a project development and HUD can allow the PHA to make payment to the development contractor. The Certification is submitted by a Public Housing Agency (PHA) to indicate to HUD that contract requirements have been satisfied for a specific project.

Respondents (i.e. affected public): Public Housing Authorities.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Certification	58	1	58	1.0	58	$25	$1,450
Total	58	1	58	1.0	58	25	1,450

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: December 20, 2013.

Deb Gross,

Deputy Assistant Secretary, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2013–31036 Filed 12–26–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5681–N–50]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers

interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Office of Enterprise Support Programs, Program Support Center, HHS, Room 12–07, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Agriculture:* Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202) 720–8873; *Air Force:* Ms. Connie Lotfi, Air Force Real Property Agency, 2261 Hughes Avenue, Suite 156, Lackland AFB, TX 78236–9852, (210) 395–9512; *Army:* Ms. Veronica Rines, Office of the Assistant Chief of Staff for Installation Management, Department of Army, Room 5A128, 600 Army Pentagon, Washington, DC 20310, (571) 256–8145; *Coast Guard:* Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2100 Second St. SW., Stop 7901, Washington, DC 20593–0001; (202) 475–5609; *Energy:* Mr. David Steinau, Department of Energy, Real Estate Division (MA–651), Office of Property Management, 1000 Independence Ave. SW., Washington, DC 20585, (202) 287–1503; *GSA:* Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (202) 501–0084; *Interior:* Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, MS–4262, 1849 C Street, Washington, DC 20240, (202) 513–0795; *Navy:* Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426 (There are not toll-free numbers).

Dated: December 19, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 12/27/2013

Suitable/Available Properties

Building

Arizona

Old Ehrenberg Office
49354 Ehrenberg-Poston Hwy.
Ehrenberg AZ
Landholding Agency: Interior
Property Number: 61201340009
Status: Unutilized
Comments: Off-site removal only; no future agency need; 800 sq. ft.; office; significant water damage; repairs a must; asbestos/lead; contact Interior for more info.

California

Los Banos Field Office
745 West J Street
Los Banos CA 93635
Landholding Agency: GSA
Property Number: 54201340006
Status: Surplus
GSA Number: 9–I–CA–0450–AC–3
Directions:
(Landholding-Agric.; Disposal & GSA) 2 Bldgs.5, 375 sq.; bldgs. sits on 0.41 acres
Comments: Significant fire damage to Admin. bldg.; bathroom; major repairs required; contamination; asbestos; contact GSA for more info.

Siphon Drop Caretaker's Reside
(RPUI #00350000600B)
Yuma Main Canal
Winterhaven CA
Landholding Agency: Interior
Property Number: 61201340010
Status: Unutilized
Comments: Off-site removal only; no future agency USE; 1,014 sq. ft.; 108+ months vacant; extensive termite damage; asbestos; mold, lead; escort required; contact Interior for more info.

Illinois

Site 50, Building A
Fermi National Accelerator Laboratory
Batavia IL 60510
Landholding Agency: Energy
Property Number: 41201340002
Status: Excess
Comments: Off-site removal only; 367 sq. ft.; storage; 108 years old; secured area; contact Energy for more information.

37 Shabbona Material Dev. Lab
Fermi National Accelerator Lab
Batavia IL 60510
Landholding Agency: Energy
Property Number: 41201340003
Status: Excess
Comments: Off-site removal only; 1,097 sq. ft.; office; 44 yrs.-old; secured area; contact Energy for more info.

37a Shabbona-Component Storage
Fermi National Accelerator Laboratory
Batavia IL 60510
Landholding Agency: Energy
Property Number: 41201340004
Status: Excess
Comments: Off-site removal only; 2,079 sq. ft.; storage; 44 years old; secured area; contact Energy for more information.

Site 50 Barn
Fermi National Accelerator Lab
Fermilab IL 60510
Landholding Agency: Energy
Property Number: 41201340005
Status: Excess
Comments: Off-site removal only; 2,952 sq. ft.; storage; 108 yrs.-old; secured area; contact Energy for more info.

33 Blackhark—Lab 8 House
Fermi National Accelerator Laboratory
Batavia IL 60510
Landholding Agency: Energy
Property Number: 41201340006
Status: Excess
Comments: Off-site removal only; 1,092 sq. ft.; office; 50 years old; secured area; contact Energy for more information.

31 Blackhawk—Lab 8 House
Fermi National Accelerator Laboratory
Batavia IL 60510
Landholding Agency: Energy
Property Number: 41201340009
Status: Excess
Comments: Off-site removal only; 1,092 sq. ft.; office; 50 years old; secured area; contact Energy for more information.

Mississippi

Modular #2; 640400B028; RPUID
13762 Small Fruits Research Station
Poplarville MS 39470
Landholding Agency: Agriculture
Property Number: 15201340003
Status: Unutilized
Comments: 1,440 sq. ft.; lab; 12+ months vacant; fair conditions; contact Agriculture for more info.

Modular #1; 640400B027; RPUID: 03.804
13762 Small Fruits Research Station
Poplarville MS 39470

Landholding Agency: Agriculture
Property Number: 15201340005
Status: Unutilized
Comments: 1,440 sq. ft.; 12+ months vacant; fair conditions; contact Agriculture for more information.

Lab/Support 2; 640400B002;
RPUID 03.54463
13762 Small Fruits Research Station
Poplarville MS 39470
Landholding Agency: Agriculture
Property Number: 15201340006
Status: Unutilized
Comments: 1,215 sq. ft.; Lab: 12+ months vacant; fair condition; need new roof; mold present; contact Agriculture for more information.

Office/Lab 1; 640400B001;
RPUD 03.54462
13762 Small Fruits Research Station
Poplarville MS 39470
Landholding Agency: Agriculture
Property Number: 15201340007
Status: Unutilized
Comments: 2,800 sq. ft.; 12+ months vacant; fair conditions; need new roof; mold present; contact Agriculture for more information.

New York

Former TSG Harold Lockwood US
Army Reserves Center
111 Finney Boulevard
Malone NY 12953
Landholding Agency: GSA
Property Number: 54201340007
Status: Excess
GSA Number: 1–D–NY–0966–AA
Comments: 29960 Sq. Ft.: office/administrative/garage; sits on 4.82+/-acres; age 1961–1983; entry by appointment with USAR/GSA; asbestos and lead based paint; contact GSA for more information.

Tennessee

Building 2250
Indiana Ave; Ft. Campbell
Ft. Campbell TN 42223
Landholding Agency: Army
Property Number: 21201340001
Status: Unutilized
Directions: Originally published under 21200330094 as 'unsuitable'
Comments: 2,500 sq. ft.; office; 36+ months vacant; poor conditions; need repairs; secured area; strict accessibility requirements; contact Army for more info.

Texas

#1658 Training Lodge Support
Building
219 K Avenue
Sheppard AFB TX 76311
Landholding Agency: Air Force
Property Number: 18201340042
Status: Underutilized
Comments: 11,743 sq. ft.; 5+ months vacant; 60+ years old; secured area; escort required to access property; contact Air Force for more information.

#1919 Technical Training
Support
921 Missile Road
Sheppard AFB TX 76311
Landholding Agency: Air Force
Property Number: 18201340043
Status: Unutilized
Comments: 10,493 sq. ft.; 7+ months vacant; 52+ years old; secured area; escort required to access property; contact Air Force for more information.

#1023 Compressed Air Plant
Building
507 10th Street
Sheppard AFB TX 76311
Landholding Agency: Air Force
Property Number: 18201340044
Status: Underutilized
Comments: 572 sq. ft.; storage; 52+ years old secured area; escort required to access property; contact Air Force for more information.

#2017 Petroleum Operations
Building
1402 K Avenue
Sheppard AFB TX 76311
Landholding Agency: Air Force
Property Number: 18201340045
Status: Underutilized
Comments: 1,811 sq. ft.; storage; 47 years old; secured area; escort required to gain access to property; contact Air Force for more information.

#1641 Be Maint Shop
Sheppard AFB
Sheppard TX 76311
Landholding Agency: Air Force
Property Number: 18201340046
Status: Underutilized
Comments: 1,546 sq. ft., storage; 40+ yrs.-old; secured area; escort required to access property; contact AF for more info.

Utah

Building 11; Hill AFB
5923 C Ave.
Layton UT 84056
Landholding Agency: Air Force
Property Number: 18201340047
Status: Excess
Comments: Off-site removal only; 18,898 sq. ft.; office/maint. shop; 72+ yrs.-old; deteriorated; asbestos; secured area; contact Air Force for more info.

Land

Alabama

(Former) Huntsville
International Airport (HSV) Outer Market
1390 Browns Ferry Road
Madison AL 35758
Landholding Agency: GSA
Property Number: 54201340008
Status: Excess
GSA Number: 4–U–AL–0787AA
Comments: 0.6 acres; outer marker; property can be accessed from Browns Ferry Road; contact GSA for more information.

Suitable/Unavailable Properties

Building

Oregon

Crescent Lehman Building, FS
Crescent Admin Site
Crescent OR
Landholding Agency: Agriculture
Property Number: 15201330017
Status: Excess
Comments: 518 sf. Conference room 81 yrs.-old; poor conditions; existing federal need Crescent Storage (Pumphouse)

Crescent Admin. Site
Crescent OR
Landholding Agency: Agriculture
Property Number: 15201330026
Status: Excess
Comments: 323 sf.; 46 yrs.-old; good condition; existing Federal need.

Unsuitable Properties

Building

Florida

MWR Rental Accommodation
Naval Air Station
Key West FL 33040
Landholding Agency: Navy
Property Number: 77201340011
Status: Unutilized
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons:
Secured Area

RV Park Office
Naval Air Station
Key West FL 33040
Landholding Agency: Navy
Property Number: 77201340012
Status: Unutilized
Comments: Public access denied & no alternative method to gain access w/out compromising national security.
Reasons:
Secured Area

Illinois

39 Shabbona-Material Dev. Lab
Fermi National Accelerator Lab
Batavia IL 60510
Landholding Agency: Energy
Property Number: 41201340008
Status: Excess
Comments: Public access denied & no alternative method to gain access w/out compromising national security
Reasons:
Secured Area

North Carolina

Building 21452
Ft. Bragg
FT. Bragg NC 28310
Landholding Agency: Army
Property Number: 21201340039
Status: Underutilized
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons:
Secured Area

Wisconsin

Coast Guard Cutter Mobile Bay
26 Neenah Avenue
Sturgeon Bay WI
Landholding Agency: Coast Guard
Property Number: 88201340005
Status: Excess
Comments: Active military facility; public access denied & no alternative method to gain access w/out compromising national security
Reasons:
Secured Area

[FR Doc. 2013–30703 Filed 12–26–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L61400000.ER0000/LLOR936000]

Renewal of Approved Information Collection

AGENCY: Bureau of Land Management, Interior.

ACTION: 30-day notice and request for comments.

SUMMARY: The Bureau of Land Management (BLM) has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information from private landowners in western Oregon who are authorized to transport timber over roads controlled by the BLM. The Office of Management and Budget (OMB) previously approved this information collection activity, and assigned it control number 1004–0168.

DATES: The OMB is required to respond to this information collection request within 60 days but may respond after 30 days. For maximum consideration, written comments should be received on or before January 27, 2014.

ADDRESSES: Please submit comments directly to the Desk Officer for the Department of the Interior (OMB #1004–0168), Office of Management and Budget, Office of Information and Regulatory Affairs, fax 202–395–5806, or by electronic mail at *OIRA_submission@omb.eop.gov*. Please provide a copy of your comments to the BLM. You may do so via mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: Jean_Sonneman@blm.gov.

Please indicate "Attn: 1004–0168" regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Dustin Wharton at 541–471–6659. Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, to leave a message for Mr. Wharton. You may also review the information collection request online at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (44 U.S.C. 3501–3521) and OMB regulations at 5 CFR part 1320 provide that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond. In order to obtain and renew an OMB control number, Federal agencies are required to seek public comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on September 16, 2013 (78 FR 56925), and the comment period ended November 15, 2013. The BLM received no public comments in response to this notice. The BLM now requests comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;
2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;
3. The quality, utility and clarity of the information to be collected; and
4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as directed under **ADDRESSES** and **DATES**. Please refer to OMB control number 1004–1068 in your correspondence. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information is provided for the information collection:

Title: Tramroads and Logging Roads (43 CFR part 2810).

OMB Control Number: 1004–0168.

Summary: This collection pertains to rights-of-way on public lands in western Oregon that were returned to the United States after being conveyed for construction of the Oregon & California Railroad. The BLM Oregon State Office has authority under the Act of August 28, 1937 (43 U.S.C. 1181a and 1181b) and subchapter V of the Federal Land Policy and Management Act (43 U.C.C. 1761–1771) to grant rights-of-way to private landowners to transport their timber over roads controlled by the BLM. The information collected under this control number enables the BLM to calculate and collect appropriate fees for this use of public lands.

Frequency of Collection: Annually, biannually, quarterly, or monthly, depending on the terms of the pertinent right-of-way.

Forms: Form 2812–6, Report of Road Use.

Description of Respondents: Private landowners who hold rights-of-way for the use of BLM-controlled roads in western Oregon.

Estimated Annual Responses: 272.

Estimated Annual Burden Hours: 2,176.

Estimated Annual Non-Hour Costs: None.

The estimated annual burdens for respondents are itemized in the following table:

A. Type of response and 43 CFR Citation	B. Number of responses	C. Hours per response	D. Total hours (column B × column C)
Form OR–2812–6, Report of Road Use 43 CFR 2812.3 and 43 CFR 2812.5	272	8	2,176
Total	272	8	2,176

Jean Sonneman,
Bureau of Land Management, Information Collection Clearance Officer.

[FR Doc. 2013–30993 Filed 12–26–13; 8:45 am]
BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY9300000 L16100000.DP0000.LXSISGST0000]

Notice of Availability of the Wyoming Greater Sage-Grouse Draft Land Use Plan Amendments and Draft Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) and the US Forest Service (USFS) have prepared the Wyoming Greater Sage-Grouse Draft Land Use Plan (LUP) Amendments and Draft Environmental Impact Statement (EIS) for the BLM Casper, Kemmerer, Newcastle, Pinedale, Rawlins, and Rock Springs field offices and Bridger-Teton National Forest, Medicine Bow National Forest, and Thunder Basin National Grassland Planning Units and by this notice is announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM and USFS must receive written comments on the Draft LUP Amendments/Draft EIS within 90 days following the date the Environmental Protection Agency publishes notice of the Draft LUP Amendments/Draft EIS in the **Federal Register**. The BLM and USFS will announce future meetings or hearings and any other public participation activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the Wyoming Greater Sage-Grouse Draft LUP Amendments/Draft EIS by any of the following methods:

- *Web site: www.blm.gov/wy/st/en/programs/Planning/amendments/sage-grouse.html*
- *Email: Sagegrouse_Amendment_WY@blm.gov*
- *Fax:* 307–775–6129
- *Mail:* BLM Wyoming State Office, 5353 Yellowstone Road, Cheyenne, WY 82003.

Copies of the Wyoming Greater Sage-Grouse Draft LUP Amendments/Draft EIS are available at the BLM Wyoming State Office at the above address or on the Web site at: *www.blm.gov/wy/st/en/programs/Planning/amendments/sage-grouse.html*

FOR FURTHER INFORMATION CONTACT: Lisa Solberg Schwab, Wyoming Greater Sage-Grouse Amendment Project Manager, by telephone, 307–367–5340; at the address above; or by email, *lsolbergschwab@blm.gov.*

Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM prepared the Wyoming Greater Sage-Grouse Draft LUP Amendments/Draft EIS to address a range of alternatives focused on specific conservation measures across the Wyoming range of the Greater Sage-grouse (GRSG). This Draft LUP Amendments/Draft EIS is one of 15 separate planning efforts that are being undertaken as part of the BLM and USFS National Greater Sage-grouse Planning Strategy. The Draft LUP Amendments/Draft EIS may amend the RMPs for the BLM Casper, Kemmerer, Newcastle, Pinedale, Rawlins and Rock Springs field offices, as well as the LRMPs for the Bridger-Teton and Medicine Bow National Forests and the Thunder Basin National Grassland. Current management decisions for resources are described in the following RMPs/LRMPs:

- Casper RMP (2007)
- Kemmerer RMP (2010)
- Newcastle RMP (2000)
- Pinedale RMP (2008)
- Rawlins RMP (2008)
- Green River RMP (1997) (being revised under the Rock Springs RMP)
- Bridger-Teton National Forest LRMP (1990)
- Medicine Bow National Forest LRMP (2003)
- Thunder Basin National Grassland LRMP (2002)

The EIS planning area includes approximately 40 million acres of BLM, National Park Service, USFS, U.S. Bureau of Reclamation, State, local, and private lands located in northwestern, southwestern, southeastern, and northeastern Wyoming in 11 counties (Albany, Carbon, Converse, Fremont, Lincoln, Natrona, Niobrara, Sublette, Sweetwater, Uinta and Weston). Within the EIS decision area, the BLM and the USFS administer approximately 16 million surface acres and 16 million acres of Federal oil and gas mineral (subsurface) estate. Surface management decisions made as a result of this Draft LUP Amendments/Draft EIS will apply only to the BLM- and the USFS-administered lands in the decision area. The decision area is defined as those BLM- and USFS-administered lands and Federal mineral estate within three categories of habitat identified by the Wyoming Game and Fish Department:

- Core Habitat—Areas identified as having the highest conservation value for maintaining sustainable GRSG populations, including breeding, late brood-rearing and winter concentration areas.
- General Habitat—Areas of seasonal or year-round habitat outside of priority habitat.
- Connectivity Habitat—Areas identified as broader regions of connectivity important to facilitating the movement of GRSG and maintain ecological processes.

The formal public scoping process for the LUP Amendments/EIS began on December 9, 2011, with the publication of a Notice of Intent in the **Federal Register** (76 FR 77008), and ended on March 23, 2012. The BLM held five scoping open houses in January and February 2011. The BLM used public scoping comments to help identify planning issues that directed the formulation of alternatives and framed the scope of analysis in the Draft LUP Amendments/Draft EIS. The scoping process was also used to introduce the public to preliminary planning criteria, which set limits on the scope of the Draft LUP Amendments/Draft EIS.

Major issues considered in the Draft LUP Amendments/Draft EIS include special status species management (GRSG specifically), energy and mineral development, lands and realty (including transmission), livestock grazing, fire, wild horses, vegetation management, special management areas (ACEC nominations), socioeconomics (particularly impacts to local communities) and invasive species.

The Draft LUP Amendments/Draft EIS evaluates five alternatives in detail, including the No Action Alternative (Alternative A) and four action alternatives (Alternatives B, C, D, and E). The BLM identified Alternative E as the preferred alternative. Identification of this alternative, however, does not represent final agency direction, and the Proposed LUP Amendments/Final EIS may reflect changes or adjustments based on information received during public comment, from other new information, or from changes in BLM policies or priorities. The Proposed LUP

Amendments/Final EIS may include objectives and actions described in the other analyzed alternatives or otherwise within the spectrum of the alternatives analyzed.

Alternative A would retain the current management goals, objectives, and direction specified in the current RMPs for each field office and the LRMPs for the Bridger-Teton, Medicine Bow, and Thunder Basin National Forests/Grasslands. Alternative B includes conservation measures from the Greater Sage-grouse National Technical Team Report. Alternative C includes conservation measures submitted by various conservation groups to the BLM. Alternative C also includes the proposed adoption of an Area of Critical Environmental Concern (ACEC). Alternatives D and E include conservation measures the BLM developed with the cooperating agencies.

Pursuant to 43 CFR 1610.7–2(b), this notice announces a concurrent public comment period on proposed ACECs. One ACEC is proposed in Alternative C. The Sage-grouse Habitat ACEC (approximately 9,876,565 acres) would include the following management prescriptions: Close to fluid mineral leasing; designate as a right-of-way exclusion area; close to livestock grazing; allow vegetation treatments only for the benefit of GRSG; and recommend withdrawal from mineral entry to the Secretary of the Interior.

Please note that public comments and information submitted including names, street addresses and email addresses of persons who submit comments will be available for public review and disclosure at the above address during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2

Donald A. Simpson,

State Director, Wyoming.

[FR Doc: 2013–30991 Filed 12–26–13; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L13100000–EI0000]

Notice of Filing of Plats of Survey; North Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on January 27, 2014.

DATES: Protests of the survey must be filed before January 27, 2014 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Blaise Lodermeier, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5128 or (406) 896–5009, *bloderme@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the BLM Montana State Office, Division of Resources, and was necessary to determine federal leasable mineral lands.

The lands we surveyed are:

Fifth Principal Meridian, North Dakota

T. 153 N., R. 93 W.

The plat, in three sheets, representing the supplemental plat of secs. 8, 18, 20, 26, 28, 33, and 35, showing the amended lottings, Township 153 North, Range 93 West, Fifth Principal Meridian, North Dakota, was accepted December 18, 2013.

T. 153 N., R. 98 W.

The plat, in four sheets, representing the supplemental plat of secs. 11, 12, 13, 14, 21, 22, 23, 24, 26, 27, 28, 29, 30, 31, and 32, showing the amended lottings, Township 153 North, Range 98 West, Fifth Principal Meridian, North Dakota, was accepted December 18, 2013.

T. 153 N., R. 100 W.

The plat, in four sheets, representing the supplemental plat of secs. 5, 6, 7, 8, 9, 27, 28, 29, 32, 33, 34, and 35, showing the amended lottings, Township 153 North, Range 100 West, Fifth Principal Meridian, North Dakota, was accepted December 20, 2013.

T. 154 N., R. 100 W.

The plat, in one sheet, representing the supplemental plat of sec. 31, showing the amended lottings, Township 154 North, Range 100 West, Fifth Principal Meridian, North Dakota, was accepted December 20, 2013.

T. 153 N., R. 101 W.

The plat, in four sheets, representing the supplemental plat of secs. 1, 6, 7, 17, 18, 19, 20, and 30, showing the amended lottings, Township 153 North, Range 101 West, Fifth Principal Meridian, North Dakota, was accepted December 23, 2013.

T. 154 N., R. 101 W.

The plat, in two sheets, representing the supplemental plat of secs. 25, 32, 33, 34, 35, and 36, showing the amended lottings, Township 154 North, Range 101 West, Fifth Principal Meridian, North Dakota, was accepted December 23, 2013.

We will place a copy of the plats, in 18 sheets, in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on these plats, in 18 sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file these plats, in 18 sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

Joshua F. Alexander,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2013–31059 Filed 12–26–13; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–DPOL–14067; PPWODIREP0; PPMPSPD1Y.YM0000]

Charter Renewal for the National Park System Advisory Board

AGENCY: National Park Service, Interior.

ACTION: Charter renewal.

SUMMARY: The Secretary of the Interior intends to renew the charter for the National Park System Advisory Board, in accordance with section 14(b) of the Federal Advisory Committee Act. This action is necessary and in the public interest in connection with the performance of statutory duties imposed upon the Department of the Interior and the National Park Service.

FOR FURTHER INFORMATION CONTACT: Shirley Sears, 202–354–3955.

SUPPLEMENTARY INFORMATION: The Board was established initially by section 3 of the Act of August 21, 1935 (49 Stat. 667; 16 U.S.C. 463), and has been in existence almost continuously since then. Pursuant to Public Law 111–8, the legislative authorization for the Board expired January 1, 2010. However, due to the importance of the issues on which the Board advises, the Secretary of the Interior exercised the authority contained in Section 3 of Public Law 91–383 (16 U.S.C. 1a–2 (c) to re-establish and continue the Board as a discretionary committee from January 1, 2010, until such time as it may be legislatively reauthorized. If the Board is reauthorized legislatively within 2 years of the date of the renewal charter, the Board will revert to a legislative Board.

The advice and recommendations provided by the Board and its subcommittees fulfill an important need within the Department of the Interior and the National Park Service, and it is necessary to re-establish the Board to ensure its work is not disrupted. The Board's twelve members will be balanced to represent a cross-section of disciplines and expertise relevant to the National Park Service mission. The renewal of the Board comports with the requirements of the Federal Advisory Committee Act, as amended.

Certification: I hereby certify that the renewal of the National Park System Advisory Board is necessary and in the public interest in connection with the performance of duties imposed on the Department of the Interior by the National Park Service Organic Act (16 U.S.C. 1 et seq.), and other statutes relating to the administration of the National Park Service.

Dated: December 18, 2013.

Sally Jewell,

Secretary of the Interior.

[FR Doc. 2013–31040 Filed 12–26–13; 8:45 am]

BILLING CODE 4310–EE–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–863]

Certain Paper Shredders, Certain Processes for Manufacturing or Relating to Same and Certain Products Containing Same and Certain Parts Thereof; Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on a Settlement Agreement, Consent Order, and Withdrawal of the Complaint; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 6) issued by the presiding administrative law judge ("ALJ") on November 20, 2013, terminating the investigation based on a settlement agreement, a consent order, and the withdrawal of the complaint.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 25, 2013, based on a complaint filed by Fellowes, Inc., and Fellowes Office Products (Suzhou) Co. Ltd. 78 FR 5496–97. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain shredders, by reason of the infringement of certain claims of U.S. Design Patent Nos. D583,859 and D598,048, and the misappropriation of certain trade secrets. The Commission's notice of investigation named as respondents New United Co. Group Ltd.; Jiangsu New United Office Equipments Co. Ltd.; Shenzhen Elite Business Office Equipment Co. Ltd.; Elite Business Machines Ltd.; New United Office Equipment USA, Inc.; Jiangsu Shinri Machinery Co. Ltd. (collectively, the "New United" respondents); and the individuals Zhou Licheng, Randall Graves, and "Jessica" Wang Chongge (collectively, the "Individual" respondents). The Office of Unfair Import Investigation ("OUII") was named a party to the investigation.

On November 7, 2013, all complainants and respondents ("the private parties") jointly moved to terminate the investigation. The private parties moved to terminate the investigation with respect to the New United respondents based on a settlement agreement and consent order, and to terminate the investigation with respect to the Individual respondents based on a withdrawal of the complaint. The private parties attached a Consent Order Stipulation, a Proposed Consent Order, and a Settlement Agreement to their motion, and represented that there are no other agreements, written or oral, express or implied between the parties concerning the subject matter of the investigation. On November 18, 2013, OUII filed a response supporting the motion.

On November 20, 2013, the ALJ issued the subject ID, granting the motion and terminating the investigation. The ALJ found that the motion complied with Commission rules, and that the public interest factors did not weigh against granting the motion.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 20, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–30959 Filed 12–26–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–895]

Certain Multiple Mode Outdoor Grills and Parts Thereof; Commission Determination Not To Review an Initial Determination Granting Complainant's Motion To Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 12) granting the Complainant's motion to amend the Complaint and the Notice of Investigation.

FOR FURTHER INFORMATION CONTACT: Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 26, 2013, based on a complaint filed on behalf of A&J Manufacturing, LLC of St. Simons, Georgia and A&J Manufacturing, Inc. of Green Cove Springs, Florida. 78 FR 59373 (Sept. 26, 2013). The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the sale for importation, importation, or sale within the United States after importation of certain multiple mode outdoor grills and parts thereof by reason of infringement of certain claims of U.S. Patent No. 8,381,712, U.S. Patent No. D660,646, and U.S. Patent No. D662,773 patent. The Commission's notice of investigation named as respondents Kamado Joe Company of Duluth, Georgia; Outdoor Leisure Products, Incorporated of Neosho, Missouri; Rankam Group of Gardena, California; Academy Ltd., d/b/a/Academy Sports + Outdoors of Katy, Texas; HEB Grocery Company, LP, d/b/a H–E–B of San Antonio, Texas; Kmart Corporation of Hoffman Estates, Illinois; Sears Brands Management Corporation, Sears Holdings Corporation, and Sears, Roebuck & Company, all of Hoffman Estates, Illinois; Tractor Supply Company of Brentwood, Tennessee; Guangdong Canbo Electrical Co., Ltd. of Foshan City, China; Chant Kitchen Equipment (HK), Ltd. of Jordan, Hong Kong; Dongguan Kingsun Enterprises Co., Ltd. of Dongguan City, China; Zhejiang Fudeer Electric Appliance Co., Ltd. of Taizhou Economic Development Zone, China; Ningbo Huige Outdoor Products Co., Ltd. of Fenghua City, China; Keesung Manufacturing Co., Ltd. of Panyu, China; Ningbo Spring Communication Technologies Co. Ltd. of Ningbo, China; Wuxi Joyray International Corporation of Wuxi, China; The Brinkmann Corporation of Dallas, Texas; W.C. Bradley Company of Columbus, Georgia; and GHP Group, Incorporated of Morton Grove, Illinois.

On November 19, 2013, Complainants filed an unopposed motion to amend the Complaint and Notice of Investigation. Complainants A&J sought to amend the Complaint and Notice of Investigation to (1) change the name of Respondent Kamado Joe Company to Premier Specialty Brands, LLC, (2) change the name of Respondent Rankam Group to Rankam Metal Products Manufactory Limited, USA, and (3) substitute Char-Broil, LLC for Respondent W.C. Bradley Co. A&J represented that Kamado Joe Company is a trade name for the legal entity Premier Specialty Brands, LLC; Rankam Metal Products Manufactory Limited, USA is the correct legal name for Rankam Group; and Char-Broil, LLC is a wholly owned subsidiary of W.C. Bradley Co.

On December 4, 2013, the ALJ granted the motion. The ALJ found that good cause exists to amend the Complaint and Notice of Investigation to correct the names of two of the Respondents and substitute Char-Broil, LLC for W.C. Bradley Co. to prevent confusion among the parties and the public by identifying the correct legal names of the parties in interest. The ALJ also found that the attorneys for the corrected parties were served in compliance with Commission Rule 210.14(b)(1). No petitions for review were filed.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

By order of the Commission.

Issued: December 23, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–31056 Filed 12–26–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–509 and 731–TA–1244 (Preliminary)]

1,1,1,2-Tetrafluoroethane From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (Commission) determines, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)) (the Act), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports from China of 1,1,1,2-Tetrafluoroethane, provided for in subheadings 2903.39.20 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value ("LTFV"), and by reason of 1,1,1,2-Tetrafluoroethane that are allegedly subsidized by the Government of China.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (Commerce) of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On October 22, 2013, a petition was filed with the Commission and Commerce by Mexichem Fluor Inc., St. Gabriel, LA, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV and subsidized imports of 1,1,1,2-Tetrafluoroethane from China. Accordingly, effective October 22, 2013, the Commission instituted countervailing duty investigation No. 701–TA–509 and antidumping duty investigation No. 731–TA–1244 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 28, 2013 (78 FR 64243). The conference was held in Washington, DC, on November 12, 2013, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on December 13, 2013. The views of the Commission are contained in USITC Publication 4444 (December 2013), entitled *1,1,1,2-Tetrafluoroethane from China, Investigation Nos. 701–TA–509 and 731–TA–1244 (Preliminary).*

Issued: December 20, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–30958 Filed 12–26–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree under the Clean Water Act

On December 19, 2013, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Connecticut in the lawsuit entitled *United States* v. *City of West Haven, Connecticut,* Civil Action No. 3:13–cv–01883–JCH.

In the Complaint the United States, on behalf of the U.S. Environmental Protection Agency (EPA), alleges that the defendant City of West Haven ("West Haven") violated the Clean Water Act ("CWA"), 33 U.S.C. 1251, et seq., and applicable regulations relating to West Haven's unauthorized discharges from the waste water collection system owned and operated by the City. Specifically, the United States alleges that on numerous occasions between January 1, 2007, and December 31, 2011, the collection system experienced sanitary sewer overflows ("SSOs"), resulting in the discharge of untreated municipal wastewater containing pollutants from unpermitted point sources to waters of the United States. The Consent Decree requires West Haven to pay a civil penalty of $125,000 in three installments, with interest, divided between the United States and the State of Connecticut, and to undertake various measures to study and correct the problems causing the SSOs in order to achieve compliance with the CWA and applicable regulations.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *City of West Haven, Connecticut,* D.J. Ref. No. 90–5–1–1–10543. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $13.00 (25 cents per page reproduction cost), not including Appendices, payable to the United States Treasury.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 2013–31032 Filed 12–26–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0024]

Proposed Information Collection; Application for Waiver of Surface Sanitary Facilities' Requirements (Pertaining to Coal Mines)

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on Application for Waiver of Surface Sanitary Facilities' Requirements (Pertaining to Coal Mines).

DATES: All comments must be postmarked or received by midnight Eastern Standard Time on February 25, 2014.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the

on-line instructions for submitting comments for docket number [MSHA–2013–0038].

• *Regular Mail:* Send comments to MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, VA 22209–3939

• *Hand Delivery:* MSHA, 1100 Wilson Boulevard, Room 2176, Arlington, VA.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Deputy Director, Office of Standards, Regulations, and Variances, MSHA, at MSHA.information.collections@dol.gov (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813, authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners.

Title 30 CFR 71.400 through 71.402 and 75.1712–1 through 75.1712–3 require coal mine operators to provide bathing facilities, clothing change rooms, and sanitary flush toilet facilities in a location that is convenient for use of the miners. If the operator is unable to meet any or all of the requirements, he/she may apply for a waiver. Title 30 CFR 71.403, 71.404, 75.1712–4, and 75.1712–5 provide procedures by which an operator may apply for and be granted a waiver. Applications are filed with the District Manager for the district in which the mine is located and must contain the name and address of the mine operator, name and location of the mine, and a detailed statement of the grounds on which the waiver is requested.

Waivers for surface mines may be granted by the District Manager for a period not to exceed one year. If the waiver is granted, surface mine operators may apply for annual extensions of the approved waiver. Waivers for underground mines may be granted by the District Manager for the period of time requested by the underground mine operator as long as the circumstances that were used to justify granting the waiver remain in effect. Waivers are not transferable to a successor coal mine operator.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to the Application for Waiver of Surface Sanitary Facilities' Requirements (Pertaining to Coal Mines). MSHA is particularly interested in comments that:

• Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

• Evaluate the accuracy of the MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

• Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This information collection request is available on *http://www.msha.gov/regs/fedreg/informationcollection/informationcollection.asp*. The information collection request will be available on MSHA's Web site and on *http://www.regulations.gov*. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov*.

The public may also examine publicly available documents at MSHA, 1100 Wilson Boulevard, Room 2176, Arlington, VA 22209–3939.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This request for collection of information contains provisions for the Application for Waiver of Surface Sanitary Facilities' Requirements (Pertaining to Coal Mines). MSHA has updated the data in respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0024.

Affected Public: Business or other for-profit.

Number of Respondents: 887.

Frequency: On occasion.

Number of Responses: 887.

Annual Burden Hours: 368 hours.

Annual Respondent or Recordkeeper Cost: $4,435.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: December 20, 2013.

George F. Triebsch,

Certifying Officer.

[FR Doc. 2013–30948 Filed 12–26–13; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0003]

Proposed Information Collection; Radiation Sampling and Exposure Records (Pertains to Underground Metal and Nonmetal Mines)

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the proposed information collection for updating Radiation Sampling and Exposure Records.

DATES: All comments must be postmarked or received by midnight Eastern Standard Time on February 25, 2014.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

• *Federal E-Rulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments for docket number [MSHA–2013–0003].

• *Regular Mail or Hand Delivery:* MSHA, Office of Standards,

Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, VA 22209–3939. Sign in at the receptionist's desk on the 21st floor.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Deputy Director, Office of Standards, Regulations, and Variances, MSHA, at *McConnell.Sheila.A@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Under the authority of Section 103 of the Federal Mine Safety and Health Act of 1977, MSHA is required to issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act.

Airborne radon and radon daughters exist in every uranium mine and in several other underground mining commodities. Radon is radioactive gas. It diffuses into the underground mine atmosphere through the rock and the ground water. Radon decays in a series of steps into other radioactive elements, which are solids, called radon daughters. Radon and radon daughters are invisible and odorless. Decay of radon and its daughters results in emissions of alpha energy.

Medical doctors and scientists have associated high radon daughter exposures with lung cancer. The health hazard arises from breathing air contaminated with radon daughters which are in turn deposited in the lungs. The lung tissues are sensitive to alpha radioactivity.

The amounts of airborne radon daughters to which most miners can be exposed with no adverse effects have been established and are expressed as working levels (WL). The current MSHA standard is a maximum personal exposure of 4 working level months (WLM) per year.

Excess lung cancer in uranium miners, just as coal workers' pneumoconiosis, silicosis, and other debilitating occupational diseases, has been recognized for many years. Thus, an adequate base of accurate exposure level data is essential to control miners' exposures and permit an evaluation of the effectiveness of existing regulations.

The standard at 30 CFR 57.5037 established the procedures to be used by the mine operator in sampling mine air for the presence and concentrations of radon daughters. Operators are required to conduct weekly sampling where concentrations of radon daughters exceed 0.3 WL. Sampling is required bi-weekly where uranium mines have readings of 0.1 WL to 0.3 WL and every 3 months in non-uranium underground mines where the readings are 0.1 WL to 0.3 WL. Mine operators are required to keep records of all mandatory samplings. Records must include the sample date, location, and results, and must be retained at the mine site or nearest mine office for at least 2 years.

The standard at 30 CFR 57.5040 requires mine operators to calculate and record individual exposures to radon daughters on MSHA Form 4000–9 "Record of Individual Exposure to Radon Daughters". The calculations are based on the results of the weekly sampling required by 30 CFR 57.5037. Records must be maintained by the operator and submitted to MSHA annually.

II. Desired Focus of Comments

MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of the MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This information collection request is available on *http://www.msha.gov/regs/fedreg/informationcollection/informationcollection.asp*. The information collection request will be available on MSHA's Web site and on *http://www.regulations.gov*. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov*.

The public may also examine publicly available documents at MSHA, 1100 Wilson Boulevard, Room 2176, Arlington, VA.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

III. Current Actions

This request for collection of information contains provisions for the Proposed Information Collection Request, Radiation Sampling and Exposure Records. MSHA has updated the data in respect to the number of respondents and responses, as well as the total burden hours and burden costs supporting this information collection request.

Type of Review: Extension.
Agency: Mine Safety and Health Administration.
Title: Radiation Sampling and Exposure Records (pertains to underground metal and nonmetal mines).
OMB Number: 1219–0003.
Affected Public: Business or other for-profit.
Form: MSHA Form 4000–9.
Total Number of Respondents: 5.
Frequency: Various.
Total Number of Responses: 505.
Total Burden Hours: 502 hours.
Total Annual Respondent or Recordkeeper Cost Burden: $25.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: December 20, 2013.

George F. Triebsch,

Certifying Officer.

[FR Doc. 2013–30922 Filed 12–26–13; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[Docket Number MSHA–2013–0037]

Criteria to Certify Coal Mine Rescue Teams

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice informs the public that the Mine Safety and Health Administration (MSHA) has updated the coal mine rescue team certification criteria. The Mine Improvement and New Emergency Response (MINER) Act of 2006 requires MSHA to update these criteria every five years. One of the criteria for a mine operator to certify the qualifications of a coal mine rescue team is that team members are properly

trained annually. MSHA has updated the prescribed instruction guides for annual training of coal mine rescue teams to provide improved advanced mine rescue training by including more hands-on skills training to enhance team performance when responding to an actual mine emergency.

FOR FURTHER INFORMATION CONTACT: George F. Triebsch, Director, Office of Standards, Regulations, and Variances, MSHA, at *triebsch.george@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Background

Under title 30 of the Code of Federal Regulations (30 CFR) part 49, underground coal mine operators must designate at least two mine rescue teams to provide mine rescue coverage at an underground coal mine at all times when miners are underground. Underground coal mine operators must annually certify the qualifications of these designated teams. MSHA provides the criteria for certifying the qualifications of coal mine rescue teams under 30 CFR 49.50.

Initial criteria to certify the qualifications of coal mine rescue teams under 30 CFR 49.50 are: (1) Team is available at all times when miners are underground; (2) Except where alternative compliance is permitted, team has five members and one alternate; (3) Members have experience working in an underground coal mine; (4) Team is available within 1-hour ground travel time from the mine rescue station to the mine; (5) Appropriate mine rescue equipment is provided, inspected, tested, and maintained; (6) Members are physically fit; and (7) Members have completed initial training.

The annual criteria to maintain mine rescue team certification under 30 CFR 49.50 are: (1) Members are properly trained annually; (2) Members are familiar with the operations of each covered mine; (3) Members participate in at least two local mine rescue contests annually; (4) Members participate in mine rescue training at each covered mine; and (5) Members are knowledgeable about the operations and ventilation of each covered mine.

The MINER Act requires MSHA to update the criteria to certify the qualifications of mine rescue teams every five years. The revised instruction guides do not change the certification criteria listed above, but rather update the prescribed training that team members need annually to be properly trained. The specific annual training requirements are listed at 30 CFR 49.18(b).

II. Revision of Instruction Guides

The annual training requirements for coal mine rescue teams include § 49.18(b)(4), which requires advanced mine rescue training and procedures as prescribed by MSHA's Office of Educational Policy and Development (EPD). Under this requirement, EPD currently prescribes Instruction Guide IG7, "Advanced Mine Rescue Training—Coal Mines," which includes best practices, handouts, visuals, and text materials for the classroom and activities or exercises for practice using equipment and developing teamwork.

To update this prescribed training, the existing lessons and exercises from the current Instruction Guide IG7 were reorganized and Instruction Guide IG7a, containing new practical exercises, was added. The materials for classroom training are retained as Instruction Guide IG7, "Advanced Mine Rescue Training—Coal Mines," and the practice exercises are moved to new Instruction Guide IG7a, "Advanced Skills Training—Activities for Coal Mine Rescue Teams." Instruction Guide IG7a also contains new exercises to assure practice on skills a team would need in a mine emergency, as well as expectations training.

MSHA published a notice in the **Federal Register** (78 FR 58567) announcing the availability of the revised instruction guides on the Agency's Web site and soliciting comments to assure that the revised instruction guides would improve the quality and effectiveness of instruction and skills training for coal mine rescue teams. The comment period closed on November 25, 2013.

MSHA received five comments from industry, state government, academia, and a mine rescue association. One commenter stated that IG7a provides a good basic format for mine rescue trainers to quickly develop training exercises for their mine rescue teams. This commenter stated that the expectations training in IG7a was important and recommended that MSHA add an expectation that team members can expect delays in movement and exploration in an actual emergency. MSHA recognizes that it is important for team members to expect delays when exploring in an actual emergency due to the time needed to coordinate their movements with the Command Center. MSHA added this expectation to IG7a.

A commenter stated that IG7a should include an exercise in the actual construction of ventilation controls. There are several different types of ventilation controls used in underground coal mining and they vary from mine to mine. In MSHA's experience, training in ventilation controls, already included in IG7, appropriately addresses how to construct a variety of ventilation controls, including temporary and permanent stoppings, air locks, and line brattice.

Another commenter stated that teams would be better trained if the training consisted of actually putting out a fire, being exposed to heat and dense smoke, and spending more time preparing for an actual emergency. MSHA believes that the exercises prescribed in IG7a will provide appropriate training in smoke, fire hose management, and firefighting.

A commenter stated that MSHA should revise IG7a to include a statement that all skills covered in Instruction Guide IG7a can be achieved by participating in a skills contest. Another commenter stated that its teams perform the exercises prescribed in IG7a through participation in a skills contest. MSHA does not require participation in a skills contest. MSHA believes, however, that skills contests provide a valuable training experience for mine rescue teams and encourages teams to participate in these contests. Participation in a skills contest can satisfy the training in IG7a, as long as an exercise is included for each skill area prescribed in IG7a.

A commenter stated that MSHA should revise IG7a to include a smoke tube exercise. This commenter also provided recommendations for additional materials that MSHA should list as needed for several exercises. MSHA revised IG7a to include a smoke tube exercise in which tubes filled with a visible chemical smoke are opened and the escaping smoke is carried away by any air flow. In the Agency's experience, smoke tube training will help prepare teams to determine the ventilation direction and measure speed in areas with low air velocity, which may be encountered in a mine emergency. Where appropriate, MSHA also revised the list of materials needed.

Another commenter stated that the fire hose management and firefighting exercises contained in IG7a are not practical for anthracite mine rescue teams because: (1) Of the coal seam's extreme pitch; (2) anthracite coal requires more heat to combust; (3) anthracite dust does not propagate an explosion; and (4) there are no anthracite mines with electrical face equipment.

MSHA recognizes that underground anthracite mines are unique. Revised IG7a does not include fire hose management or firefighting exercises for mine rescue teams for anthracite coal mines that have no electrical equipment at the face or working section. In MSHA's experience, a mine rescue team would use fire extinguishers, rather than hoses, to fight a fire in an underground anthracite mine due to the pitch of the entry. MSHA believes that appropriate training in the use of fire extinguishers is already provided through the Emergency Response Plans at anthracite mines.

Some commenters stated that the existing requirement that teams train at covered mines two times per year be revised to require training once per year. This requirement was a provision of the MINER Act and is outside the scope of this notice. Another commenter suggested that MSHA revise the guidelines for Mine Emergency Response Drills (MERD) to allow for rescue training in the MERD format without three total teams and a declared winner. Under the existing standard, a local mine rescue contest can be a MERD exercise or a practical simulation exercise. If a mine operator choses a MERD exercise to satisfy the requirements for a local mine rescue contest, the MERD exercise must have three teams and a winner.

In MSHA's experience, revised Instruction Guide IG7 and new Instruction Guide IG7a are resources that will assist coal mine rescue team trainers in providing team members with the necessary knowledge and skills to respond effectively in the event of an emergency. Changes in mine rescue team technologies and practices may necessitate changes in advance mine rescue skills training. When these changes become available, MSHA will provide the public an opportunity to comment.

Beginning in 2014, coal mine rescue teams must complete advanced skills training prescribed in IG7 and IG7a to be properly trained under the criteria for certification of coal mine rescue teams in 30 CFR 49.50.

The comments and the final instruction guides for advanced mine rescue training of coal mine rescue teams are posted on *www.regulations.gov* (docket number MSHA–2013–0037) and on MSHA's Web site at *http://www.msha.gov/MineRescue/Training/TeamTraining.asp.*

Authority: 30 U.S.C. 811, 825(e).

Dated: December 23, 2013.

Joseph A. Main,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 2013–31033 Filed 12–26–13; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB Review; Comment Request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. This is the second notice for public comment; the first was published in the **Federal Register** at 78 FR 22916, and one comment was received. NSF is forwarding the proposed renewal submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission (including comments) may be found at: *http://www.reginfo.gov/public/do/PRAMain.* Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725 17th Street NW., Room 10235, Washington, DC 20503, and to Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 1265, Arlington, Virginia 22230 or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling 703–292–7556.

NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

SUPPLEMENTARY INFORMATION:

Comments: As required by 5 CFR 1320.8(d), comments on the information collection activities as part of this study were solicited through publication of a 60-Day Notice in the **Federal Register** on April 17, 2013, at 78 FR 22916. We received one comment, to which we here respond.

Commenter: The Council on Governmental Relations (COGR) raised a general concern that additional reporting requirements presented added burden on their members.

Response: The reporting requirements and estimates on the hourly burden were discussed with the management of the Centers. Center Directors and their management staff, the primary respondents to this data collection, were consulted for feedback on the availability of data, frequency of data collection, the clarity of instructions, and the data elements. Their feedback confirmed that the frequency of data collection was appropriate and that they did not provide these data in other data collections. After consideration of this comment, we are moving forward with our submission to OMB.

Title of Collection: Grantee Reporting Requirements for National user facilities managed by the NSF Division of Materials Research.

OMB Approval Number: 3145—NEW.

Type of Request: Intent to seek approval to establish an information collection.

Abstract: The NSF Division of Materials Research (DMR) supports a number of National user facilities that provide specialized capabilities and instrumentation to the scientific community on a competitive proposal basis. In addition to the user program, these facilities support in-house research, development of new instrumentation or techniques, education, and knowledge transfer.

The facilities integrate research and education for students and post-docs

involved in experiments, and support extensive K–12 outreach to foster an interest in Science Technology Engineering and Mathematics (STEM) and STEM careers. Facilities capitalize on diversity through participation in center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering. National User Facilities will be required to submit annual reports on progress and plans, which will be used as a basis for performance review and determining the level of continued funding. User facilities will be required to develop a set of management and performance indicators for submission annually to NSF via the Research Performance Project Reporting (RPPR) module in Research.gov. These indicators are both quantitative and descriptive and may include, for example, lists of successful proposal and users, the characteristics of facility personnel and students; sources of financial support and in-kind support; expenditures by operational component; research activities; education activities; knowledge transfer activities; patents, licenses; publications; degrees granted to students supported through the facility or users of the facility; descriptions of significant advances and other outcomes of this investment. Such reporting requirements are included in the cooperative agreement, which is binding between the academic institution and the NSF.

Each facility's annual report will address the following categories of activities: (1) Research, (2) education, (3) knowledge transfer, (4) partnerships, (5) diversity, (6) management, and (7) budget issues. For each of the categories the report will describe overall objectives and metrics for the reporting period, challenges or problems the facility has encountered in making progress towards goals, anticipated problems in the following year, and specific outputs and outcomes. Facilities are required to file a final report through the RPPR. Final reports contain similar information and metrics as annual reports, but are retrospective.

Use of the Information: NSF will use the information to continue funding of the DMR national user facilities, and to evaluate the progress of the program.

Estimate of Burden: 790 hours per facility for three national user facilities for a total of 2,370 hours.

Respondents: Non-profit institutions.

Estimated Number of Responses per Report: One from each of the DMR user facilities.

Dated: December 20, 2013.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2013–30869 Filed 12–26–13; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB Review; Comment Request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. This is the second notice for public comment; the first was published in the **Federal Register** at 78 FR 22916, and one comment was received. NSF is forwarding the proposed renewal submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission (including comments) may be found at: *http://www.reginfo.gov/public/do/PRAMain*. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725 17th Street NW., Room 10235, Washington, DC 20503, and to Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 1265, Arlington, Virginia 22230 or send email to *splimpto@nsf.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling 703–292–7556.

NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

SUPPLEMENTARY INFORMATION:

Comments: As required by 5 CFR 1320.8(d), comments on the information collection activities as part of this study were solicited through publication of a 60-Day Notice in the **Federal Register** on April 17, 2013, at 78 FR 22916. We received one comment, to which we here respond.

Commenter: The Council on Governmental Relations (COGR) raised a general concern that additional reporting requirements presented added burden on their members.

Response: The reporting requirements and estimates on the hourly burden were discussed with the management of the Centers. Center Directors and their management staff, the primary respondents to this data collection, were consulted for feedback on the availability of data, frequency of data collection, the clarity of instructions, and the data elements. Their feedback confirmed that the frequency of data collection was appropriate and that they did not provide these data in other data collections. After consideration of this comment, we are moving forward with our submission to OMB.

Title of Collection: Grantee Reporting Requirements for National user facilities managed by the NSF Division of Materials Research.

OMB Approval Number: 3145—NEW.

Type of Request: Intent to seek approval to establish an information collection.

Abstract: The NSF Division of Materials Research (DMR) supports a number of National user facilities that provide specialized capabilities and instrumentation to the scientific community on a competitive proposal basis. In addition to the user program, these facilities support in-house research, development of new instrumentation or techniques, education, and knowledge transfer.

The facilities integrate research and education for students and post-docs

involved in experiments, and support extensive K–12 outreach to foster an interest in Science Technology Engineering and Mathematics (STEM) and STEM careers. Facilities capitalize on diversity through participation in center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering. National User Facilities will be required to submit annual reports on progress and plans, which will be used as a basis for performance review and determining the level of continued funding. User facilities will be required to develop a set of management and performance indicators for submission annually to NSF via the Research Performance Project Reporting (RPPR) module in Research.gov. These indicators are both quantitative and descriptive and may include, for example, lists of successful proposal and users, the characteristics of facility personnel and students; sources of financial support and in-kind support; expenditures by operational component; research activities; education activities; knowledge transfer activities; patents, licenses; publications; degrees granted to students supported through the facility or users of the facility; descriptions of significant advances and other outcomes of this investment. Such reporting requirements are included in the cooperative agreement, which is binding between the academic institution and the NSF.

Each facility's annual report will address the following categories of activities: (1) Research, (2) education, (3) knowledge transfer, (4) partnerships, (5) diversity, (6) management, and (7) budget issues. For each of the categories the report will describe overall objectives and metrics for the reporting period, challenges or problems the facility has encountered in making progress towards goals, anticipated problems in the following year, and specific outputs and outcomes. Facilities are required to file a final report through the RPPR. Final reports contain similar information and metrics as annual reports, but are retrospective.

Use of the Information: NSF will use the information to continue funding of the DMR national user facilities, and to evaluate the progress of the program.

Estimate of Burden: 790 hours per facility for three national user facilities for a total of 2,370 hours.

Respondents: Non-profit institutions.

Estimated Number of Responses per Report: One from each of the DMR user facilities.

Dated: December 20, 2013.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2013–30889 Filed 12–26–13; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Computer and Information Science and Engineering Notice of Meeting

In accordance with Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

NAME: Advisory Committee for Computer and Information Science and Engineering (1115)

DATE/TIME: January 14, 2014, 3:00 p.m. to 5:00 p.m.

PLACE: National Science Foundation, 4201 Wilson Boulevard, Room 375, Arlington, Virginia 22203

TYPE OF MEETING: Open

CONTACT PERSON: Carmen Whitson, National Science Foundation, 4201 Wilson Boulevard, Suite 1105, Arlington, Virginia 22203 703/292–8900

PURPOSE OF MEETING: To advise NSF on the impact of its policies, programs and activities on the CISE community. To provide advice to the Assistant Director for CISE on issues related to long-range planning, and to form ad hoc subcommittees and working groups to carry out needed studies and tasks.

AGENDA:

- CISE programmatic updates
- Update from Advisory Committee subcommittees
- Status of Fiscal Year 2014 activities
- Closing remarks and wrap up

Dated: December 20, 2013.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2013–30911 Filed 12–26–13; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2013–0167]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* DOE/NRC Form 741, Nuclear Material Transaction Report and NUREG/BR–0006, Revision 7, "Instructions for Completing Nuclear Material Transaction Reports."

2. *Current OMB approval number:* 3150–0003.

3. *How often the collection is required:* Form 741 is submitted when specified events occur (nuclear materials or source material transfers, receipts, or inventory changes).

4. *Who is required or asked to report:* Persons licensed to possess specified quantities of special nuclear material or source material. Any licensee who ships, receives, or otherwise undergoes an inventory change of special nuclear or source material is required to submit a Form 741 to document the change.

5. *The number of annual respondents: 340.*

6. *The number of hours needed annually to complete the requirement or request:* 12,500.

7. *Abstract:* NRC is required to collect nuclear material transaction information for domestic safeguards use and make it available to the International Atomic Energy Agency (IAEA). Licensees use Form 741 to make inventory and accounting reports for certain source or special nuclear material, or for transfer or receipt of 1 kilogram or more of course material. This form enables the NRC to collect, retrieve, analyze, and submit the data to IAEA to fulfill its reporting responsibilities.

Submit, by February 25, 2014 comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/*. The document will be available on the NRC's home page site for 60 days after the signature date of this notice.

Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2013–0167. You may submit your comments by any of the following methods: Electronic comments go to *http://www.regulations.gov* and search for Docket No. NRC–2013–0167. Mail comments to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV*.

Dated at Rockville, Maryland, this 20th day of December, 2013.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2013–31030 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2013–0206]

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on September 12, 2013 (78 FR 56247). No comments were received.

1. *Type of submission, new, revision, or extension:* Extension.

2. *The title of the information collection:* NRC Form 314, Certificate of Disposition of Materials.

3. *Current OMB approval number:* 3150–0028.

4. *The form number if applicable:* NRC Form 314.

5. *How often the collection is required:* This form is submitted once, when a licensee terminates its license.

6. *Who will be required or asked to report:* Persons holding an NRC license for the possession and use of radioactive byproduct, source, or special nuclear material who are ceasing licensed activities and terminating the license.

7. *An estimate of the number of annual responses:* 136.

8. *The estimated number of annual respondents:* 136.

9. *An estimate of the total number of hours needed annually to complete the requirement or request:* 68.

10. *Abstract:* NRC Form 314 furnishes information to the NRC regarding transfer or other disposition of radioactive material by licensees who wish to terminate their licenses. The information is used by the NRC as part of the basis for its determination that the facility has been cleared of radioactive material before the facility is released for unrestricted use.

The public may examine and have copied for a fee publicly available documents, including the final supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/*. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by January 27, 2014. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Chad Whiteman, Desk Officer, Office of Information and Regulatory Affairs (3150–0028), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be emailed to *Chad_S_Whiteman@omb.eop.gov* or submitted by telephone at 202–395–4718.

The NRC Clearance Officer is Tremaine Donnell, telephone: 301–415–6258.

Dated at Rockville, Maryland, this 19th day of December, 2013.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2013–31031 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2013–0166]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* DOE/NRC Form 740M, "Concise Note" and NUREG/BR–0006, Revision 7, "Instructions for Completing Nuclear Material Transaction Reports, (DOE/NRC Forms 741 and 740M)."

2. *Current OMB approval number:* 3150–0057.

3. *How often the collection is required:* DOE/NRC Form 740M is requested as necessary to inform the U.S. or the International Atomic Energy Agency (IAEA) of any qualifying statement or exception to any of the data contained in other reporting forms required under the U.S.—IAEA Safeguards Agreement.

4. *Who is required or asked to report:* Persons licensed to possess specified

quantities of special nuclear material or source material, and licensees of facilities on the U.S. Eligible Facilities List who have been notified in writing by the NRC that they are subject to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR).

5. *The number of annual respondents:* 15.

6. *The number of hours needed annually to complete the requirement or request:* 113.

7. *Abstract:* Licensees affected by Part 75 and related sections of Parts 40, 50, 70, and 150 are required to submit DOE/NRC Form 740M to inform the U.S. or the IAEA of any qualifying statement or exception to any of the data contained in any of the other reporting forms required under the U.S.—IAEA Safeguards Agreement. The use of the Form 740M enables the NRC to collect, retrieve, analyze, and submit the data to IAEA to fulfill its reporting responsibilities.

Submit, by February 25, 2014, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.*

The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

Comments submitted should reference Docket No. NRC–2013–0166. You may submit your comments by any of the following methods: Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2013–0166. Mail comments to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 19th day of December, 2013.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2013–31029 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2013–0270]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* Comprehensive Decommissioning Program, Including Annual Data Collection.

2. *Current OMB approval number:* 3150–0206.

3. *How often the collection is required:* Annually.

4. *Who is required or asked to report:* All Agreement States who have signed Section 274(b) Agreements with the NRC.

5. *The number of annual respondents:* 37 (14 Agreement States respondents with sites of interest + 23 Agreement States respondents with no sites of interest).

6. *The number of hours needed annually to complete the requirement or request:* 469 (400 hours from Agreement States with sites of interest + 69 hours from Agreement States with no sites of interest).

7. *Abstract:* Agreement States will be asked to provide information about uranium recovery and complex sites undergoing decommissioning regulated by the Agreement States on an annual basis. The information request will allow the NRC to compile, in a centralized location, more complete information on the status of decommissioning and decontamination in the United States in order to provide a national perspective on decommissioning. The information will be made available to the public by the NRC in order to ensure openness and promote communication to enhance public knowledge of the national decommissioning program. This does not apply to information, such as trade secrets and commercial or financial information provided by the Agreement States, that is considered privileged or confidential. Information such as financial assurance and the status of decommissioning funding would need to be identified by the Agreement State as privileged or confidential, whereupon the NRC would withhold such information from public access and treat it as sensitive or non-sensitive, per the considerations in 10 CFR 2.390 and 9.17. This does not apply to financial assurance or decommissioning funding information that is already available to the public. Although specific details of the funding mechanisms are treated as confidential, beneficial lessons learned regarding the improvement of decommissioning-related funding will be shared with the Agreement States.

Submit, by February 25, 2014, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at

the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/*. The document will be available on the NRC's home page site for 60 days after the signature date of this notice.

Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2013–0270. You may submit your comments by any of the following methods: Electronic comments go to *http://www.regulations.gov* and search for Docket No. NRC–2013–0270. Mail comments to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV*.

Dated at Rockville, Maryland, this 20th day of December, 2013.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2013–31028 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–295 and 50–304; NRC–2011–0145]

Zion Solutions, LLC; Zion Nuclear Power Station, Units 1 and 2; Exemption From Certain Physical Security Requirements

1.0 Background

Zion Nuclear Power Station (ZNPS) Units 1 and 2 were permanently shut down in February 1998, for economic reasons. On February 13, 1998, ComEd, the licensee at that time, submitted a letter certifying the permanent cessation of operations at ZNPS, Units 1 and 2. On March 9, 1998, ComEd submitted a letter certifying the permanent removal of fuel from the reactor vessels at ZNPS. Pursuant to Title 10, *Code of Federal Regulations* (10 CFR) 50.82(a)(2), upon docketing of the certification for permanent cessation of operations and permanent removal of fuel from the reactor vessels, the 10 CFR part 50 license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel. Subsequently ZNPS was placed in SAFSTOR. SAFSTOR is an NRC approved method of decommissioning a nuclear facility where the nuclear facility is placed and maintained in such condition that the nuclear facility can be safely stored and subsequently decontaminated to safe levels. All irradiated fuel is currently stored in the spent fuel pool at ZNPS. In September 2010, ownership of the permanently shut down facility and responsibility for its decommissioning was transferred to Zion*Solutions* (ZS), a subsidiary of Energy*Solutions*. ZS was established solely for the purpose of acquiring and decommissioning the ZNPS for release for unrestricted use, while transferring the spent nuclear fuel and Greater-Than-Class C (GTCC) radioactive waste to the ZNPS Independent Spent Fuel Storage Installation (ISFSI). As part of the process ZS revised the ZNPS Physical Security Plan (PSP) for the protection of the nuclear material while in transit to, and while stored in, the ISFSI.

On December 2, 2010, ZNPS submitted a letter to the NRC (Document contains sensitive security related information and is not publically available) regarding compliance with the new physical security requirements in 10 CFR 73.55. The December 2, 2010, letter included exemption requests for portions of 10 CFR 73.55 which ZNPS believed no longer applied to their facility due to their permanently shut-down and defueled condition. On November 10, 2011, the NRC issued a letter to ZNPS (Agencywide Documents Access Management System (ADAMS) Accession Number ML112010331) providing the Commission's determination regarding the exemptions which ZNPS requested. During the technical review of the ZNPS exemption request, staff completed a Safety Evaluation Report (SER) (Document contains sensitive security related information and is not publically available). The staff concluded that exemptions from the following provisions should be granted: 10 CFR 73.55(c)(5); 10 CFR 73.55(h)(3)(ii); 10 CFR 73.55(i)(4)(i); 10 CFR 73.55(i)(4)(ii)(G); 10 CFR 73.55(k)(5)(ii); 10 CFR 73.55(k)(5)(iii); 10 CFR 73.55(n)(i); 10 CFR 73.55(n)(ii); 10 CFR 73.55(n)(iii); 10 CFR 73.55(p)(1)(i); and 10 CFR 73.55(p)(ii).

2.0 Request/Action

Section 50.54(p)(1) of 10 CFR states, "The licensee shall prepare and maintain safeguards contingency plan procedures in accordance with Appendix C of part 73 of this chapter for affecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan."

Part 73 of 10 CFR, "Physical Protection of Plant and Materials," provides, "This part prescribes requirements for the establishment and maintenance of a physical protection system which will have capabilities for the protection of special nuclear material at fixed sites and in transit and of plants in which special nuclear material is used." In section 73.55, entitled "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage," paragraph (b)(1) states, "The licensee shall establish and maintain a physical protection program, to include a security organization, which will have as its objective to provide high assurance that activities involving special nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety."

By application dated June 18, 2012 (ADAMS Accession No. ML12179A498), as supplemented by letters dated June 5, 2013 (ADAMS Accession No. ML13157A308) and October 4, 2013 (ADAMS Accession No. ML13283A004), ZS submitted a proposed revision to the ZNPS PSP which included a transfer plan that described the ZNPS plan for moving spent fuel currently in wet spent fuel storage to dry cask storage at the ZNPS ISFSI Facility. ZS also submitted the proposed ZNPS ISFSI PSP. Associated with the submittal of the revised and new PSPs, ZS submitted exemption requests from 10 CFR 73.55(c)(5); 10 CFR 73.55(h)(3)(ii); 10 CFR 73.55(i)(4)(i); 10 CFR 73.55(i)(4)(ii)(G); 10 CFR 73.55(k)(5)(ii); and 10 CFR 73.55(k)(5)(iii) for the ZNPS facility and ISFSI.

3.0 Discussion

Pursuant to 10 CFR 73.5, "Specific exemptions," the Commission may grant exemptions from the regulations in this part either at the request of a licensee or on its own initiative as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

The NRC evaluated the proposed exemptions and documented the review in a Safety Evaluation which contains safeguards information and has been withheld from public disclosure pursuant to 10 CFR 2.390(d)(1).

The NRC determined that the ZNPS ISFSI PSP is adequate, and consistent

with the reduced radiological risk and protective strategy for a decommissioning facility or a stand-alone ISFSI. As discussed in the SER, and consistent with the Commission's authority 10 CFR 73.5, the Commission is issuing exemptions from the following requirements:10 CFR 73.55(c)(5); 10 CFR 73.55(h)(3)(ii); 10 CFR(i)(2); 10 CFR 73.55(i)(4)(i); 10 CFR 73.55(i)(4)(ii)(G); 10 CFR 73.55(k)(5)(ii); 10 CFR 73.55(k)(5)(iii); 10 CFR 73.55(n)(i); 10 CFR 73.55(n)(ii); 10 CFR 73.55(n)(iii); 10 CFR 73.55(p)(1)(i); and 10 CFR 73.55(p)(ii).

In Enclosure 1 to ZNPS letter of October 4, 2013, ZNPS requested that NRC affirm that specific exemptions previously granted to ZNPS for the defueled reactor as also applicable for the ZNPS ISFSI PSP. Specifically, the licensee requested affirmation of the exemptions to the following requirements for the ISFSI PSP: 10 CFR 73.55(b)(3)(i); 10 CFR 73.55(b)(4); 10 CFR 73.55(b)(6); 10 CFR 73.55(b)(9); 10 CFR 73.55(c)(4); 10 CFR 73.55(d)(3)(i); 10 CFR 73.55(e)–(e)(1)(i); 10 CFR 73.55(e)(7)(i)–(ii); 10 CFR 73.55(e)(9)(1)–(vi); 10 CFR 73.55(e)(10)(ii); 10 CFR 73.55(f)(1)–(4); 10 CFR 73.55(h)(2); 10 CFR 73.55(i); 10 CFR 73.55(i)(2); and 10 CFR 73.55(k)(1).

The ZNPS ISFSI PSP is, however, a stand-alone security plan that has been evaluated against the requirements of 10 CFR part 73. No application of a previous exemption is necessary.

Based on the evaluation in the associated safety evaluation, which considered the permanently shut-down and defueled conditions at the ZNPS, and the new ZNPS ISFSI facility where the fuel will be located within the protected area of the dry storage facility, the NRC has concluded that: (1) there is reasonable assurance that the health and safety of the public will not be endangered by granting said exemptions; (2) such activities will be conducted in compliance with the Commission's regulations and orders; and (3) the approval of these exemptions will not be inimical to the common defense and security or the health and safety of the public and are otherwise in the public interest. These conclusions are discussed in greater detail in the staff's SER.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 73.5, an exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest based on permanently shut down and defueled conditions at the ZNPS. Therefore, the Commission hereby grants ZionSolutions an exemption from the requirements of 10 CFR part 73 as delineated above.

Pursuant to 10 CFR 51.22(c)(25), the Commission has determined the granting of these exemptions is categorically excluded and pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared. The exemption involves safeguard plans, as described in 10 CFR 51.22(c)(25)(vi)(F). Approval of this exemption request involves no significant hazards consideration; no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; no significant increase in individual or cumulative public or occupational radiation exposure; no significant construction impact; and no significant increase in the potential for or consequences from radiological accidents.

These exemptions are effective upon issuance.

Dated at Rockville, Maryland, this 13th day of December 2013.

For the Nuclear Regulatory Commission.

Aby Mohseni,

Deputy Director, Environmental Protection and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2013–31086 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Request for a License To Export Deuterium

Pursuant to 10 CFR 110.70 (b) "Public Notice of Receipt of an Application," please take notice that the U.S. Nuclear Regulatory Commission (NRC) has received the following request for an export license. Copies of the request are available electronically through ADAMS and can be accessed through the Public Electronic Reading Room (PERR) link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within thirty days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Office of Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. To ensure timely electronic filing, at least 5 (five) days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV*, or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty (30) days after publication of this notice in the **Federal Register** to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this export license application follows.

NRC EXPORT LICENSE APPLICATION

[Description of material]

Name of applicant, date of application, date received, application no., docket no.	Material type	Total quantity	End use	Recipient country
Concert Pharmaceuticals, Inc. ..... August 29, 2013 ..... December 5, 2013 ..... XMAT431 ..... 11006131	Heavy water (D_2O)	~20,000.0 kgs	Non-nuclear end-use in active pharmaceutical ingredient manufacturing..	Portugal, Austria

Dated this 20th day of December 2013 in Rockville, Maryland.

For the Nuclear Regulatory Commission.

Stephen Dembek,

Acting Deputy Director, Office of International Programs.

[FR Doc. 2013–31026 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Materials, Metallurgy & Reactor Fuels; Notice of Meeting

The ACRS Subcommittee on Materials, Metallurgy & Reactor Fuels will hold a meeting on January 14, 2014, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, January 14, 2014—1:00 p.m. until 5:00 p.m.

The Subcommittee will discuss fuel research in support of the ACRS Biannual Review and Evaluation of Research Projects. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Zena Abdullahi (Telephone 301–415–8716 or Email: *Zena.Abdullahi@nrc.gov)* five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on November 8, 2013 (78 FR 67205–67206).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: December 18, 2013.

Cayetano Santos,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–31035 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Materials, Metallurgy & Reactor Fuels; Notice of Meeting

The ACRS Subcommittee on Materials, Metallurgy & Reactor Fuels will hold a meeting on January 14, 2014, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, January 14, 2014–8:30 a.m. Until 12:00 p.m.

The Subcommittee will discuss the NRC's research activities in materials and metallurgy. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christopher Brown (Telephone 301–415–7111 or Email: *Christopher.Brown@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting

that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on November 8, 2013 (78 CFR 67205–67206).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Date: December 18, 2013.

Cayetano Santos,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–31034 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Reliability & PRA; Notice of Meeting

The ACRS Subcommittee on Reliability & PRA will hold a meeting on January 15, 2014, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, January 15, 2014—8:30 a.m. until 5:00 p.m.

The Subcommittee will be briefed on the progress of Human Reliability Analysis (HRA) methods. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), John Lai (Telephone 301–415–5197 or Email: *John.Lai@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on November 8, 2013 (78 FR67205–67206).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: December 17, 2013.

Cayetano Santos,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–31023 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee On Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Radiation Protection and Nuclear Materials; Notice of Meeting

The ACRS Subcommittee on Radiation Protection and Nuclear Materials will hold a meeting on January 16, 2014, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, January 16, 2014—8:30 a.m. until 5:00 p.m.

The Subcommittee will discuss the Part 61 rulemaking revisions and technical justifications. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Derek Widmayer (Telephone 301–415–7366 or Email: *Derek.Widmayer@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on November 8, 2013 (78 FR67205–67206).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained

from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: December 18, 2013

Cayetano Santos,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–31027 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0001]

Sunshine Act Meeting Notice

DATES: Weeks of December 30, 2013, January 6, 13, 20, 27, February 3, 2014.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of December 30, 2013

There are no meetings scheduled for the week of December 30, 2013.

Week of January 6, 2014—Tentative

Monday, January 6, 2014

9:00 a.m. Briefing on Spent Fuel Pool Safety and Consideration of Expedited Transfer of Spent Fuel to Dry Casks (Public Meeting) (Contact: Kevin Witt, 301–415–2145).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

1:30 p.m. Briefing on Flooding and Other Extreme Weather Events (Public Meeting) (Contact: George Wilson, 301–415–1711).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Friday, January 10, 2014

9:00 a.m. Briefing on the NRC Staff's Recommendations to Disposition Fukushima Near-Term Task Force (NTTF) Recommendation 1 on Improving NRC's Regulatory Framework (Public Meeting) (Contact: Dick Dudley, 301–415–1116).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of January 13, 2014—Tentative

There are no meetings scheduled for the week of January 13, 2014.

Week of January 20, 2014—Tentative

There are no meetings scheduled for the week of January 20, 2014.

Week of January 27, 2014—Tentative

Wednesday, January 29, 2014

9:30 a.m. Briefing on Equal Employment Opportunity and Civil Rights Outreach (Public Meeting) (Contact: Larniece McKoy Moore, 301–415–1942)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of February 3, 2014—Tentative

There are no meetings scheduled for the week of February 3, 2014.

* * * * *

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—301–415–1292. Contact person for more information: Rochelle Bavol, 301–415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an email to *Darlene.Wright@nrc.gov.*

December 23, 2013.

Rochelle C. Bavol,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2013–31197 Filed 12–24–13; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Request for a License To Export; Deuterium

Pursuant to 10 CFR 110.70 (b) "Public Notice of Receipt of an Application," please take notice that the Nuclear Regulatory Commission (NRC) has received the following request for an export license. Copies of the request are available electronically through ADAMS and can be accessed through the Public Electronic Reading Room (PERR) link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within thirty days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Office of Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 Fed. Reg 49139 (Aug. 28, 2007). Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* To ensure timely electronic filing, at least 5 (five) days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV*, or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty (30) days after publication of this notice in the **Federal Register** to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this export license application follows.

NRC EXPORT LICENSE APPLICATION

[Description of material]

Name of applicant, date of application, date received, application no., docket No.	Material type	Total quantity	End use	Recipient country
Matheson Tri Gas, Inc., October 15,2013, November 12, 2013, XMAT430, 11006125.	Deuterium (Heavy Hydrogen).	14,000.0 kgs	Non-nuclear end-use for semiconductor devices.	Republic of Korea, Taiwan.

Dated this 16th day of December 2013 in Rockville, Maryland.

For the Nuclear Regulatory Commission.

Mark R. Shaffer,

Deputy Director, Office of International Programs.

[FR Doc. 2013–30879 Filed 12–26–13; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2014–12 and CP2014–16; Order No. 1919]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting the addition of Priority Mail Express Contract 16 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 30, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority Mail Express Contract 16 to the competitive product list.[1] The Postal Service asserts that Priority Mail Express Contract 16 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). *Id.* at 1. The Request has been assigned Docket No. MC2014–12.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B. The instant contract has been assigned Docket No. CP2014–16.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 11–6, authorizing the new product;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list with the addition underlined;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract and related financial information under seal.

In the Statement of Supporting Justification, Dennis R. Nicoski, Manager, Field Sales Strategy and Contracts, asserts that the contract will cover its attributable costs, make a positive contribution to covering institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.* Attachment D at 1. Mr. Nicoski contends that there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.* Attachment B. The contract is scheduled to become effective one business day following the day that the Commission issues all necessary regulatory approval. *Id.* at 3. The contract will expire three years from the effective date unless, among other things, either party terminates the agreement upon 30 days' written notice to the other party or renewed by mutual written agreement. *Id.* at 4. The contract also allows two 90-day extensions of the agreement if the preparation of a successor agreement is active and the Commission is notified within at least seven days of the contract's expiration date. *Id.* The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a).[2]

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.* Attachment F. It maintains that the redacted portions of the Governors' Decision, contract, customer-identifying information, and related financial information, should remain confidential. *Id.* at 3. This information includes the price structure, underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2014–12 and CP2014–16 to consider the Request pertaining to the proposed Priority Mail Express Contract 16 product and the related contract, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned

[1] Request of the United States Postal Service to Add Priority Mail Express Contract 16 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, December 19, 2013 (Request).

[2] Although the Request appears to state that the certification only pertains to paragraphs (1) and (3) of 39 U.S.C. 3633(a), the certification itself contains an assertion that the prices are in compliance with 39 U.S.C. 3633(a)(1), (2), and (3). *See* Request at 2; Attachment E.

dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than December 30, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Pamela A. Thompson to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2014–12 and CP2014–16 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Pamela A. Thompson is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments by interested persons in these proceedings are due no later than December 30, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register.**

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013–30971 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2014–11 and CP2014–15; Order No. 1918]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting the addition of Priority Mail Contract 73 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 30, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a request and associated supporting information to add Priority Mail Contract 73 to the competitive product list.[1] The Postal Service asserts that Priority Mail Contract 73 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). Request at 1. The Request has been assigned Docket No. MC2014–11.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product. *Id.* Attachment B. The instant contract has been assigned Docket No. CP2014–15.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 11–6, authorizing the new product;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list with the addition underlined;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract and related financial information under seal.

In the Statement of Supporting Justification, Dennis R. Nicoski, Manager, Field Sales Strategy and Contracts, asserts that the contract will cover its attributable costs and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.* Attachment D at 1. Mr. Nicoski contends that there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.* Attachment B. The contract is scheduled to become effective on "January 10, 2014, after the Commission issues all necessary regulatory approval." *Id.* at 3. The contract will expire two years from the effective date unless, among other things, either party terminates the agreement upon 90 days' written notice to the other party or the contract is renewed by mutual written agreement. *Id.* The contract also allows two 90-day extensions of the agreement if the preparation of a successor agreement is active and the Commission is notified within at least seven days of the contract's expiration date. *Id.* The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a).[2]

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.* Attachment F. It maintains that the redacted portions of the Governors' Decision, contract, customer-identifying information, and related financial information should remain confidential. *Id.* at 3. This information includes the price structure, underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2014–11 and CP2014–15 to consider the Request pertaining to the proposed Priority Mail Contract 73 product and the related contract, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than December 30, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Manon A. Boudreault to serve as Public Representative in these dockets.

III. Request for Supplemental Information

Section I.F. of the contract provides that the contract "will be measured and adjusted quarterly." Request, Attachment B at 2. The first contract

[1] Request of the United States Postal Service to Add Priority Mail Contract 73 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, December 19, 2013 (Request).

[2] Although the Request appears to state that the certification only pertains to paragraphs (1) and (3) of 39 U.S.C. 3633(a), the certification itself contains an assertion that the prices are in compliance with 39 U.S.C. 3633(a)(1), (2), and (3). *See* Request at 2; Attachment E.

quarter begins on January 1. *Id.* Section I.H.2. of the contract appears to provide for an "annual" price adjustment "following the First Year End Date." *Id.* at 3. In section I.H.1., the First Year End Date is defined as February 1, 2015. *Id.* at 2. The Postal Service is requested to (1) specify whether contract prices will be adjusted on a quarterly basis or an annual basis; (2) provide the date(s) on which the contract prices will be adjusted; and (3) provide a written amendment to the contract, if necessary. The Postal Service response is due no later than December 27, 2013.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2014–11 and CP2014–15 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Manon A. Boudreault is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. The response to the request for supplemental information is due no later than December 27, 2013.

4. Comments by interested persons in these proceedings are due no later than December 30, 2013.

5. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013–30970 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2011–50; Order No. 1922]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting an amendment to Priority Mail Express Contract 11. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 30, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On December 19, 2013, the Postal Service filed notice that it has agreed to an amendment to the existing Priority Mail Express Contract 11 subject to this docket.[1] The Postal Service includes two attachments in support of its Notice:

- Attachment A—a redacted copy of the amendment to the existing Priority Mail Express Contract 11, and
- Attachment B—a certification of compliance with 39 U.S.C. 3633(a).

The Postal Service also filed the unredacted amendment and supporting financial documentation under seal. The Postal Service seeks to incorporate by reference the Application for Non-Public Treatment originally filed in this docket for the protection of information that it has filed under seal. *Id.* at 1.

The amendment modifies the annual adjustment provision by annually adjusting the prices in Table A of Priority Mail Express Contract 11 by the most recent cell by cell increases/decreases in prices of general applicability for Priority Mail Express Commercial Base. *Id.* Attachment A at 1. In addition, the amendment modifies the annual adjustment of Table B, by adjusting the prices by the most recent cell by cell increases/decreases in prices of general applicability for Priority Mail Express Commercial Plus. *Id.* The amendment will become effective one business day following the day that the Commission issues all necessary regulatory approval. *Id.*

II. Notice of Filings

Interested persons may submit comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than December 30, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

Lawrence Fenster, previously designated to serve as Public Representative in this proceeding, will continue in that capacity.[2]

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2011–50 for consideration of matters raised by the Postal Service's Notice.

2. Lawrence Fenster, previously designated to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding, will continue in that capacity.

3. Comments are due no later than December 30, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013–30957 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2011–49; Order No. 1921]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting an amendment to Priority Mail Contract 33. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 30, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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[1] Notice of United States Postal Service of Change in Prices Pursuant to Amendment to Priority Mail Express Contract 11, December 19, 2013 (Notice). When originally filed, the contract was named "Express Mail Contract 11". The contract name has been changed to reflect the new product name. *Id.* at 1 n.1.

[2] Order No. 1735, Notice and Order Concerning Amendment to Express Mail Contract 11, May 30, 2013, at 3.

III. Ordering Paragraphs

I. Introduction

On December 19, 2013, the Postal Service filed notice that it has agreed to an amendment to the existing Priority Mail Contract 33 subject to this docket.[1] The Postal Service includes two attachments in support of its Notice:

- Attachment A—a redacted copy of the amendment to the existing Priority Mail Contract 33, and
- Attachment B—a certification of compliance with 39 U.S.C. 3633(a).

The Postal Service also filed the unredacted amendment and supporting financial documentation under seal. The Postal Service seeks to incorporate by reference the Application for Non-Public Treatment originally filed in this docket for the protection of information that it has filed under seal. *Id.* at 1.

The amendment modifies the annual adjustment provision by annually adjusting the prices in Tables A, B, and C of Priority Mail Contract 33 by the most recent cell by cell increases/decreases in prices of general applicability for Priority Mail Commercial Base. *Id.* Attachment A at 1. In addition, the amendment modifies the annual adjustment of Table D, by adjusting the prices by the most recent cell by cell increases/decreases in prices of general applicability for Priority Mail Commercial Plus. *Id.* The amendment will become effective one business day following the day that the Commission issues all necessary regulatory approval. *Id.*

II. Notice of Filings

Interested persons may submit comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than December 30, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

Kenneth R. Moeller, previously designated to serve as Public Representative in this proceeding, will continue in that capacity.[2]

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2011–49 for consideration of matters raised by the Postal Service's Notice.

2. Kenneth R. Moeller, previously designated to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding, will continue in that capacity.

3. Comments are due no later than December 30, 2013.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013–30956 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Change in Prices Pursuant to Amendment to Priority Mail Contract 33, December 19, 2013 (Notice).

[2] Order No. 1734, Notice and Order Concerning Amendment to Priority Mail Contract 33, May 30, 2013, at 3.

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2014–13 and CP2014–17; Order No. 1920]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting the addition of Priority Mail Express Contract 17 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 30, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority Mail Express Contract 17 to the competitive product list.[1] The Postal Service asserts that Priority Mail Express Contract 17 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). *Id.* at 1. The Request has been assigned Docket No. MC2014–13.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B. The instant contract has been assigned Docket No. CP2014–17.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 11–6, authorizing the new product;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list with the addition underlined;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract and related financial information under seal.

In the Statement of Supporting Justification, Dennis R. Nicoski, Manager, Field Sales Strategy and Contracts, asserts that the contract will cover its attributable costs, make a positive contribution to covering institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.* Attachment D at 1. Mr. Nicoski contends that there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.* Attachment B. The contract will expire three years from the effective date unless, among other things, the customer terminates the agreement, with or without cause and without penalty, upon 60 days' written notice to the other party or the agreement is renewed by mutual written agreement. *Id.* at 4. The contract also allows two 90-day extensions of the agreement if the preparation of a successor agreement is active and the Commission is notified within at least seven days of the contract's expiration date. *Id.* The Postal

[1] Request of the United States Postal Service to Add Priority Mail Express Contract 17 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, December 19, 2013 (Request).

Service represents that the contract is consistent with 39 U.S.C. 3633(a).[2]

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.* Attachment F. It maintains that the redacted portions of the Governors' Decision, contract, customer-identifying information, and related financial information, should remain confidential. *Id.* at 3. This information includes the price structure, underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2014–13 and CP2014–17 to consider the Request pertaining to the proposed Priority Mail Express Contract 17 product and the related contract, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than December 30, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Request for Supplemental Information

Section I.B. of the contract defines the "Effective Date" as "the day following the date on which the Commission issues all necessary regulatory approval." Request, Attachment B at 1. Section III of the contract provides that the "Effective Date of this Contract shall be one business day following the day on which the Commission issues all necessary regulatory approval." *Id.* at 4. The Postal Service is requested to clarify which provision is controlling, and, if necessary, file an amendment to the contract. The Postal Service response is due no later than December 27, 2013.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2014–13 and CP2014–17 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. The response to the request for supplemental information is due no later than December 27, 2013.

4. Comments by interested persons in these proceedings are due no later than December 30, 2013.

5. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013–30973 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–FW–P

[2] Although the Request appears to state that the certification only pertains to paragraphs (1) and (3) of 39 U.S.C. 3633(a), the certification itself contains an assertion that the prices are in compliance with 39 U.S.C. 3633(a)(1), (2), and (3). *See* Request at 2; Attachment E.

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

DATES AND TIMES: January 7, 2014, at 2:30 p.m., and January 8, 2014, at 7:15 a.m.

PLACE: Las Vegas, Nevada.

STATUS: Closed.

MATTERS TO BE CONSIDERED

Tuesday, January 7, 2014, at 2:30 p.m.

1. Strategic Issues.
2. Pricing.
3. Governors' Executive Session.

Wednesday, January 8, 2014, at 7:15 a.m.

1. Financial Matters.
2. Strategic Issues (Continued).
3. Personnel Matters and Compensation Issues.
4. Board Executive Session—Discussion of prior agenda items and Board Governance.

CONTACT PERSON FOR MORE INFORMATION: Julie S. Moore, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW., Washington, DC 20260–1000. Telephone (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2013–31100 Filed 12–24–13; 11:15 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service™.

ACTION: Notice of modification to existing systems of records.

SUMMARY: The United States Postal Service® (Postal Service) is proposing to modify a General Privacy Act System of Records. These updates will account for an additional data element that the Postal Service uses to identify applicants, as well as how employee and applicant information is retrieved after a complaint or inquiry is received by the Postal Service from an employee or applicant who is deaf or hard of hearing.

DATES: These revisions will become effective without further notice on January 27, 2014 unless comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be mailed or delivered to the Records Office, United States Postal Service, 475 L'Enfant Plaza SW., Room 9431, Washington, DC 20260–1101. Copies of all written comments will be available at this address for public inspection and photocopying between 8 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Matthew J. Connolly, Chief Privacy Officer, Privacy and Records Office, 202–268–8582.

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their amended systems of records in the **Federal Register** when there is a revision, change, or addition. The Postal Service™ has reviewed this system of records and has determined that this General Privacy Act System of Records should be revised to modify categories of records in the system and retrievability.

I. Background

The Postal Service has entered into a settlement to resolve all claims in a national employment discrimination class action lawsuit regarding deaf or hard of hearing employees and applicants. Among other things, the settlement requires the Postal Service to competitively select and enter into a contract with an independent ombudsperson. The ombudsperson will serve for a period of three (3) years, beginning October 29, 2013. In cooperation with the Postal Service Headquarters Disability Program Manager, the ombudsperson will monitor the Postal Service's compliance with the injunctive relief provisions of the settlement through the establishment of a call center and designed email address. Deaf and hard of hearing Postal Service employees will

be advised that they can register a comment or concern about communication accommodation issues via a designated email address and/or through a toll-free number or other device provided by the call center. Deaf and hard of hearing Postal Service employees will further be advised that use of the email address and toll-free number or device to register a comment or concern does not affect their rights to file a grievance or complaint in any other process, nor does it serve as initial contact for any other process such as a grievance or EEO pre-complaint processing pursuant to 29 CFR 1614.105. The Disability Program Manager will provide qualifying deaf and hard of hearing employees and applicants with information regarding how to contact the ombudsperson. Such individuals may register a comment or concern about communication and accommodation issues they have experienced in the workplace or during their employment application process with the Postal Service. To be able to identify and address specific comments and/or concerns, individuals will be asked to supply information specific to them, such as their name, residential addresses, and identification numbers such as their Employee Identification Number (EIN) or Applicant Identification Number (AIN). If necessary, the Ombudsperson will investigate the comments and/or concerns in order to make an independent assessment.

II. Rationale for Changes to USPS Privacy Act Systems of Records

Currently, Postal Service system of records 100.900 Employee Inquiry, Complaint, and Investigative Records does not explicitly permit the Postal Service to collect AINs or retrieve records by AINs or EINs. The system of records 100.900 is being modified to account for the collection of applicant identification numbers from applicants who file an inquiry or complaint with the ombudsperson via the call center or designated email address. Additionally, to facilitate the record location process, retrievability is being updated to include Employee Identification Numbers and Applicant Identification Numbers.

III. Description of Changes to Systems of Records

The Postal Service is modifying one system of records listed below. Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed modifications has been sent to Congress and to the Office of Management and Budget for their evaluation. The Postal Service does not expect this amended notice to have any adverse effect on individual privacy rights. The affected systems are as follows:

USPS 100.900

SYSTEM NAME:

Employee Inquiry, Complaint, and Investigative Record.

Accordingly, for the reasons stated, the Postal Service proposes changes in the existing system of records as follows:

USPS 100.900

SYSTEM NAME:

Employee Inquiry, Complaint, and Investigative Record

CATEGORIES OF RECORDS IN THE SYSTEM

* * * * *

[CHANGE TO READ]

2. Non-employee information: Name, gender, Applicant Identification Number, and contact information.

* * * * *

RETREIVABILITY

[CHANGE TO READ]

By employee and non-employee name, Employee Identification Number, Applicant Identification Number, subject category, facility, finance number, district, area, nationally, or case number.

* * * * *

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–31105 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* December 27, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 19, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 17 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2014–13, CP2014–17.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–30954 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* December 27, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 19, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 73 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2014–11, CP2014–15.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–30953 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* December 27, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 19, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 16 to Competitive Product List*. Documents are available at *www.prc.gov*, Docket Nos. MC2014–12, CP2014–16.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–30955 Filed 12–26–13; 8:45 am]

BILLING CODE 7710–12–P

PRESIDIO TRUST

Notice of Public Meeting

AGENCY: The Presidio Trust.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with § 103(c)(6) of the Presidio Trust Act, 16 U.S.C. 460bb appendix, and in accordance with the Presidio Trust's bylaws, notice is hereby given that a public meeting of the Presidio Trust Board of Directors will be held commencing 6:30 p.m. on Monday, January 27, 2014, at Herbst Hall, 385 Moraga Street, Presidio of San Francisco, California. The Presidio Trust was created by Congress in 1996 to manage approximately eighty percent of the former U.S. Army base known as the Presidio, in San Francisco, California.

The purposes of this meeting are to take action on the minutes of a previous Board meeting, to provide the Chairperson's report, to provide the Executive Director's report, to present revised proposals for the Mid-Crissy Field Site Project, and to receive public comment on the Mid-Crissy Field Site Project and on other matters in accordance with the Trust's Public Outreach Policy.

Individuals requiring special accommodation at this meeting, such as needing a sign language interpreter, should contact Mollie Matull at 415.561.5300 prior to January 20, 2014.

Time: The meeting will begin at 6:30 p.m. on Monday, January 27, 2017.

ADDRESSES: The meeting will be held at Herbst Hall, 385 Moraga Street, Presidio of San Francisco.

FOR FURTHER INFORMATION CONTACT: Karen Cook, General Counsel, the Presidio Trust, 103 Montgomery Street, P.O. Box 29052, San Francisco, California 94129–0052, Telephone: 415.561.5300.

Dated: December 20, 2013.

Karen A. Cook,

General Counsel.

[FR Doc. 2013–31061 Filed 12–26–13; 8:45 am]

BILLING CODE 4310–4R–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 8c–1, SEC File No. 270–455, OMB Control No. 3235–0514.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 8c–1 (17 CFR 240.8c–1), under the Securities Exchange Act of 1934 ("Exchange Act") (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 8c–1 generally prohibits a broker-dealer from using its customers' securities as collateral to finance its own trading, speculating, or underwriting transactions. More specifically, Rule 8c–1 states three main principles: (1) A broker-dealer is prohibited from commingling the securities of different customers as collateral for a loan without the consent of each customer; (2) a broker-dealer cannot commingle customers' securities with its own securities under the same pledge; and (3) a broker-dealer can only pledge its customers' securities to the extent that customers are in debt to the broker-dealer.[1]

The information required by Rule 8c–1 is necessary for the execution of the Commission's mandate under the Exchange Act to prevent broker-dealers from hypothecating or arranging for the hypothecation of any securities carried for the account of any customer under certain circumstances. In addition, the information required by Rule 8c–1 provides important investor protections.

There are approximately 82 respondents as of year-end 2012 (*i.e.*, broker-dealers that conducted business with the public, filed Part II of the FOCUS Report, did not claim an exemption from the Reserve Formula computation, and reported that they had a bank loan during at least one quarter of the current year). Each respondent makes an estimated 45 annual responses, for an aggregate total of 3,690 responses per year.[2] Each response takes approximately 0.5 hours to complete. Therefore, the total third-party reporting burden per year is 1,845 burden hours.[3]

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov*.

Dated: December 20, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30931 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71156; File No. SR–NSCC–2013–13]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Proposed Rule Change To Discontinue its Stock Borrow Program

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

[1] *See* Exchange Act Release No. 2690 (November 15, 1940); Exchange Act Release No. 9428 (December 29, 1971).

[2] 82 respondents × 45 annual responses = 3,690 aggregate total of annual responses.

[3] 3,690 responses × 0.5 hours = 1,845 hours.

("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 10, 2013, National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by NSCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consist of amendments to the Rules & Procedures ("Rules") of NSCC to discontinue its Stock Borrow Program, as more fully described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Over the past few years the use of NSCC's Stock Borrow Program, which allows NSCC Members to elect to loan their excess positions to NSCC's Continuous Net Settlement ("CNS") System in order to facilitate the completion of CNS long allocations, has declined. As such, NSCC is proposing to amend its Rules in order to discontinue the Stock Borrow Program.

One of NSCC's core services as a central counterparty is trade clearance and settlement through CNS, where compared and recorded transactions in eligible securities for a particular settlement date are netted by issue into one net long (buy) or net short (sell) position. As a continuous net settlement system, those positions are further netted with positions of the same issue that remain open after their originally scheduled settlement date (usually T+3), so that trades scheduled to settle on any day are netted with fail positions to result in a single deliver or receive obligation for each Member for each issue in which it has activity. Today, NSCC Members may elect to participate in the Stock Borrow Program by designating specific securities that are in their inventory at DTC to be available to be borrowed by CNS. If CNS cannot complete a delivery to a long Member because a short Member has not completed its delivery to CNS, NSCC looks to those designated securities and initiates deliveries from lenders to CNS if the lending Member has free excess positions at DTC. In turn, CNS delivers the position to a long Member and sets up a pending receive for the lending Member. If the position is not returned to the lender by the end of settlement day, i.e., the Member with the original obligation to deliver to CNS does not complete that delivery, the lender receives full market value for the securities through NSCC settlement.

In 2007, NSCC borrowed a daily average of approximately $1.85 billion in market value at the close of each day from the approximately 21 Members that participated in the Stock Borrow Program that year. Usage of the Stock Borrow Program has since dropped by almost 95%. In October 2013 only three Members participated in the Stock Borrow Program, and the average daily value borrowed at the close of day during that month was approximately $81 million. Usage of the program has continued to drop since the end of October 2013. Given this dramatic reduction in the use of the program, NSCC has determined that it is not economically efficient to maintain the service, and NSCC is proposing to amend its Rules in order to discontinue the Stock Borrow Program. NSCC has informed the Members using the Stock Borrow Program of its intent to discontinue the program.

Implementation Timeframe

Subject to approval of this filing, NSCC will implement the proposed rule changes on a date announced by Important Notice.

Proposed Rule Changes

NSCC will remove reference to the Stock Borrow Program from Section E of Procedure VII (CNS Accounting Operation), and will remove Addendum C (NSCC Automated Stock Borrow Program Program) from its Rules as reflected in Exhibit 5 hereto.[3] Addendum C will be designated as reserved for future use.

2. Statutory Basis

NSCC believes the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to NSCC, in particular Section 17A(b)(3)(F) of the Securities Exchange Act of 1934, as amended ("Act"), which requires that NSCC's Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions. Given the dramatic reduction in the use of the Stock Borrow Program by NSCC's Members, NSCC has determined that it is not economically efficient to maintain the service, and, as such, its proposed rule change will promote its ability to perform the prompt and accurate clearance and settlement of securities transactions.

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have any impact, or impose any burden on competition due to the dramatic reduction in use of the Stock Borrow Program by NSCC Members, as described above.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change, [*sic*] and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such a proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing,

[1] 15 U.S.C. 78s(b)(1). Defined terms that are not defined in this notice are defined in Exhibit 5 of the proposed rule change filing, available at *http://www.sec.gov/rules/sro/nscc.shtml* under File No. SR–NSCC–2013–13, Additional Materials.

[2] 17 CFR 240.19b–4.

[3] The Commission notes that Exhibit 5 to the proposed rule change is available at *http://www.sec.gov/rules/sro/nscc.shtml* under File No. SR–NSCC–2013–13, Additional Materials.

including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–NSCC–2013–13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NSCC–2013–13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of NSCC and on NSCC's Web site at (*http://dtcc.com/legal/rule_filings/nscc/2013.php*).

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NSCC–2013–13 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[4]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30936 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71162; File No. SR–BATS–2013–066]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Adopt Rules To Hold a Volatility Closing Auction

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 19, 2013, BATS Exchange, Inc. (the "Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.23, which governs auctions conducted on the Exchange for Exchange listed-securities.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

[4] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Introduction

The Exchange proposes to add a new auction type to its rules, a Volatility Closing Auction, which will apply any time that an Exchange-listed security is halted between 3:50 p.m. and 4:00 p.m. E.T. In particular, the Exchange proposes to add the Volatility Closing Auction in preparation for the operation during the last 15 minutes of Regular Trading Hours [3] of the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the "Limit Up-Limit Down Plan" or "Plan"), as further described below.[4] The Plan is designed to prevent trades in individual NMS Stocks from occurring outside of specified Price Bands.[5] The requirements of the Plan are coupled with Trading Pauses, or halts, to accommodate more fundamental price moves (as opposed to erroneous trades or momentary gaps in liquidity).

Background

On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[6] The Plan first became operational in April of 2013, with a staged rollout with respect to the portion of the trading day to which the Plan applies as well as the securities subject to the Plan. All trading centers in NMS Stocks, including both those operated by Participants and those operated by members of Participants, are required to establish, maintain, and enforce written policies and procedures that are reasonably designed to comply with the requirements specified in the Plan.[7] As set forth in more detail in the Plan, Price Bands consisting of a Lower Price Band and an Upper Price Band for each NMS Stock are calculated by the Processors.[8] When the National Best Bid (Offer) is below (above) the Lower (Upper) Price Band, the Processors disseminate the National Best Bid (Offer) with an appropriate flag

[3] Regular Trading Hours are defined in Exchange Rule 1.5(w) as the time between 9:30 a.m. to 4:00 p.m. E.T.

[4] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4–631) (Order Approving, on a Pilot Basis, the National Market System Plan To Address Extraordinary Market Volatility).

[5] Unless otherwise specified, capitalized terms used in this rule filing are based on the defined terms of the Plan.

[6] *See supra* note 4.

[7] The Exchange is a Participant in the Plan.

[8] *See* Section (V)(A) of the Plan.

identifying it as non-executable. When the National Best Bid (Offer) is equal to the Upper (Lower) Price Band, the Processors distribute the National Best Bid (Offer) with an appropriate flag identifying it as a Limit State Quotation.[9]

Trading in an NMS Stock immediately enters a Limit State if the National Best Offer (Bid) equals but does not cross the Lower (Upper) Price Band.[10] Trading for an NMS stock exits a Limit State if, within 15 seconds of entering the Limit State, all Limit State Quotations were executed or canceled in their entirety. If the market does not exit a Limit State within 15 seconds, then the Primary Listing Exchange declares a five-minute Trading Pause pursuant to Section VII of the Limit Up-Limit Down Plan, which Trading Pause is applicable to all markets trading the security.[11] In addition, the Plan defines a Straddle State as when the National Best Bid (Offer) is below (above) the Lower (Upper) Price Band and the NMS Stock is not in a Limit State. For example, assume the Lower Price Band for an NMS Stock is $9.50 and the Upper Price Band is $10.50, such NMS stock would be in a Straddle State if the National Best Bid were below $9.50, and therefore non-executable, and the National Best Offer were above $9.50 (including a National Best Offer that could be above $10.50). If an NMS Stock is in a Straddle State and trading in that stock deviates from normal trading characteristics, the Primary Listing Exchange may declare a Trading Pause for that NMS Stock.

As currently implemented, the Limit Up-Limit Down Plan applies to securities between 9:30 a.m. and 3:45 p.m. E.T. each trading day. In the near future, the operation of the Plan will be extended to include the time between 3:45 p.m. and 4:00 p.m. E.T., which is the end of Regular Trading Hours on the Exchange and is when the Exchange typically conducts a Closing Auction for each of its listed securities. The Exchange proposes to adopt rules for a Volatility Closing Auction in connection with the extension of the Plan to the end of Regular Trading Hours. As described in additional detail below, the Volatility Closing Auction will operate in some ways like a Halt Auction, for which the Exchange's process is described in Rule 11.23(d), and in some ways like a Closing Auction, for which the Exchange's process is described in Rule 11.23(c).

Proposed Amendment to Rule 11.23

The Exchange proposes to add new paragraph (e) to Rule 11.23 to govern the operation of Volatility Closing Auctions on the Exchange, which will be auctions of Exchange-listed securities that are halted in the last 10 minutes of Regular Trading Hours. As noted above, a Volatility Closing Auction would operate in certain respects like an Exchange Halt Auction and in other respects like an Exchange Closing Auction.

Similar to a Halt Auction on the Exchange, a Volatility Closing Auction will have a period of time that orders are accepted for participation in such auction during which no trading is occurring on the Exchange (the "Quote-Only Period"). The Quote-Only Period with respect to a Volatility Closing Auction would commence at the time a security is halted between 3:50 p.m. and 4:00 p.m. and will end at 4:00 p.m. Thus, to the extent the Exchange halts a security after 3:55 p.m. but before 4:00 p.m., such security will be halted for less than five minutes prior to the Volatility Closing Auction. The Exchange believes this is appropriate because it will ensure that the final auction of the day in all Exchange-listed securities consistently occurs at 4:00 p.m. E.T.

During the Quote-Only Period of a Volatility Closing Auction the Exchange will accept all orders eligible to participate in both a Halt Auction and a Closing Auction in order to avoid participant confusion and to facilitate participation in the Volatility Closing Auction. This includes limit and market orders as well as any Eligible Auction Orders applicable to a Closing Auction on the Exchange. Thus, the Exchange will accept Regular Hours Only orders ("RHOs"), Limit-On-Close orders ("LOCs"), Late-Limit-On-Close orders ("LLOCs") and Market-On-Close orders ("MOCs") for participation in a Volatility Closing Auction, and the typical restrictions on such orders will apply. For instance, as with a Closing Auction, the Exchange will not accept any LOCs or MOCs after 3:55 p.m. E.T. Similarly, the Exchange will not accept any LLOCs before 3:55 p.m. E.T. The Exchange would like to note, however, that, while these restrictions remain in place, regular limit and market orders can be entered and cancelled without restriction at any time prior to execution. In contrast to a typical Closing Auction, however, because the Exchange is accepting Eligible Auction Orders only to facilitate participation in and avoid confusion during the Volatility Closing Auction and because a User could alternatively enter and cancel limit orders and market orders without restriction during the Quote-Only Period, Eligible Auction Orders associated with a Volatility Closing Auction may also be cancelled at any time prior to execution.[12]

The Exchange will disseminate the same information that it does for other auctions conducted on the Exchange. Thus, coinciding with the beginning of the Quote-Only Period for a security and updated every five seconds thereafter, the Reference Price, Indicative Price, Auction Only Price, and the lesser of Reference Buy Shares and Reference Sell Shares associated with the Volatility Closing Auction will be disseminated by the Exchange via electronic means.

As a general matter, the Exchange will not extend the Quote-Only Period associated with a Volatility Closing Auction, which is the same as with a Closing Auction. In contrast, the Exchange's rules related to Exchange Halt Auctions provide that the Quote-Only Period may be extended where there are unmatched market orders on the auction book associated with the auction and where the indicative price moves the greater of 10% or fifty (50) cents in the fifteen (15) seconds prior to the Halt Auction, both to ensure that there is sufficient interest and stability after a halt to reopen the security for trading. Halt Auctions, however, occur during Regular Trading Hours and the Exchange retains discretion to not extend the Quote-Only Period of a Halt Auction such that it would interfere with a Closing Auction. While the Exchange acknowledges that some of the same issues for which the ability to extend the Quote-Only Period of a Halt Auction may exist where there are unmatched market orders or dramatic price movements near the end of the Quote-Only Period of the Volatility Closing Auction, the Exchange believes that these concerns are outweighed by the importance of providing Members and the investing public with a definitive market close and a BATS Official Closing Price at 4:00 p.m. E.T. More specifically, the Exchange believes that the clarity that comes from requiring that a Volatility Closing Auction occurs at 4:00 p.m. E.T. will help reduce uncertainty for Members participating in the Volatility Closing

[9] See Section VI(A) of the Plan.

[10] See Section VI(B)(1) of the Plan.

[11] The primary listing market would declare a trading pause in an NMS Stock; upon notification by the primary listing market, the Processor would disseminate this information to the public. No trades in that NMS Stock could occur during the trading pause, but all bids and offers may be displayed. See Section VII(A) of the Plan.

[12] In a Closing Auction, LOC and MOC orders cannot be cancelled in the five minutes leading up to the auction.

Auction. Even where a halt is declared very near 4:00 p.m. E.T., the Exchange believes that it is in the interest of a fair and orderly market to hold the Volatility Closing Auction at 4:00 p.m. E.T. and has proposed that all Volatility Closing Auctions be required to close at a price level within the Collar Price Range in order to ensure that the Volatility Closing Auction price is based on rational and based on current market conditions. The Exchange further restricts the price of a Volatility Closing Auction by using the Final Last Sale Eligible Trade as the Volatility Closing Auction price where no limit orders from one or both sides would participate in the Volatility Closing Auction. This restriction ensures that there is crossed limit interest in the Volatility Closing Auction if the Volatility Closing Auction price is going to look to the entered limit interest to determine the price, which prevents a single limit order from interacting with market orders to determine the Volatility Closing Auction Price. Finally, the Exchange notes that it retains discretion under Rule 11.23(f) (re-numbered pursuant to this proposal, as described below) to adjust the timing of or suspend an auction with prior notice to Users where the interests of a fair and orderly market so require. In a situation where the Exchange deemed it necessary to adjust the timing of a Volatility Closing Auction in order to maintain a fair and orderly market, i.e., to a time later than 4:00 p.m. E.T., the Exchange would notify Exchange Users in advance of the time that the auction would occur and would provide for a Quote-Only period prior to such auction.

The Exchange will conduct a Volatility Closing Auction in a manner similar to a Halt Auction. Specifically, orders will be executed at the price that maximizes the number of shares executed in the auction. For ETPs, orders will be executed at the price level within the Collar Price Range that maximizes the number of shares executed in the auction. In the event of a volume based tie at multiple price levels, the price level closest to the Final Last Sale Eligible Trade will be used for Volatility Closing Auctions. Where no limit orders from one or both sides (the buy side, the sell side, or both the buy and sell side) would participate in a Volatility Closing Auction, the Volatility Closing Auction will occur at the price of the Final Last Sale Eligible Trade. The only differences between the processing of a Halt Auction and a Volatility Closing Auction are that: (1) The Volatility Closing Auction price will be used as the official closing price for dissemination to the consolidated tape (the "BATS Official Closing Price"), and (2) a Volatility Closing Auction will not be delayed due to a market order imbalance or due to a significant change in the Indicative Price, which can extend the Quote-Only Period of a Halt Auction, as explained above.

The Exchange also proposes to process a Volatility Closing Auction in a manner consistent with both all auctions conducted by the Exchange, in that, as proposed, market orders, including MOCs, will have higher priority than other Volatility Closing Auction Eligible Orders. To the extent there is executable contra side interest, such market orders will be executed at the BATS Official Closing Price according to time priority. After the execution of all market orders. the remaining orders priced at or more aggressively than the BATS Official Closing Price will be executed on the basis of price/time priority.

The Exchange will transition to the After Hours Trading Session [13] following a Volatility Closing Auction in much the way that it does for a Closing Auction. Thus, limit order shares that are not executed in the Volatility Closing Auction will remain on the Exchange's order book during the After Hours Trading Session, subject to a User's instructions and the fact that certain auction specific limit orders will be cancelled. RHO, LOC, LLOC, MOC and market order shares that are not executed in the Volatility Closing Auction will be cancelled at the conclusion of the Volatility Closing Auction. Thus, the only difference between this transition and a typical Closing Auction is that market orders are also cancelled, which differs only because such orders may enter the Volatility Closing Auction in the first place. Other than MOCs, which are specifically designated for a Closing Auction, market orders cannot participate in Closing Auctions because they do not post to the Continuous Book,[14] and thus the Exchange does not address their transition to the After Hours Trading Session in its Closing Auction transition process.

In addition to the changes described above, in order to correct a typographical error in the original filing that proposed Rule 11.23, the Exchange proposes to re-number paragraphs (g), (h) and (f) as (f), (g) and (h), respectively. Finally, the Exchange proposes to add a reference to the new auction type, a Volatility Closing Auction, to current paragraph (h) (to be re-numbered as (g)).

2. Statutory Basis

Approval of the rule changes proposed in this submission is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[15] In particular, the proposed change is consistent with Section 6(b)(5) of the Act,[16] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest. The Exchange believes that operation of a Volatility Closing Auction for securities listed on the Exchange will assist in the price discovery process and help to ensure a fair and orderly market for securities listed on the Exchange that are halted at the end of the trading day. Specifically, the proposed Volatility Closing Auction will address situations where a security is halted in the last 10 minutes of the trading day in order to hold a single auction at the end of Regular Trading Hours. The Exchange believes this proposal is consistent with the Act and the Plan as it will ensure that market participants have a single closing price at the end of the trading day. Consistent with this belief, as discussed above, although the same conditions could occur with a Volatility Closing Auction that in certain circumstances cause the extension of the Quote-Only Period for a Halt Auction on the Exchange (i.e., a significant imbalance or price movement), the Exchange believes that concerns related to these conditions are outweighed by the importance of providing Members and the investing public with a definitive market close and a BATS Official Closing Price at 4:00 p.m. E.T. More specifically, the Exchange believes that the clarity that comes from requiring that a Volatility Closing Auction occurs at 4:00 p.m. E.T. will help reduce uncertainty for Members participating in the Volatility Closing Auction. As explained above, the Exchange has proposed various price and execution constraints for the

[13] The After Hours Trading Session is defined in Exchange Rule 1.5(c) and currently means the time between 4:00 p.m. to 5:00 p.m. E.T.

[14] Market orders received by the Exchange are executed or routed by the Exchange to other market centers but do not post to the Exchange's Continuous Book. *See* Rules 11.9(a)(2), 11.13(a)(1) and 11.13(a)(2). The Continuous Book is defined in Exchange Rule 11.23(a)(7) as all orders on the BATS Book that are not Eligible Auction Orders.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

Volatility Closing Auction to ensure that the auction occurs at a price that is based on rational and based on current market conditions. Finally, the Exchange reiterates that it retains discretion under Rule 11.23(f) to adjust the timing of or suspend an auction with prior notice to Users where the interests of a fair and orderly market so require. Without the proposal, the Exchange could potentially have a Halt Auction within minutes of the Closing Auction, which could cause unnecessary confusion. The Exchange reiterates that all aspects of the proposed Volatility Closing Auction are based upon existing processes built into both the Exchanges' Halt Auction and the Exchange's Closing Auction. The Exchange further believes that its proposal to allow participants to cancel orders specifically designated for a Closing Auction up to the time of the Volatility Closing Auction is appropriate because the halt in the last 10 minutes of the trading day necessitating a Volatility Closing Auction may be indicative of price dislocation in a security and because such orders may have been entered well before such halt occurred. The Exchange believes it is appropriate and in the best interests of investors and the public interest to allow orders to be cancelled in such an event. Finally, the Exchange notes that its existing Halt Auction process allows orders to be cancelled prior to such auction.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposal enhances cooperation among markets and other trading venues to promote fair and orderly markets and to protect the interests of the public and of investors. The Limit Up-Limit Down Plan is part of a coordinated effort amongst various parties including the Exchange and other self-regulatory organizations as well as other market participants. While the specific proposals to implement changes to Exchange functionality consistent with the Plan may differ in certain ways from the implementation adopted by other market centers, the Exchange believes its proposals are consistent with the requirements and purpose of the Plan. Specifically, the proposed Volatility Closing Auction will address situations where a security is halted in the last 10 minutes of the trading day in order to hold a single auction at the end of Regular Trading Hours.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BATS–2013–066 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2013–066. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2013–066, and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30933 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71167; File No. SR–NASDAQ–2013–160]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the Definition of "System Securities" in NASDAQ Rule 4751

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 19, 2013, The NASDAQ Stock Market LLC ("NASDAQ" or "Exchange"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the definition of "System Securities" set forth in NASDAQ Rule 4751.

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available from NASDAQ's Web site at *http://nasdaq.cchwallstreet.com/Filings/*, at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the definition of "System Securities" set forth in NASDAQ Rule 4751(b) to clarify that while all securities covered by the Consolidated Tape Association Plan and Consolidated Quotation Plan ("CT/CQ Securities") are eligible to be traded on NASDAQ and NASDAQ intends to trade all CT/CQ Securities, NASDAQ will not trade certain securities within that class. By making both a "positive" and a "negative" designation, NASDAQ will clearly signal to its members and to investors that NASDAQ intends to trade certain CT/CQ Securities and not to trade others, and which securities fall into each category.

NASDAQ proposes to effectuate this designation by maintaining a list on the www.nasdaqtrader.com Web site of securities that are excluded from this designation and thus excluded from trading on NASDAQ. The NasdaqTrader Web site is the primary mechanism for NASDAQ to communicate with its members about trading on the exchange. NASDAQ members already receive daily information from the Web site including a daily list of active System Securities, as well as a list of corporate actions and other trading information. Adding a list of CT/CQ securities that are excluded from trading will be an effective complement to the daily information already provided. The rules of other exchanges also provide a designation process that clearly contemplates the trading of less than all eligible securities (*see, e.g.*, BATS Rule 11.2).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(5) of the Act,[4] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transaction in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

NASDAQ believes that the proposal is consistent with the Act in that it provides for greater clarity about the securities traded on the Exchange and, thereby, enhances the Exchange and the national market system. The proposal does not permit unfair discrimination; rather all designated securities may be traded by all members in a free and open market. The proposal does not unfairly discriminate against securities that will not trade on NASDAQ. NASDAQ is not obligated by the Exchange Act to extend unlisted trading privileges to all CT/CQ Securities. Additionally, all CT/CQ Securities will continue to trade on their listing market and on numerous other exchanges that have extended unlisted trading privileges to them.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed change will simply clarify the manner by which NASDAQ extends unlisted trading privileges to CT/CQ Securities, a practice provided for under the Act and already exercised by NASDAQ. CT/CQ Securities will continue to be subject to meaningful competition because they will trade on their listing market and on numerous exchanges that have extended unlisted trading privileges to them.

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[5] and Rule 19b–4(f)(6) thereunder.[6] Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[7]

A proposed rule change filed under Rule 19b–4(f)(6)[8] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[9] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become effective and operative immediately. According to the Exchange, the proposal is designed to provide clarity about securities traded on the Exchange. The Exchange noted that it is not obligated by the Act to extend unlisted trading privileges to all CT/CQ Securities. Additionally, all CT/CQ Securities will continue to trade on their listing market and on other exchanges that have extended unlisted trading privileges to them. Based on the Exchange's statements, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[7] 17 CFR 240.19b–4(f)(6).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii).

designates the proposal as operative upon filing.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[11] of the Act to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2013–160 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number *SR–NASDAQ–2013–160*. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2013–160 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30967 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[10] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78s(b)(2)(B).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71152; File No. SR–CBOE–2013–100]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Relating to CBSX Trading Permit Holder Eligibility

December 20, 2013.

I. Introduction

On October 23, 2013, Chicago Board Options Exchange, Incorporated ("Exchange" or "CBOE") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change regarding eligibility for CBSX Trading Permit Holders. The proposed rule change was published for comment in the **Federal Register** on November 12, 2013.[3] The Commission received four comments on the proposal.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is December 27, 2013.

The Commission is hereby extending the 45-day period for Commission action on the proposed rule change. The Commission has determined that it is appropriate to designate a longer period within which to take action on the proposed rule change. In particular, the extension of time will ensure that the Commission has sufficient time to consider and take action on CBOE's proposal in light of, among other things, the comments received on the proposal and the Exchange's forthcoming response to the comments.

Accordingly, pursuant to Section 19(b)(2)(A)(ii)(I) of the Act[6] and for the reasons stated above, the Commission designates February 10, 2014, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change File No. SR–CBOE–2013–100.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30937 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 70806 (November 5, 2013), 78 FR 67424.

[4] *See* letter from Chris Concannon, Executive Vice President, Virtu Financial BD, LLC, to Elizabeth M. Murphy, Secretary, Commission, dated November 11, 2013; letter from Martin H. Kaplan, Gusrae Kaplan Nusbaum PLLC, to Kevin M. O'Neill, Deputy Secretary, Commission, dated November 18, 2013; letter from James Ongena, General Counsel, Chicago Stock Exchange, Inc., to Elizabeth M. Murphy, Secretary, Commission, dated December 3, 2013; and letter from Mary Ann Burns, Chief Operating Officer, Futures Industry Association, to Elizabeth M. Murphy, Secretary, Commission, dated December 3, 2013.

[5] 15 U.S.C. 78s(b)(2).

[6] 15 U.S.C. 78s(b)(2)(A)(ii)(I).

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71155; File No. SR–NSCC–2013–14]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Its Fee Schedule

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 17, 2013, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by NSCC. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii)[3] of the Act and Rule 19b–4(f)(2)[4] thereunder; the proposed rule change was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consist [*sic*] of amendments to the Rules & Procedures ("Rules") of NSCC to modify its fee schedule, as more fully described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(i) Introduction

The purpose of the proposed rule change is to revise NSCC's fee schedule (as listed in Addendum A of the Rules) in connection with the recent approval of additional alternative investment products eligible for processing through the Alternative Investment Product Services ("AIP") of NSCC, as well as to eliminate the fee cap currently applicable to AIP Distributors[5] processing Registered Hedge Fund transactions through AIP. In general, AIP fees are grouped by volume—higher volume alternative investment products are charged reduced fees, while lower volume alternative investment products are charged higher fees. The newly approved additional alternative investment products eligible for AIP processing are being added to the higher volume category. Under the current AIP fee structure, AIP Distributors are eligible for a fee cap of $50,000 annually ("Fee Cap") on higher volume alternative investment products, such as Non-Traded REITs and Managed Futures. Currently, Registered Hedge Funds are included within the annual Fee Cap. NSCC is amending the existing fee structure to eliminate this Fee Cap as applicable to Registered Hedge Fund transactions and to include the newly added alternative investment products within the Fee Cap.

Additionally, NSCC is proposing to revise its fee schedule with respect to its trade clearance fees in order to align these fees with the costs of delivering services.

Implementation Timeframe

The proposed fee changes will take effect on January 1, 2014.

Proposed Rule Changes

These proposed rule changes are marked on Exhibit 5 to this proposed rule change. No other changes to the Rules are contemplated by this proposed rule change.

(ii) Statutory Basis

The proposed rule change will align NSCC's fees with the costs of delivering services, and will allocate those fees equitably among the NSCC members that use those services. Therefore, NSCC believes the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to NSCC, in particular Section 17A(b)(3)(D) of the Act, which requires that NSCC's Rules provide for the equitable allocation of reasonable dues, fees, and other charges among its participants.

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have any impact, or impose any burden, on competition. As stated above, the proposed changes will align NSCC's fees with the costs of delivering services to its members, and will not disproportionally impact any NSCC members.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The forgoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[6] and Rule 19b–4(f)(2)[7] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–NSCC–2013–14 on the subject line.

Paper Comments

- Send in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NSCC–2013–14. This file number should be included on the subject line if email is used. To help the Commission process and review your

[1] 15 U.S.C. 78s(b)(1).
[2] 17 CFR 240.19b–4.
[3] 15 U.S.C. 78s(b)(3)(A)(ii).
[4] 17 CFR 240.19b–4(f)(2).
[5] AIP Distributors are generally broker/dealers, or otherwise, the buy-side of an AIP transaction.
[6] 15 U.S.C. 78s(b)(3)(A)(ii).
[7] 17 CFR 240.19b–4(f)(2).

comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of NSCC and on NSCC's Web site at (*http://dtcc.com/legal/rule_filings/nscc/2013.php*).

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NSCC–2013–14 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30934 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71153; File No. SR–ISE–2013–67]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Make Non-Controversial Changes to ISE Rules

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on December 5, 2013, the International Securities Exchange, LLC (the "Exchange" or the "ISE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make a number of non-controversial changes and technical corrections to its rules. Examples of such corrections include updating ISE rule number citations and cross references, correcting typographical errors, deleting obsolete rule text, and updating the table of contents. The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.ise.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to make a number of non-controversial and technical changes to its rules. Examples of such corrections include updating ISE rule number citations and cross-references, correcting typographical errors, and deleting obsolete rule text. Following is a narrative description of each of the corrections:

- The Table of Contents to the ISE Rules is being amended to correct a typo in the title of Rule 311 and to reflect the adoption of ISE Rule 703A (Trading During Limit Up-Limit Down States in Underlying Securities), since this rule was not added to the Table of Contents when this rule was initially adopted.[3]
- ISE Rule 413 (Exemptions from Position Limits) is being amended to update an incorrect rule cross-reference numbers in paragraphs (a), (a)(7)(A) and (a)(7)(F). The cross-references are incorrect due to amendments to the cross-referenced rules which changed the numbering and therefore made the cross-reference incorrect.
- ISE Rule 701 (Trading Rotations) is being amended to make a non-substantive change to correct a typographical error in paragraph (b)(2) and to remove the first sentence in paragraph (c), which states that trading in options will close 2 minutes after the primary market on which the underlying stock trades closes for trading. This reference to a 4:02 p.m. closing should have been removed when the hours of trading on the Exchange were amended,[4] but was inadvertently overlooked.
- ISE Rule 705 (Limitation of Liability) is being amended to change a non-substantive word to update the sentence structure of paragraph (a).
- ISE Rule 715 (Types of Orders) is being amended to delete the duplicate definition of "Minimum Quantity Orders" in paragraph (l) and replace it with the defined term of "Day Order." Paragraph (r) is being added to define the term "Good-Till-Cancelled Order (GTC Order)." The addition of these two order types qualify for non-controversial treatment as there is nothing new or novel with respect to these types of orders because they already exist on other exchanges, for example, the Chicago Board Options Exchange has identical order types.[5]
- Supplementary Material .08 to ISE Rule 716 (Block Trades) is being amended to make a non-substantive change to delete the term "Indications" and replace it with the term "Responses" for consistency throughout the rule.
- ISE Rule 802 (Appointment of Market Makers) is being amended to insert a non-substantive word to correct the sentence structure of paragraph (c)(3).
- ISE Rules 803, 810 and 811 are being amended to remove cross-references to Rule 803(c)(2) and replace them with the correct cross-references, where applicable.

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 69148 (March 15, 2013), 78 FR 17462 (March 21, 2013) (SR–ISE–2013–20).

[4] *See* Securities Exchange Act Release No. 53248 (February 7, 2006), 71 FR 8015 (February 15, 2006) (SR–ISE–2005–58).

[5] *See* CBOE Rule 43.2(5) and (7).

These cross-references were inadvertently missed when paragraph 803(c)(2) was deleted from the rules.[6]

- ISE Rule 804(d)(3) is being deleted as this provision is obsolete and no longer applicable.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[7] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes it is appropriate to make these technical corrections to its rules so that Exchange members and investors have a clear and accurate understanding of the meaning of the Exchange's rules. By removing obsolete rule text, the Exchange is eliminating any potential for confusion about how its systems operate, particularly since the Exchange had operated two trading systems while it migrated from its prior system to Optimise, its new trading system. By updating cross-references in its rules, the Exchange is eliminating any inaccuracies. The addition of a Day Order and a GTC Order qualifies for non-controversial treatment as there is nothing new or novel with respect to these order types. Day Orders and GTC Orders merely address the time-in-force of an order and are standard, generic orders. In addition, CBOE has both of these order types in its rules.[8] The Exchange further believes that the proposed rule change is not unfairly discriminatory because it treats all market participants equally and will not have an adverse impact on any market participant.

B. Self-Regulatory Organization's Statement on Burden on Competition

Most of the proposed rule changes are non-substantive corrections to the Exchange's rules and therefore do not implicate the competition analysis. The change proposing to adopt two new order types is non-controversial as they already exist on another exchange and merely address the time-in-force of an order, and will therefore not impact competition because these order types already exist. The proposed rule changes will serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)[9] of the Act and Rule 19b–4(f)(6)[10] thereunder. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing the proposed rule change.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ISE–2013–67 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2013–67. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2013–67 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30932 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[6] *See* Securities Exchange Act Release No. 69396 (April 18, 2013), 78 FR 24273 (April 24, 2013) (SR–ISE–2013–18).

[7] 15 U.S.C. 78f(b)(5).

[8] *See* note 5.

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR. 240.19b–4(f)(6).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71169; File No. SR–PHLX–2013–127]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Modify the Definition of "System Securities" in PSX Rule 3301(b)

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 19, 2013, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the definition of "System Securities" set forth in PSX Rule 3301(b) which governs the operation of the trading system of the NASDAQ OMX PSX equities market.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the definition of "System Securities" set forth in PHLX Rule 3301(b) to clarify that while all securities covered by the Consolidated Tape Association Plan and Consolidated Quotation Plan ("CT/CQ Securities") are eligible to be traded on PSX and PHLX intends to trade all CT/CQ Securities, PHLX will not trade certain securities within that class. By making both a "positive" and a "negative" designation, PHLX will clearly signal to its members and to investors that PHLX intends to trade certain CT/CQ Securities and not to trade others, and which securities fall into each category.

PHLX proposes to effectuate this designation by maintaining a list on the *www.nasdaqtrader.com* Web site of securities that are excluded from this designation and thus excluded from trading on PSX. The NasdaqTrader Web site is the primary mechanism for PHLX to communicate with its members about trading on the exchange. PHLX members already receive daily information from the Web site including a daily list of active System Securities, as well as a list of corporate actions and other trading information. Adding a list of CT/CQ securities that are excluded from trading will be an effective complement to the daily information already provided. The rules of other exchanges also provide a designation process that clearly contemplates the trading of less than all eligible securities (*see, e.g.,* BATS Rule 11.2).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(5) of the Act,[4] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transaction in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

PHLX believes that the proposal is consistent with the Act in that it provides for greater clarity about the securities traded on the Exchange and, thereby, enhances the Exchange and the national market system. The proposal does not permit unfair discrimination; rather all designated securities may be traded by all members in a free and open market. The proposal does not unfairly discriminate against securities that will not trade on PSX. PHLX is not obligated by the Exchange Act to extend unlisted trading privileges to all CT/CQ Securities. Additionally, all CT/CQ Securities will continue to trade on their listing market and on numerous other exchanges that have extended unlisted trading privileges to them.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed change will simply clarify the manner by which PHLX extends unlisted trading privileges to CT/CQ Securities, a practice provided for under the Act and already exercised by PHLX. CT/CQ Securities will continue to be subject to meaningful competition because they will trade on their listing market and on numerous exchanges that have extended unlisted trading privileges to them.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[5] and Rule 19b–4(f)(6) thereunder.[6] Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(5).

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[7]

A proposed rule change filed under Rule 19b–4(f)(6)[8] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[9] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become effective and operative immediately. According to the Exchange, the proposal is designed to provide clarity about securities traded on the Exchange. The Exchange noted that it is not obligated by the Act to extend unlisted trading privileges to all CT/CQ Securities. Additionally, all CT/CQ Securities will continue to trade on their listing market and on other exchanges that have extended unlisted trading privileges to them. Based on the Exchange's statements, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposal as operative upon filing.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[11] of the Act to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–PHLX–2013–127 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–PHLX–2013–127. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PHLX–2013–127 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30969 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[7] 17 CFR 240.19b–4(f)(6).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii).

[10] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78s(b)(2)(B).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71168; File No. SR–BX–2013–064]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Modify the Definition of "System Securities" in BX Rule 4751(b)

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 19, 2013, NASDAQ OMX BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the definition of "System Securities" set forth in BX Rule 4751(b). The text of the proposed rule change is available at *http://nasdaqomxbx.cchwallstreet.com/*, at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the definition of "System Securities" set forth in BX Rule 4751(b) to clarify that while all securities covered by the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Consolidated Tape Association Plan and Consolidated Quotation Plan ("CT/CQ Securities") are eligible to be traded on BX and BX intends to trade all CT/CQ Securities, BX will not trade certain securities within that class. By making both a "positive" and a "negative" designation, BX will clearly signal to its members and to investors that BX intends to trade certain CT/CQ Securities and not to trade others, and which securities fall into each category.

BX proposes to effectuate this designation by maintaining a list on the *www.nasdaqtrader.com* Web site of securities that are excluded from this designation and thus excluded from trading on BX. The NasdaqTrader Web site is the primary mechanism for BX to communicate with its members about trading on the exchange. BX members already receive daily information from the Web site including a daily list of active System Securities, as well as a list of corporate actions and other trading information. Adding a list of CT/CQ securities that are excluded from trading will be an effective complement to the daily information already provided. The rules of other exchanges also provide a designation process that clearly contemplates the trading of less than all eligible securities (*see, e.g.*, BATS Rule 11.2).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(5) of the Act,[4] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transaction in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

BX believes that the proposal is consistent with the Act in that it provides for greater clarity about the securities traded on the Exchange and, thereby, enhances the Exchange and the national market system. The proposal does not permit unfair discrimination; rather all designated securities may be traded by all members in a free and open market. The proposal does not unfairly discriminate against securities that will not trade on BX. BX is not obligated by the Exchange Act to extend unlisted trading privileges to all CT/CQ Securities. Additionally, all CT/CQ Securities will continue to trade on their listing market and on numerous other exchanges that have extended unlisted trading privileges to them.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed change will simply clarify the manner by which BX extends unlisted trading privileges to CT/CQ Securities, a practice provided for under the Act and already exercised by BX. CT/CQ Securities will continue to be subject to meaningful competition because they will trade on their listing market and on numerous exchanges that have extended unlisted trading privileges to them.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[5] and Rule 19b–4(f)(6) thereunder.[6] Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[7]

A proposed rule change filed under Rule 19b–4(f)(6)[8] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[9] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become effective and operative immediately. According to the Exchange, the proposal is designed to provide clarity about securities traded on the Exchange. The Exchange noted that it is not obligated by the Act to extend unlisted trading privileges to all CT/CQ Securities. Additionally, all CT/CQ Securities will continue to trade on their listing market and on other exchanges that have extended unlisted trading privileges to them. Based on the Exchange's statements, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposal as operative upon filing.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[11] of the Act to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comment

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BX–2013–064 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary,

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(5).

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[7] 17 CFR 240.19b–4(f)(6).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii).

[10] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78s(b)(2)(B).

Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2013–064. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2013–064 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30968 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71159; File No. SR–NYSEARCA–2013–145]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Proposes To Amend Commentary .02 to Exchange Rule 6.72 in Order To Extend the Penny Pilot in Options Classes In Certain Issues Previously Approved by the Securities and Exchange Commission Through June 30, 2014

December 20, 2013.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 18, 2013, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .02 to Exchange Rule 6.72 in order to extend the Penny Pilot in options classes in certain issues ("Pilot Program") previously approved by the Securities and Exchange Commission ("Commission") through June 30, 2014. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange hereby proposes to amend Commentary .02 to Exchange Rule 6.72 to extend the time period of the Pilot Program,[4] which is currently scheduled to expire on December 31, 2013 through June 30, 2014. The Exchange also proposes that the dates to replace issues in the Pilot Program that have been delisted be revised to the second trading day following January 1, 2014.[5]

This filing does not propose any substantive changes to the Pilot Program: all classes currently participating will remain the same and all minimum increments will remain unchanged. The Exchange believes the benefits to public customers and other market participants who will be able to express their true prices to buy and sell options have been demonstrated to outweigh the increase in quote traffic.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[6] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5),[7] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. The Exchange believes that the Pilot Program promotes just and equitable principles of trade by enabling public customers and other market participants to express their true prices to buy and sell options. The proposal to extend the Pilot Program is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating

[4] *See* Securities Exchange Act Release No. 69106 (March 11, 2013), 78 FR 16552 (March 15, 2013) (SR–NYSEArca-2013–22).

[5] The month immediately preceding a replacement class's addition to the Pilot Program (i.e., December) would not be used for purposes of the analysis for determining the replacement class. Thus, a replacement class to be added on the second trading day following January 1, 2014 would be identified based on The Option Clearing Corporation's trading volume data from June 1, 2013 through November 30, 2013. The Exchange will announce the replacement issues to the Exchange's membership through a Trader Update.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system, by allowing the Exchange and the Commission additional time to analyze the impact of the Pilot Program while also allowing the Exchange to continue to compete for order flow with other exchanges in option issues trading as part of the Pilot Program.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the Pilot Program, the proposed rule change will allow for further analysis of the Pilot Program and a determination of how the Program should be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. The Pilot Program is an industry wide initiative supported by all other option exchanges. The Exchange believes that extending the Pilot Program will allow for continued competition between Exchange market participants trading similar products as their counterparts on other exchanges, while at the same time allowing the Exchange to continue to compete for order flow with other exchanges in option issues trading as part of the Pilot Program.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of the filing.[12] However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because doing so will allow the Pilot Program to continue without interruption in a manner that is consistent with the Commission's prior approval of the extension and expansion of the Pilot Program and will allow the Exchange and the Commission additional time to analyze the impact of the Pilot Program.[14] Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.[15]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[16] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2013–145 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2013–145. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549–1090. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com*. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2013–145 and should be submitted on or before January 17, 2014.

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this pre-filing requirement.

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *See* Securities Exchange Act Release No. 61061 (November 24, 2009), 74 FR 62857 (December 1, 2009) (SR–NYSEArca-2009–44).

[15] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30941 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71164; File No. SR–NYSE–2013–80]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Offer Risk Management Tools Designed to Allow Member Organizations to Monitor and Address Exposure to Risk

December 20, 2013.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 12, 2013, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to offer risk management tools designed to allow member organizations to monitor and address exposure to risk. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. *Purpose*

In order to assist member organizations' efforts to manage their risk level, the Exchange proposes to offer risk management tools designed to allow member organizations to monitor and address exposure to risk.

On October 2, 2012, the Commission conducted a roundtable entitled "Technology and Trading: Promoting Stability in Today's Markets" (the "Roundtable").[4] While a number of issues were discussed at the Roundtable, a large amount of time was devoted to discussing "kill-switches," a mechanism that would deactivate trading when certain thresholds were met. Panelists and commenters on the Roundtable's topics generally supported a kill-switch mechanism that would permit market centers to terminate a firm's trading activity if such activity was posing a threat to market integrity. But there was concern that firms would "be reluctant to systemically cut themselves off from the market"[5] and therefore, any kill-switch-triggering threshold would be set by the firm at a conservative level such that the automated disconnect would not occur when actually needed. At the same time though, the ability to detect unusual behavior would be invaluable to a firm in assessing whether an error was causing an unwanted buildup in risk.

To address the concerns raised during the Roundtable, the Exchange proposes to offer optional risk management tools for its member organizations that would facilitate, among other things, blocking of a member organization's orders if certain thresholds were met. As proposed, the risk management tools seek to balance the conflicting viewpoints raised during the Roundtable by providing risk monitoring services that grant discretion to the member organizations to define pre-set risk thresholds. The tools are designed to act as a backstop for member organizations' risk controls by providing them with the ability to take action to more effectively manage their risk levels with respect to orders at the Exchange.

The risk management tools will provide member organizations with the ability to segment activity into risk groups and to monitor exposure in real time as trades execute. Member organizations may also take certain actions in response to an unwanted buildup in risk levels, such as bulk blocking or bulk cancelling orders by risk group. Additionally, member organizations may define risk limits that may be adjusted intraday and elect to have the Exchange take action based on these pre-set limits, such as sending alerts as exposure limits are approached and breached or automatically blocking orders upon a breach. The tools are meant to be supplemental, acting as a backstop for a member organization's internal monitoring and procedures related to risk management. The Exchange does not guarantee that the tools will be sufficiently comprehensive to meet all of a member organization's needs, and the tools are not designed to be the sole means of risk control. Moreover, the use of the Exchange's risk management tools will not automatically constitute compliance with Exchange or federal rules.

As noted above, the proposed risk management tools will be optional for member organizations. The Exchange will not provide preferential treatment to member organizations using the Exchange-offered risk management tools and will not charge a fee for use of the risk management tools. Should the Exchange determine to charge a fee for use of the risk management tools, such fee will be proposed through a subsequent rule filing.

The Exchange will be phasing in its risk management tools as the technology supporting the functionality is being implemented and will announce by Trader Update when specific risk management tools will be available. The Exchange intends to make available the ability to segment activity into risk groups, define risk limits, and enter bulk block and bulk cancel messages during the first rollout.[6] Additional functionality, such as allowing member organizations to elect to have the Exchange take automated action based on pre-set limits, will be phased in over subsequent months.

2. *Statutory Basis*

The Exchange believes the proposed rule change is consistent with the

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 67802 (Sept. 7, 2012), 77 FR 56697 (Sept. 13, 2012) (File No. 4–652). A webcast of the Roundtable is available at *www.sec.gov/news/otherwebcasts/2012/ttr100212.shtml*.

[5] *See* Transcript of Roundtable, Sections 0151–0152 (Oct. 2, 2012) (remarks of Lou Steinberg, TD Ameritrade).

[6] The Exchange expects the first rollout to begin in the first quarter of 2014.

requirements of Section 6(b) of the Act,[7] in general, and Section 6(b)(5) of the Act,[8] in particular, in that it is designed to foster cooperation and coordination with persons facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change will foster cooperation and coordination with persons facilitating transactions in securities because the Exchange will provide alerts to member organizations when their trading reaches certain thresholds. As such, the Exchange will help member organizations monitor their risk levels and provide tools for the firms to take action. Additionally, the Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because the tools will provide member organizations with the ability to self-manage their levels of risk while providing an alert system that will help to ensure that member organizations are aware of developing issues. As such, the Exchange believes that the tools will provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

Further, the Exchange believes that the proposed rule change is designed to protect investors and the public interest because the tools are a form of impact mitigation that will aid member organizations in minimizing their risk exposure and reduce the potential for disruptive, market-wide events. The Exchange understands that firms test their trading systems in order to identify and mitigate latent defects. The proposed tools will serve as a back stop for member organizations to assist them in identifying any such issues. The Exchange believes the risk management tools will assist member organizations in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's member organizations because use of the risk management tools is optional and is not a prerequisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal will have a positive effect on competition because, by providing member organizations with additional means to monitor and control risk, the proposal will increase confidence in the proper functioning of the markets. The Exchange believes the risk management tools will assist member organizations in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. As a result, the level of competition should increase as public confidence in the markets is solidified.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6)[10] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2013–80 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2013–80. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2013–80 and should be submitted on or before January 17, 2014. For the Commission, by the Division of Trading

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30964 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71166; File No. SR–NYSEArca–2013–142]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Offer Risk Management Tools Designed To Allow ETP Holders To Monitor and Address Exposure to Risk

December 20, 2013.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 12, 2013, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to offer risk management tools designed to allow ETP Holders to monitor and address exposure to risk. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In order to assist ETP Holders' efforts to manage their risk level, the Exchange proposes to offer risk management tools designed to allow ETP Holders to monitor and address exposure to risk.

On October 2, 2012, the Commission conducted a roundtable entitled "Technology and Trading: Promoting Stability in Today's Markets" (the "Roundtable").[4] While a number of issues were discussed at the Roundtable, a large amount of time was devoted to discussing "kill-switches," a mechanism that would deactivate trading when certain thresholds were met. Panelists and commenters on the Roundtable's topics generally supported a kill-switch mechanism that would permit market centers to terminate a firm's trading activity if such activity was posing a threat to market integrity. But there was concern that firms would "be reluctant to systemically cut themselves off from the market"[5] and therefore, any kill-switch-triggering threshold would be set by the firm at a conservative level such that the automated disconnect would not occur when actually needed. At the same time though, the ability to detect unusual behavior would be invaluable to a firm in assessing whether an error was causing an unwanted buildup in risk.

To address the concerns raised during the Roundtable, the Exchange proposes to offer optional risk management tools for its ETP Holders that would facilitate, among other things, blocking of an ETP Holder's orders if certain thresholds were met. As proposed, the risk management tools seek to balance the conflicting viewpoints raised during the Roundtable by providing risk monitoring services that grant discretion to the ETP Holder to define pre-set risk thresholds. The tools are designed to act as a backstop for ETP Holders' risk controls by providing them with the ability to take action to more effectively manage their risk levels with respect to orders at the Exchange.

The risk management tools will provide ETP Holders with the ability to segment activity into risk groups and to monitor exposure in real time as trades execute. ETP Holders may also take certain actions in response to an unwanted buildup in risk levels, such as bulk blocking or bulk cancelling orders by risk group. Additionally, ETP Holders may define risk limits that may be adjusted intraday and elect to have the Exchange take action based on these pre-set limits, such as sending alerts as exposure limits are approached and breached or automatically blocking orders upon a breach. The tools are meant to be supplemental, acting as a backstop for an ETP Holder's internal monitoring and procedures related to risk management. The Exchange does not guarantee that the tools will be sufficiently comprehensive to meet all of an ETP Holder's needs, and the tools are not designed to be the sole means of risk control. Moreover, the use of the Exchange's risk management tools will not automatically constitute compliance with Exchange or federal rules.

As noted above, the proposed risk management tools will be optional for ETP Holders. The Exchange will not provide preferential treatment to ETP Holders using the Exchange-offered risk management tools and will not charge a fee for use of the risk management tools. Should the Exchange determine to charge a fee for use of the risk management tools, such fee will be proposed through a subsequent rule filing.

The Exchange will be phasing in its risk management tools as the technology supporting the functionality is being implemented and will announce by Trader Update when specific risk management tools will be available. The Exchange intends to make available the ability to segment activity into risk groups, define risk limits, and enter bulk block and bulk cancel messages during the first rollout.[6] Additional functionality, such as allowing ETP Holders to elect to have the Exchange take automated action based on pre-set limits, will be phased in over subsequent months.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[7] in general, and Section 6(b)(5) of the Act,[8] in particular, in that it is designed to foster cooperation and coordination

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 67802 (Sept. 7, 2012), 77 FR 56697 (Sept. 13, 2012) (File No. 4–652). A webcast of the Roundtable is available at *www.sec.gov/news/otherwebcasts/2012/ttr100212.shtml*.

[5] *See* Transcript of Roundtable, Sections 0151–0152 (Oct. 2, 2012) (remarks of Lou Steinberg, TD Ameritrade).

[6] The Exchange expects the first rollout to begin in the first quarter of 2014.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

with persons facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change will foster cooperation and coordination with persons facilitating transactions in securities because the Exchange will provide alerts to ETP Holders when their trading reaches certain thresholds. As such, the Exchange will help ETP Holders monitor their risk levels and provide tools for the firms to take action. Additionally, the Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because the tools will provide ETP Holders with the ability to self-manage their levels of risk while providing an alert system that will help to ensure that ETP Holders are aware of developing issues. As such, the Exchange believes that the tools will provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

Further, the Exchange believes that the proposed rule change is designed to protect investors and the public interest because the tools are a form of impact mitigation that will aid ETP Holders in minimizing their risk exposure and reduce the potential for disruptive, market-wide events. The Exchange understands that firms test their trading systems in order to identify and mitigate latent defects. The proposed tools will serve as a back stop for ETP Holders to assist them in identifying any such issues. The Exchange believes the risk management tools will assist ETP Holders in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's ETP Holders because use of the risk management tools is optional and is not a prerequisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal will have a positive effect on competition because, by providing ETP Holders with additional means to monitor and control risk, the proposal will increase confidence in the proper functioning of the markets. The Exchange believes the risk management tools will assist ETP Holders in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. As a result, the level of competition should increase as public confidence in the markets is solidified.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6)[10] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comment

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email *to rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2013–142 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2013–142. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2013–142 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30966 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71157; File No. SR–NYSEMKT–2013–88]

Self-Regulatory Organizations; NYSE MKT LLC; Order Approving Proposed Rule Change Amending Certain Rules That Address Wash Sales in Order To Harmonize the Exchange's Rules With the Rules of New York Stock Exchange LLC and the Financial Industry Regulatory Authority

December 20, 2013.

I. Introduction

On October 29, 2013, NYSE MKT LLC ("NYSE MKT" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend certain rules that address wash sales in order to harmonize the Exchange's rules with the rules of New York Stock Exchange LLC ("NYSE") and the Financial Industry Regulatory Authority ("FINRA"). The proposed rule change was published for comment in the **Federal Register** on November 14, 2013.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

In the filing, the Exchange proposed to amend its wash sale rules to achieve a greater level of internal consistency as well as consistency with FINRA's and NYSE's rules. First, the Exchange proposed to eliminate Rule 476(a)(8), instead utilizing Rule 6140—Equities for wash sale disciplinary actions in its equities market, as the Exchange believes that the conduct described in that rule should not be treated as a wash sale violation in all instances. The Exchange stated that it believes that the scienter requirement in Exchange Rule 6140—Equities, NYSE Rule 6140 and FINRA Rule 6140 recognizes that in today's markets, there can be certain instances of trading activity that may inadvertently and unknowingly result in executions with no change in beneficial ownership, and that such conduct should not always be treated as a wash sale violation if the market participant did not act with purpose—for example, the Exchange noted that activity involving an off-floor market participant's algorithmic orders that inadvertently execute against themselves due to latency issues could be deemed a violation of the second prong of Rule 476(a)(8).

Second, so that there is no change in the scope of equity market participants subject to disciplinary action for wash sales, the Exchange proposed a conforming amendment to Rule 6140(a) and (b)—Equities to provide that the rule applies not only to members and member organizations, but also to principal executives, approved persons, registered or non-registered employees of a member or member organization or persons otherwise subject to the jurisdiction of the Exchange.[4]

The Exchange also proposed to delete Rule 4,[5] marking it "Reserved." Finally, the Exchange proposed to add substantially the same text of Rule 6140(a) and (b)—Equities to (options) Rule 995NY, in new subparagraphs (e) and (f). As such, the Exchange is extending the substance of the specific wash sale prohibitions in Rule 6140(a) and (b)—Equities to trading on the Exchange's options market.[6] The Exchange stated that locating these provisions in the options rules will give options market participants better notice of this prohibited conduct.[7]

III. Discussion and Commission Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act[8] and the rules and regulations thereunder applicable to a national securities exchange.[9] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[10] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange is deleting Rule 476(a)(8), a rule which the Exchange explained was originally adopted by the NYSE (and subsequently adopted by the Exchange) to address manual, floor-based trading activity. In its place, the Exchange proposes to use Rule 6140—Equities for wash sale disciplinary actions in its equities market. The Exchange stated that Rule 6140—Equities, which has a scienter standard that the second prong of Rule 476(a)(8) lacks, recognizes that certain inadvertent trading activity, such as algorithmic trading, that results unintended executions with no change in beneficial ownership should not always be treated as a wash sale violation. In addition, the Exchange is amending Exchange Rule 6140(a) and (b)—Equities to cover the same persons that Exchange Rule 476(a)(8) covered. Finally, the Exchange is proposing to delete Rule 4, and to add substantially the same text as Rule 6140(a) and (b)—Equities to Exchange Rule 995NY so that the substance of the wash sale prohibitions in Rule 6140(a) and (b)—Equities also applies to trading on the Exchange's options market.

The Commission understands that algorithmic trading can result in inadvertent executions with no change in beneficial ownership.[11] The Exchange has represented that the proposed rule change would not result in any material change in the surveillance of potentially violative activity nor any material diminution of the Exchange's enforcement authority as it may still bring a disciplinary action in cases where a market participant engages in a significant number of trades without a change of beneficial ownership, even if such activity does not per se violate Rule 6140(b)—Equities or proposed Rule 995NY(f)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 70832 (November 7, 2013), 78 FR 68488 ("Notice").

[4] These persons were subject to Rule 476(a)(8).

[5] Rule 4 in Part 1 of the General Rules provides that "[n]o member or member organization shall execute or cause to be executed, or participate in an account for which there is executed on the Exchange, the purchase of any security at successively higher prices or the sale of any security at successively lower prices for the purpose of creating or inducing a false, misleading or artificial appearance of activity in such security or for the purpose of unduly or improperly influencing the market price of such security or for the purpose of making a price which does not reflect the true state of the market in such security." Rule 4 applies to both the Exchange's equities and options markets.

[6] The references to a "designated security" in the text of Rule 6140(a) and (b)—Equities would be replaced with "listed option" in proposed Rule 995NY and similarly references to a "member" or "member organization" would be replaced with "ATP Holder."

[7] The Exchange also proposed a technical amendment to move a definition of a term that is used in Rule 995NY(c) to that subparagraph of the rule. Specifically, the definition of the term "related instrument" currently appears at the end of the rule following the designation of subparagraph (d) and the text thereof, although that term is used in subparagraph (c). As such, the Exchange proposed to move the text of the definition of "related instrument" to Rule 995NY(c).

[8] 15 U.S.C. 78f.

[9] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[10] 15 U.S.C. 78f(b)(5).

[11] The Commission notes that algorithmic trading resulting in executions with no change in beneficial ownership, even if unintended, raises concerns.

because the participant did not act with "purpose." The Exchange further represented that such unintended activity could also give rise to other violations, such as a failure to supervise under Rule 342—Equities or Rule 922, or a violation of just and equitable principles of trade or could otherwise constitute unethical activity under Rule 476(a)(6) or Rule 2010—Equities. Accordingly, the Commission expects the Exchange to continue to surveil for potential wash sale activity and to take necessary action as appropriate.

The Commission believes that the proposed deletion of Rule 476(a)(8) and Rule 4 promotes harmonization, consistency and clarity with respect to the Exchange's rules [12] by resolving the current inconsistent scienter standards of Exchange Rule 476(a)(8) and Exchange Rule 4,[13] Exchange Rule 6140—Equities, NYSE Rule 6140 and FINRA Rule 6140, as well as extending the breadth of persons covered by Rule 6140—Equities to those persons covered by Rule 476(a)(8). The Commission also believes that the additions to Exchange Rule 995NY to apply the specific provisions of Rule 6140(a) and (b)—Equities to the Exchange's options market are appropriate because the Exchange's ATP Holders will be subject to a rule that prohibits wash sales that were designed to create or induce a false or misleading appearance of activity in a designated security. The change will provide clear notice to the ATP Holders of such prohibited activity, as well as make the prohibited activity consistent across both the Exchange's equities and options markets, as well as across NYSE and FINRA. The Commission believes that the proposed rule change should result in less burdensome and more efficient regulatory compliance for firms that are members of the Exchange, NYSE and FINRA. As such, the Exchange's rules would continue to protect investors and the public interest.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act [14] and the rules and regulations thereunder applicable to a national securities exchange.

[12] The Exchange stated that it can bring disciplinary actions under Rule 476(a)(8) for conduct that occurred prior to the time the rule is deleted. Thus, the proposed rule change would have no impact on ongoing disciplinary actions involving violations of Rule 476(a)(8).

[13] The Exchange noted that Rule 4 is substantially the same as Rule 6140(a)—Equities.

[14] 15 U.S.C. 78f(b)(5).

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[15] that the proposed rule change (SR–NYSEMKT–2013–88) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30938 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(2).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71163; File No. SR–NYSEMKT–2013–104]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Proposes to Amend Commentary .02 to NYSE Amex Options Rule 960NY in order to Extend the Penny Pilot in Options Classes in Certain Issues Previously Approved by the Securities and Exchange Commission through June 30, 2014

December 20, 2013.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the "Act") [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 18, 2013, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .02 to NYSE Amex Options Rule 960NY in order to extend the Penny Pilot in options classes in certain issues ("Pilot Program") previously approved by the Securities and Exchange Commission ("Commission") through June 30, 2014. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange hereby proposes to amend Commentary .02 to Exchange Rule 960NY to extend the time period of the Pilot Program,[4] which is currently scheduled to expire on December 31, 2013 through June 30, 2014. The Exchange also proposes that the dates to replace issues in the Pilot Program that have been delisted be revised to the second trading day following January 1, 2014.[5]

This filing does not propose any substantive changes to the Pilot Program: All classes currently participating will remain the same and all minimum increments will remain unchanged. The Exchange believes the benefits to public customers and other market participants who will be able to express their true prices to buy and sell options have been demonstrated to outweigh the increase in quote traffic.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[6] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5),[7] in

[4] *See* Securities Exchange Act Release No. 69105 (March 11, 2013), 78 FR 16554 (March 15, 2013) (SR–NYSEMKT–2013–17).

[5] The month immediately preceding a replacement class's addition to the Pilot Program (i.e., December) would not be used for purposes of the analysis for determining the replacement class. Thus, a replacement class to be added on the second trading day following January 1, 2014 would be identified based on The Option Clearing Corporation's trading volume data from June 1, 2013 through November 30, 2013. The Exchange will announce the replacement issues to the Exchange's membership through a Trader Update.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. The Exchange believes that the Pilot Program promotes just and equitable principles of trade by enabling public customers and other market participants to express their true prices to buy and sell options. The proposal to extend the Pilot Program is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system, by allowing the Exchange and the Commission additional time to analyze the impact of the Pilot Program while also allowing the Exchange to continue to compete for order flow with other exchanges in option issues trading as part of the Pilot Program.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the Pilot Program, the proposed rule change will allow for further analysis of the Pilot Program and a determination of how the Program should be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. The Pilot Program is an industry wide initiative supported by all other option exchanges. The Exchange believes that extending the Pilot Program will allow for continued competition between NYSE Amex Options market participants trading similar products as their counterparts on other exchanges, while at the same time allowing the Exchange to continue to compete for order flow with other exchanges in option issues trading as part of the Pilot Program.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of the filing.[12] However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because doing so will allow the Pilot Program to continue without interruption in a manner that is consistent with the Commission's prior approval of the extension and expansion of the Pilot Program and will allow the Exchange and the Commission additional time to analyze the impact of the Pilot Program.[14] Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.[15]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[16] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2013–104 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2013–104. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this pre-filing requirement.

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *See* Securities Exchange Act Release No. 61061 (November 24, 2009), 74 FR 62857 (December 1, 2009) (SR–NYSEArca-2009–44).

[15] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78s(b)(2)(B).

provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549–1090. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com*. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2013–104 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30940 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71160; File No. SR–ISE–2013–60]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Rent Cabinet Space to Telecommunication Vendors in the Exchange's Backup Datacenter

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 13, 2013, the International Securities Exchange, LLC (the "Exchange" or the "ISE") filed with the Securities and Exchange Commission the proposed rule change, as described in Items I and II below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE proposes to provide cabinet space in its backup datacenter to telecommunication vendors to replace substantially similar services currently provided by the Exchange's third party datacenter operator in connection with the move of this datacenter to an ISE facility, and to adopt a corresponding disaster recovery network fee. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

ISE is in the process of moving its backup datacenter from the current third-party site in New Jersey ("Telx") to the Exchange's headquarters in New York, and, in connection with this move, is proposing to allow telecommunication vendors to rent cabinet space in the ISE facility, and to adopt a corresponding disaster recovery network fee.

Currently, market participants, including members and non-members, may rent cabinet space in the backup datacenter run by Telx in order to maintain connectivity to the Exchange in the event that the ISE's primary datacenter is not operational. As the Exchange is moving its hardware to an ISE-run facility, the Exchange proposes to offer this service itself. In particular, the ISE proposes to facilitate connectivity to the backup datacenter by providing telecommunication vendors with cabinet space,[3] in either half cabinet or full cabinet options, along with power and cooling in a secure, controlled environment.[4] The proposed services are substantially the same as services currently provided through Telx to market participants that wish to connect to the ISE's backup datacenter. The Exchange believes that it is important that it continue to provide these services so that market participants may connect to the backup datacenter in the event that the ISE's primary datacenter is not operational.

Like the ISE's third party datacenter operator, the Exchange intends to charge a fee to telecommunication vendors that wish to rent cabinet space in the ISE's backup datacenter when it is moved to the new facility. Operating the backup datacenter takes a significant amount of ISE resources, and the proposed "disaster recovery network fee" will allow the Exchange to recoup associated expenses. As explained above, the proposed fee will entitle vendors to obtain cabinet space in the datacenter, along with power and cooling. The fees assessed will reflect the amount of cabinet space used by each vendor, and will be $2,300 per month for a half-cabinet and $2,800 per month for a full cabinet. The Exchange will not charge any installation or other fees to telecommunication vendors for connecting to the backup datacenter.

As proposed, firms that currently connect to the backup datacenter at Telx will be able to continue to do so through telecommunication vendors who have entered into a contractual agreement with the Exchange to provide these services, and who will be responsible for redistributing connectivity to market participants that desire access. This would include members that currently connect to Telx in order to maintain connectivity in the event that the Exchange must operate using its backup datacenter.[5] It would also include non-members (e.g., extranet providers) that currently connect to Telx in order to redistribute that connectivity to others.[6] For operational reasons, market participants will not be permitted to connect directly to the backup datacenter at the ISE facility, and must go through a telecommunication vendor. The Exchange believes that this provides a more efficient means of managing connectivity to the backup datacenter as the ISE would not need to set up and maintain many separate connections from market participants.

The Exchange expects that initially four telecommunication vendors will provide connectivity to the backup

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Cabinet space will be provided in industry standard 19" open air racks, which will be secured in a caged meet-me-room that is controlled by 24x7 access based on a registration process for access.

[4] This service is being provided as a means of establishing connectivity to the backup datacenter. Renting cabinet space does not entitle telecommunications vendors to receive or redistribute market data.

[5] Members are not required to establish connectivity to the Exchange's backup datacenter, which is purely voluntary.

[6] An "extranet provider" is a technology provider that connects with ISE systems and in turn provides such connectivity to market participants that do not connect directly with the Exchange.

datacenter to market participants. Each of these vendors currently rents cabinet space in the Telx datacenter, and will continue to provide market participants with access to the backup datacenter when it is moved to the ISE facility. The ISE is not affiliated with any of these telecommunication vendors, and has no financial interest in, and will not be involved in billing or collecting, fees that the vendors may charge their customers to connect to the backup datacenter.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Securities Exchange Act of 1934 (the "Act"),[7] in general, and with Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange also believes that the proposed rule change furthers the objectives of Section 6(b)(4) of the Act,[9] in that it provides for the equitable allocation of reasonable dues, fees and other charges among Exchange members and other persons using its facilities.

The Exchange believes that it is necessary in the public interest that it facilitate connectivity to the backup datacenter in order to minimize any potential disruption and market impact that may otherwise occur if the ISE's primary datacenter is not operational. The proposed services will replace services currently provided by Telx in connection with the move of the Exchange's backup datacenter to an ISE-operated facility. The Exchange believes that it is important to continue to provide the proposed services, which will provide a robust, efficient, and, as discussed below, cost effective means of facilitating access to the ISE's backup datacenter.

Furthermore, the Exchange believes that the proposed disaster recovery network fee, which will replace fees currently charged by Telx, is fair and equitable as it compares favorably with the fees charged by other options exchanges that rent cabinet space in their datacenters. For example, NASDAQ OMX PHLX, LLC ("PHLX") charges members that rent space in its datacenter a fee of $3,000 per month for a half cabinet and between $4,000 per month to $13,000 per month for a full cabinet depending on the options that members of that exchange specify.[10] Moreover, telecommunication vendors are expected to recoup the cost of the proposed fee, plus a premium, by redistributing connectivity to market participants. Similarly, the Exchange expects that telecommunication vendors will spread the cost of this service among their clients, resulting in a lower overall fee to market participants that establish connectivity through such vendors. Since all market participants must connect through a telecommunications vendor rather than establishing a direct connection to the backup datacenter, the Exchange believes that its proposed fee will ultimately be spread among many parties, resulting in a significantly lower cost of connecting to the disaster recovery network. The Exchange also believes the proposed disaster recovery network fee is equitably allocated in that all telecommunication vendors will be charged the same amount to maintain a connection. Moreover, the Exchange believes the proposed fee is not unfairly discriminatory in that there is no differentiation among vendors with regard to the fees charged for connectivity to the Exchange's backup datacenter.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange believes that the proposed rule change will not impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change will enhance intermarket competition by enabling the Exchange to continue to provide an important competitive service to market participants. The Exchange believes that it is important that market participants are able to connect to the backup datacenter in the event that the ISE's primary datacenter is not operational, and is proposing to offer services that would allow market participants to establish such connectivity. Facilitating this connectivity will not have any impact on intramarket competition as the services are substantially the same as services currently provided by the Exchange's third party datacenter operator for a fee that will now be replaced by an ISE fee. The Exchange notes that while, for operational reasons, it is only renting cabinet space to telecommunications vendors; this will have no impact on competition because these vendors are tasked with redistributing this connectivity to market participants as they currently do today. The Exchange believes that selecting multiple telecommunications vendors to provide connectivity to the backup datacenter will allow market participants to also benefit from competition between such vendors. The Exchange will not discriminate in contracting with telecommunication vendors to connect to the backup datacenter, and all contracted vendors will be charged the same fees and granted the same level of access to the backup datacenter at the ISE facility.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (1) Significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) by its terms does not become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(4).

[10] *See* PHLX Pricing Schedule, Co-Location Services, Cabinets; Securities Exchange Act Release No. 62395 (June 28, 2010), 75 FR 38584 (July 2, 2010) (PHLX–2010–18) (order approving initial cabinet fees). In addition to the monthly fee PHLX also charges an installation fee that ranges from $3,500 to $7,000 depending on the type of cabinet.

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to provide the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change; or such shorter time as designated by the Commission. The Exchange has met this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing noting that it is in the public interest that the Exchange facilitate connectivity to the backup datacenter in order to minimize any potential disruption and market impact that may otherwise occur if the Exchange's primary datacenter is not operational. The Exchange further represents that the waiver is necessary to permit the Exchange to continue to facilitate access to its backup datacenter when it is moved over to an ISE-operated facility. The Exchange stated that it is vital that market participants be able to access the ISE through the Exchange's backup datacenter should the need arise. Moreover, the Exchange believes that its proposal, which will allow market participants to access the backup datacenter through one of multiple telecommunication vendors, provides a robust, efficient, and cost effective means of facilitating this access. For the above reasons, the Commission believes that waiving the 30 day operative delay is consistent with the protection of investors and the public interest in that the Exchange may immediately provide connectivity to the backup datacenter to minimize any disruption to the market in case ISE's primary datacenter is not operational. Accordingly, the Commission hereby grants the Exchange's request and designates the proposal operative upon filing.[16]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[17] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ISE–2013–60 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2013–60. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2013–60 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30963 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78s(b)(2)(B).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71165; File No. SR–NYSEMKT–2013–102]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Offer Risk Management Tools Designed To Allow Member Organizations To Monitor and Address Exposure to Risk

December 20, 2013.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 12, 2013, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to offer risk management tools designed to allow equity member organizations to monitor and address exposure to risk. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In order to assist equity member organizations' efforts to manage their risk level, the Exchange proposes to offer risk management tools designed to allow member organizations to monitor and address exposure to risk. These tools are designed for the Exchange's equity trading market and are identical to the tools that will be offered by the New York Stock Exchange LLC.

On October 2, 2012, the Commission conducted a roundtable entitled "Technology and Trading: Promoting Stability in Today's Markets" (the "Roundtable").[4] While a number of issues were discussed at the Roundtable, a large amount of time was devoted to discussing "kill-switches," a mechanism that would deactivate trading when certain thresholds were met. Panelists and commenters on the Roundtable's topics generally supported a kill-switch mechanism that would permit market centers to terminate a firm's trading activity if such activity was posing a threat to market integrity. But there was concern that firms would "be reluctant to systemically cut themselves off from the market" [5] and therefore, any kill-switch-triggering threshold would be set by the firm at a conservative level such that the automated disconnect would not occur when actually needed. At the same time though, the ability to detect unusual behavior would be invaluable to a firm in assessing whether an error was causing an unwanted buildup in risk.

To address the concerns raised during the Roundtable, the Exchange proposes to offer optional risk management tools for its member organizations that would facilitate, among other things, blocking of a member organization's orders if certain thresholds were met. As proposed, the risk management tools seek to balance the conflicting viewpoints raised during the Roundtable by providing risk monitoring services that grant discretion to the member organizations to define pre-set risk thresholds. The tools are designed to act as a backstop for member organizations' risk controls by providing them with the ability to take action to more effectively manage their risk levels with respect to orders at the Exchange.

The risk management tools will provide member organizations with the ability to segment activity into risk groups and to monitor exposure in real time as trades execute. Member organizations may also take certain actions in response to an unwanted buildup in risk levels, such as bulk blocking or bulk cancelling orders by risk group. Additionally, member organizations may define risk limits that may be adjusted intraday and elect to have the Exchange take action based on these pre-set limits, such as sending alerts as exposure limits are approached and breached or automatically blocking orders upon a breach. The tools are meant to be supplemental, acting as a backstop for a member organization's internal monitoring and procedures related to risk management. The Exchange does not guarantee that the tools will be sufficiently comprehensive to meet all of a member organization's needs, and the tools are not designed to be the sole means of risk control. Moreover, the use of the Exchange's risk management tools will not automatically constitute compliance with Exchange or federal rules.

As noted above, the proposed risk management tools will be optional for member organizations. The Exchange will not provide preferential treatment to member organizations using the Exchange-offered risk management tools and will not charge a fee for use of the risk management tools. Should the Exchange determine to charge a fee for use of the risk management tools, such fee will be proposed through a subsequent rule filing.

The Exchange will be phasing in its risk management tools as the technology supporting the functionality is being implemented and will announce by Trader Update when specific risk management tools will be available. The Exchange intends to make available the ability to segment activity into risk groups, define risk limits, and enter bulk block and bulk cancel messages during the first rollout.[6] Additional functionality, such as allowing member organizations to elect to have the Exchange take automated action based on pre-set limits, will be phased in over subsequent months.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[7] in general, and Section 6(b)(5) of the Act,[8] in particular, in that it is designed to foster cooperation and coordination with persons facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change will foster cooperation and coordination with persons facilitating transactions in securities because the Exchange will provide alerts to member organizations when their trading reaches certain thresholds. As such, the Exchange will help member organizations monitor their risk levels and provide tools for the firms to take action. Additionally, the Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because the tools will provide member organizations with the ability to self-manage their levels of risk while providing an alert system that will help to ensure that member organizations are aware of developing issues. As such, the Exchange believes that the tools will provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

Further, the Exchange believes that the proposed rule change is designed to protect investors and the public interest because the tools are a form of impact mitigation that will aid member organizations in minimizing their risk exposure and reduce the potential for disruptive, market-wide events. The Exchange understands that firms test their trading systems in order to identify and mitigate latent defects. The proposed tools will serve as a back stop for member organizations to assist them in identifying any such issues. The Exchange believes the risk management tools will assist member organizations in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's member organizations because use of the risk management tools is optional and is not a

[4] *See* Securities Exchange Act Release No. 67802 (Sept. 7, 2012), 77 FR 56697 (Sept. 13, 2012) (File No. 4–652). A webcast of the Roundtable is available at *www.sec.gov/news/otherwebcasts/2012/ttr100212.shtml.*

[5] *See* Transcript of Roundtable, Sections 0151–0152 (Oct. 2, 2012) (remarks of Lou Steinberg, TD Ameritrade).

[6] The Exchange expects the first rollout to begin in the first quarter of 2014.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

prerequisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal will have a positive effect on competition because, by providing member organizations with additional means to monitor and control risk, the proposal will increase confidence in the proper functioning of the markets. The Exchange believes the risk management tools will assist member organizations in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. As a result, the level of competition should increase as public confidence in the markets is solidified.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) [10] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2013–102 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2013–102. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2013–102 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30965 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 71158; File No. SR–NASDAQ–2013–158]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Acceptable Trade Range

December 20, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 16, 2013, The NASDAQ Stock Market LLC ("NASDAQ" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to delay the implementation of a recent proposed amendment to rule text related to Acceptable Trade Range.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaq.cchwallstreet.com*, at the principal office of the Exchange, at the Commission's Public Reference Room, and on the Commission's Web site at *http://www.sec.gov*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to delay the implementation of a recent proposed amendment to rule text in Chapter VI, Section 10 entitled "Book Processing" to add additional rule text regarding Acceptable Trade Range. The Acceptable Trade Range enhancements would be implemented as of December 23, 2013.[3] At this time, the Exchange needs additional time to implement the applicable technology. Accordingly, the Exchange seeks to be able to implement the changes in January 2014. The Exchange will announce the specific date in advance through an Options Trader Alert.

The Acceptable Trade Range is a mechanism to prevent the system[4] [sic] from experiencing dramatic price swings by creating a level of protection that prevents the market from moving beyond set thresholds. The thresholds consist of a Reference Price plus (minus) set dollar amounts based on the nature of the option and the premium of the option.

With the rule amendment, the System will calculate an Acceptable Trade Range by taking the reference price, plus or minus a value to be determined by the Exchange. (i.e., the reference price—(x) for sell orders and the reference price + (x) for buy orders).[5] Upon receipt of a new order, the reference price is the National Best Bid (NBB) for sell orders and the National Best Offer (NBO) for buy orders or the last price at which the order is posted whichever is higher for a buy order or lower for a sell order. If an order reaches the outer limit of the Acceptable Trade Range (the "Threshold Price") without being fully executed, it will be posted at the Threshold Price for a brief period, not to exceed one second ("Posting Period"), to allow more liquidity to be collected. Upon posting, either the current Threshold Price of the order or an updated NBB for buy orders or the NBO for sell orders (whichever is higher for a buy order/lower for a sell order) then becomes the reference price for calculating a new Acceptable Trade Range. If the order remains unexecuted, a new Acceptable Trade Range will be calculated and the order will execute, route, or post up to the new Acceptable Trade Range Threshold Price. Today, this process will repeat until either (i) the order/quote is executed, cancelled, or posted at its limit price or (ii) the order has been subject to a configurable number of instances of the Acceptable Trade Range as determined by the Exchange.[6] Once the maximum number of instances has been reached, the order is returned.

The Exchange posts a maximum number of Acceptable Trade Range iterations, until the order is cancelled on its Trading System Settings page located on the NASDAQTrader.com Web site.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[7] in general, and furthers the objectives of Section 6(b)(5) of the Act[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest by enhancing the ATR [sic] to make the Exchange's markets more efficient, to the benefit of the investing public. Although the Exchange needs additional time to finalize the enhancements, the delay is expected to be short and will involve advance notice to the Exchange membership.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes this proposed rule change would provide NOM Participants greater certainty when transacting orders on the Exchange and continue to reduce the negative impacts of sudden, unanticipated volatility in and enhance the price-discovery process.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that waiver of the operative delay would permit the Exchange to delay the implementation of a recent proposed amendment to rule text related to Acceptable Trade Range.

Under the proposal, the Exchange would delay the implementation of the Acceptable Trade Range rule text changes from December 23, 2013, to January on a specific date to be announced in advance through an Options Trader Alert. The Exchange represents that a waiver of the 30-day operative delay is necessary and appropriate to ensure that the

[3] Securities Exchange Act Release No. 70985 (December 4, 2013), 78 FR 74206, (December 10, 2013) (SR–NASDAQ–2013–145).

[4] The term "System" shall mean the automated System for order execution and trade reporting owned and operated by The Nasdaq Options Market LLC. *See* NOM Rules at Chapter VI, Section 1(a).

[5] The Acceptable Trade Range settings are tied to the option premium.

[6] NOM Participants may elect to have their orders cancelled by the System after the first iteration.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 15 U.S.C. 78s(b)(3)(A)

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

technology for the changes is ready for implementation. The Exchange further represents that the delay will be short and that it will provide advance notice of the implementation date to its membership. Based on the Exchange's representations, the Commission waives the 30-day operative delay requirement and designates the proposed rule change as operative upon filing.[15]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[16] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2013–158 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number *SR–NASDAQ–2013–158*. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2013–158 and should be submitted on or before January 17, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–30939 Filed 12–26–13; 8:45 am]

BILLING CODE 8011–01–P

[15] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78s(b)(2)(B).

[17] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

Public Notice; Culturally Significant Objects Imported for Exhibition Determinations: "Treasures from Korea: Arts and Culture of the Joseon Dynasty, 1392–1910"

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Treasures from Korea: Arts and Culture of the Joseon Dynasty, 1392–1910," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Philadelphia Museum of Art, Philadelphia, PA, from on or about March 2, 2014, until on or about May 26, 2014; the Los Angeles County Museum of Art, Los Angeles, CA, from on or about June 29, 2014, until on or about September 28, 2014; the Museum of Fine Arts, Houston, TX, from on or about November 11, 2014, until on or about January 11, 2015, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: December 20, 2013.

Evan M. Ryan,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–31090 Filed 12–26–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8575]

Culturally Significant Objects Imported for Exhibition Determinations: "Gauguin: Metamorphoses"

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000, I hereby determine that the objects to be included in the exhibition, "Gauguin: Metamorphoses," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Museum of Modern Art, New York, New York, from on or about March 8, 2014, until on or about June 8, 2014, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of

the exhibit objects, contact Paul W. Manning, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6469). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: December 17, 2013.

Evan Ryan,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–31091 Filed 12–26–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8577]

Culturally Significant Objects Imported for Exhibition Determinations: "Chinese Paintings from Japanese Collections"

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Chinese Paintings from Japanese Collections," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Los Angeles County Museum of Art, Los Angeles, CA, from on or about May 11, 2014, until on or about July 6, 2014, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: December 18, 2013.

Evan M. Ryan,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–31088 Filed 12–26–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2013–0217]

Proposed Information Collection Request; Notice of New Requirements and Procedures for Grant Payment Request Submission

AGENCY: Department of Transportation (DOT).

ACTION: Notice with request for comments.

SUMMARY: The DOT invites the public and other Federal agencies to comment on a revision to a previously approved information collection concerning new requirements and procedures for grant payment request submission. DOT will submit the proposed renewal of information collection request to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506 (c)(2)(A)). This notice sets forth new requirements and procedures for grantees that submit and receive payments from DOT Operating Administrations (OAs).[1] DOT is updating systems that support grant payments and there will be changes to the way grantees complete and submit payment requests. Simplifying the DOT grant payment process will save both the grantee and the Federal Government time and expense that come with paper-based grant application and payment administration. Note: At this time, this requirement is not applicable to DOT grant recipients requesting payment electronically through the National Highway Traffic Safety Administration's Grant Tracking System (GTS), the Federal Highway Administration's Rapid Approval State Payment System (RASPS), or Federal Transit Administration (FTA) grant recipients requesting payment through the Electronic Clearing House Operation System (ECHO-Web).

DATES: Comments must be submitted on or before February 25, 2014.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Department of Transportation, Office of Financial Management, B–30, Room W93–431, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, (202) 366–1306, *DOTElectronicInvoicing@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Notice of Requirements and Procedures for Grant Payment Request Submission.

OMB Control Number: 2105–0564.

Type of Request: Revision to previously approved information collection.

Background: This notice sets forth requirements and procedures for grantees that receive payments from DOT OAs, with the exception of DOT grant recipients requesting payment electronically through the NHTSA's GTS, the FHWA's RASPS, or FTA grant recipients requesting payment through the Electronic Clearing House Operation System (ECHO-Web). The proposed procedures provide that—

- Grantees will now be required to have electronic internet access to register in the Delphi eInvoicing system.
- Grantees will be required to submit payment requests electronically and DOT OAs must process payment requests electronically.
- The identities of system users must be verified prior to receiving access to the Delphi eInvoicing system. Users must complete a user request form and provide the following information: full name, work address, work phone number, work email address, home address and home phone number. Once completed, this form must be presented to a Notary Public for verification. Once notarized, the prospective grantee user will return the form to receive their login credentials.
- DOT Office of Financial Management officials may allow exceptions to the requirement that grantees register and submit payment requests through the Delphi eInvoicing system under limited circumstances. Recipients may apply for an exemption by submitting an electronic Waiver Request Form to the DOT Office of Financial Management. The exceptions will be considered on a case by case basis via Waiver Request Form.

Affected Public: DOT Grant Recipients.

Estimated Number of Respondents: 3,000.

[1] The DOT OAs are: Office of the Secretary of Transportation (OST), Federal Aviation Administration (FAA), Federal Highway Administration (FHWA), Federal Motor Carrier Safety Administration (FMCSA), Federal Railroad Administration (FRA), Federal Transit Administration (FTA), Maritime Administration (MARAD), National Highway Traffic Safety Administration (NHTSA), Office of Inspector General (OIG), Pipeline and Hazardous Materials Safety Administration (PHMSA), Research and Innovative Technology Administration (RITA), Saint Lawrence Seaway Development Corporation (SLSDC) and Surface Transportation Board (STB).

Estimated Number of Responses: 3,000.

Annual Estimated Total Annual Burden Hours: 6,000 (initial registration only).

Frequency of Collection: One time.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to U.S. Department of Transportation, Office of Financial Management, B–30, Room W93–431, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, (202) 366–1306, *DOTElectronicInvoicing@dot.gov.*

Comments: Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents.

Issued in Washington, DC on December 19, 2013

David Rivait,

Deputy Chief Financial Officer, Department of Transportation.

[FR Doc. 2013–30995 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice for Waiver of Aeronautical Land-Use Assurance

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent of waiver with respect to land; Wayne County Airport, Wooster, Ohio.

SUMMARY: The FAA is considering a proposal to change approximately 44.7 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property located at Wayne County Airport, Wooster, Ohio. The aforementioned land is not needed for aeronautical use.

The property is located near the southeast corner of Geyers Chapel Road (T.R. 68) and Hutton Road (C.R. 78). The property is currently being farmed and the proposed use after the sale would be farmland.

DATES: Comments must be received on or before January 27, 2014.

ADDRESSES: Documents are available for review by appointment at the FAA Airports District Office, Irene Porter, Program Manager, 11677 South Wayne Road, Suite 107, Romulus, Michigan 48174 Telephone: (734) 229–2900/Fax: (734) 229–2950 and Wayne County Commissioners, 428 West Liberty Street, Wooster, Ohio, (330) 287–5400.

Written comments on the Sponsor's request must be delivered or mailed to: Irene Porter, Program Manager, Federal Aviation Administration, Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, Michigan 48174, Telephone Number: (734) 229–2900/FAX Number: (734) 229–2950.

FOR FURTHER INFORMATION CONTACT: Irene Porter, Program Manager, Federal Aviation Administration, Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, Michigan 48174. Telephone Number: (734) 229–2900/FAX Number: (734) 229–2950.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of Title 49, *United States Code,* this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

The property was originally acquired by the County for the ultimate development of a cross-wind runway for the airport. The Federal Aviation Administration (FAA) participated in the acquisition of this property under Airport Improvement Program grant 3–39–0093–02. Current FAA standards do not require a cross-wind runway at this airport. The sponsor is now proposing to sell this parcel for Fair Market Value and utilize the proceeds to help improve the existing airport infrastructure and bring it up to FAA standards.

The disposition of proceeds from the sale of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999 (64 FR 7696).

This notice announces that the FAA is considering the release of the subject airport property at the Wayne County Airport, Wooster, Ohio from federal land covenants, subject to a reservation for continuing right of flight as well as restrictions on the released property as required in FAA Order 5190.6B section 22.16. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA.

Situated in the State of Ohio, County of Wayne, Township of Wayne in the southwest quarter of Section 12, T–16N, R–13W and being part of the land described in deeds to The Board of County Commissioners, Wayne County, Ohio recorded in deed volume 426, page 153, volume 555, page 185 and volume 600, page 281 of Wayne County records.

Described as follows:

Commencing at a one inch diameter steel pin found in the intersection of Geyers Chapel Road (Township Road 68) and Hutton Road (County Road 78) marking northwest corner of the southwest quarter of Section 12.

Thence N 89°40′14″ E 430.52 feet, along the north line of the quarter section and in Hutton Road, to the Point of Beginning for the parcel herein described—witnessed by a capped reference pin set S 17°07′20″ W 28.90 feet.

Thence with the following SEVEN courses:

(1) N 89°40′14″ E 1214.67 feet, along the north line of the quarter section and in Hutton Road, to a 5/8 inch diameter steel pin found at the northwest corner of James E. and Janet E. Kasserman, Trustees as described in official record volume 684, page 1857—witnessed by a capped reference pin found S 00°22′01″ E 23.00 feet.

(2) S 00°22′01″ E 1304.74 feet, along the west line of Kasserman, to a 3/4 inch diameter steel pin found.

(3) S 89°32′39″ W 1624.85 feet to a point on the west line of the quarter section—witnessed by a capped reference pin set N 89°32′39″ E 13.98 feet.

(4) N 01°15′27″ W 721.03 feet, along the west line of the quarter section, to a point—witnessed by a capped reference pin set N 88°44′33″ E 10.26 feet.

(5) N 88°44′33″ E 151.46 feet to a capped pin set.

(6) N 39°48′02″ E 211.97 feet to a capped pin set.

(7) N 17°07′20″ E 443.27 feet to the Point of Beginning.

This parcel contains 44.713 acres.

Issued in Romulus, Michigan, on December 5, 2013.

John L. Mayfield, Jr.,

Manager, Detroit Airports District Office, Federal Aviation Administration, Great Lakes Region.

[FR Doc. 2013–31074 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice for Waiver of Aeronautical Land-Use Assurance

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent of waiver with respect to land; DuPage Airport, West Chicago, Illinois.

SUMMARY: The FAA is considering a proposal to change a 1.771–acre portion

of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property located at DuPage Airport, West Chicago, Illinois.

The subject portion of airport property considered for release from obligation to be maintained for aeronautical use and sale includes a 0.672-acre portion of Parcel 601 (83.62 total acres), a 0.298-acre portion of Parcel 8 (1.21 total acres), and a 0.795-acre portion of Tract A (136.95 total acres) that are located in the northeast quadrant of the airport along Illinois Route 64 (North Avenue) and currently not being used directly for aeronautical purposes. Currently, ownership of the property provides for protection of FAR Part 77 surfaces and compatible land use which would continue to be protected with deed restrictions required in the transfer of land ownership. The change from aeronautical to non-aeronautical use would allow for the widening of Route 64 which is directly adjacent to the airport. The aforementioned land is not needed for aeronautical use.

DATES: Comments must be received on or before January 27, 2014.

ADDRESSES: Documents are available for review by prior appointment at the FAA Airports District Office, Mr. Richard Pur, Airports Engineer, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7527/Fax: (847) 294–7046, and DuPage Airport Authority, 2700 International Drive, Suite 200, West Chicago, Illinois 60185, and (630) 584–2211.

Written comments on the Sponsor's request must be delivered or mailed to: Mr. Richard Pur, Airports Engineer, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7527/Fax: (847) 294–7046.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Pur, Airports Engineer, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7527/Fax: (847) 294–7046.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

The acquisition of Parcel 601 was originally funded under Federal ADAP Grant 8–17–0017–01 in June, 1972, with Parcel 8 acquisition funded with local funds. Tract A was acquired via a Quitclaim Deed from the US Government and Reconstruction Finance Corporation (War Assets Administration) in December, 1947. The subject portions of those parcels are currently used for FAR Part 77 protection and to ensure compatible land use. The DuPage Airport Authority plans to sell the subject property to the Illinois Department of Transportation—Division of Highways for the purpose of improvements to be made on Illinois Route 64 (North Avenue) adjacent to the airport. Fair Market Value will be obtained from the sale of the subject property.

This notice announces that the FAA is considering the release of the subject airport property at DuPage Airport, West Chicago, Illinois, from Federal land covenants, subject to a reservation for continuing right of flight as well as restrictions on the released property as required in FAA Order 5190.6B Section 22.16. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA. The use of the revenue generated from the sale of the airport property will be in accordance with FAA's Policy and Procedures concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999 (64 FR 7696).

Parcel 601–A—Subject Portion of Parcel 601 (Legal Description)

That part of the West Half of the West Half of Section 29, Township 40 North, Range 9 East of the Third Principal Meridian, Beginning at the intersection of the north right of way line of Illinois Route 64 (North Avenue and the west right of way of Powis Road per Document #95–67851; thence North 78 degrees 10 minutes 29 seconds West along said north right of way line a distance of 89.34 feet; thence North 51 degrees 30 minutes 35 seconds East a distance of 80.63 feet; thence North 00 degrees 33 minutes 42 seconds East a distance of 359.96 feet to the north line of the Southwest Quarter of said Section 29; thence South 89 degrees 25 minutes 44 seconds East a distance of 30.00 feet; thence South 02 degrees 17 minutes 34 seconds West a distance of 165.52 feet; thence South 00 degrees 33 minutes 42 seconds West a distance of 262.76 feet to the Point of Beginning.

Said parcel contains ± 13,037.99 square feet, ± 0.299 acres.

Parcel 601–B—Subject Portion of Parcel 601 (Legal Description)

That part of the West Half of the West Half of Section 29, Township 40 North, Range 9 East of the Third Principal Meridian, Commencing at the intersection of the north right of way line of Illinois Route 64 (North Avenue) and the west right of way line of Powis Road per Document #95–67851; thence North 78 degrees 10 minutes 29 seconds West along said north right of way line a distance of 89.34 feet; thence North 51 degrees 30 minutes 35 seconds East a distance of 80.63 feet; thence North 00 degrees 33 minutes 42 seconds East a distance of 359.96 feet to the Point of Beginning; thence North 00 degrees 30 minutes 50 seconds East a distance of 137.76 feet; thence South 89 degrees 29 minutes 10 seconds East a distance of 18.00 feet; thence North 00 degrees 30 minutes 50 seconds East a distance of 397.30 feet; thence South 89 degrees 29 minutes 10 seconds East a distance of 15.00 feet; thence North 00 degrees 30 minutes 50 seconds East a distance of 356.05 feet; thence South 89 degrees 29 minutes 10 seconds East a distance of 9.00 feet; thence South 00 degrees 30 minutes 50 seconds West a distance of 726.13 feet; thence North 89 degrees 29 minutes 10 seconds West a distance of 12.00 feet to a point on the west right of way line of Powis Road per Document #95–67851; thence South 00 degrees 30 minutes 50 seconds West along said right of way line a distance of 160.01 feet; thence North 89 degrees 25 minutes 44 seconds West a distance of 30.00 feet to the Point of Beginning.

Said parcel contains ± 16,485.33 square feet, ±0.378 acres.

Parcel 8–B—Subject Portion of Parcel 8 (Legal Description)

That Part of Tract 8 Lying within IDOT Parcel 1EA0006, described as follows.

That part of the Southwest Quarter of Section 29, Township 40 North, Range 9 East of the Third Principal Meridian, in DuPage County, State of Illinois, more particularly described as follows:

Beginning at the intersection of the South Right of Way line of North Avenue (Illinois Route 64) with the West Right of Way line of Powis Road per Document 95–67851; thence South 00 degrees 33 minutes 19 seconds West along the east line of IDOT Parcel 1EA 0006 a distance of 223.29 feet; thence continuing along said east line South 01 degrees 13 minutes 52 seconds East a distance of 111.18 feet to the south line of Tract 8; thence North 80 degrees 06 minutes 09 seconds West along said south line a distance of 30.91 feet to the west line of said IDOT Parcel 1EA0006; thence north along the west line of said IDOT Parcel, North 00 degrees 33 minutes 42 seconds East a

distance of 90.69 feet, thence North 89 degrees 26 minutes 18 seconds West a distance of 11.00 feet; thence North 00 degrees 33 minutes 42 seconds East a distance of 198.39 feet; thence North 37 degrees 33 minutes 19 seconds West a distance of 72.17 feet to the southerly right of way line of North Avenue (Illinois Route 64); thence South 78 degrees 10 minutes 29 seconds East along said southerly right of way line a distance of 84.17 feet to the Point of Beginning.

Said part of Tract 8 as described lying within IDOT Parcel 1EA0006 contains +/- 12,974.3 square feet, +/- 0.298 Acres.

Parcel A–E—Subject Portion of Tract A (Legal Description)

That Part of Tract A lying within IDOT Parcel 1EA0006, described as follows.

That part of the Southwest Quarter of Section 29, Township 40 North, Range 9 East of the Third Principal Meridian, in DuPage County, State of Illinois, more particularly described as follows:

Commencing at the intersection of the South Right of Way line of North Avenue (Illinois Route 64) with the West Right of Way line of Powis Road per Document 95–67851; thence South 78 degrees 10 minutes 29 seconds East along the southerly extension of North Avenue (Illinois Route 64) a distance of 51.06 feet to the east line of the west half of the Southwest Quarter (SW ¼) of Section 29, Township 40 North, Range 9 East of the Third Principal Meridian; thence South 00 degrees 33 minutes 42 seconds West along said east line of the west half of the Southwest Quarter of Section 29 a distance of 758.35 feet to the south line of Right of Way Document 95–67851; thence North 89 degrees 28 minutes 49 seconds West a distance of 33.00 feet to the Point of Beginning: thence South 00 degree 33 minutes 42 seconds West a distance of 539.03 feet; thence west and north along and following IDOT Parcel 1EA0006, North 89 degrees 18 minutes 55 seconds West a distance of 35.00 feet: thence North 00 degree 33 minutes 42 seconds East a distance of 583.11 feet; thence North 89 degrees 18 minutes 55 seconds West a distance of 9.00 feet; thence North 00 degrees 33 minutes 42 seconds East a distance of 394.67 feet to the south line of Tract 8; thence South 80 degrees 06 minutes 09 East seconds along said south line a distance of 30.91 feet to the west line of Right of Way Document 95–67851; thence south and east along said right of way, South 01 degrees 13 minutes 52 seconds East a distance of 434.12 feet to the Point of Beginning.

Said Part of Tract A as described lying within IDOT Parcel 1EA0006 contains +/- 34,635.8 square feet, +/- 0.795 Acres.

Issued in Des Plaines, Illinois, on December 18, 2013.

James G. Keefer,

Manager, Chicago Airports District Office, Federal Aviaition Administration, Great Lakes Region.

[FR Doc. 2013–31073 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice; Key West International Airport, Key West, FL

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the Noise Exposure Maps submitted by Monroe County for the Key West International Airport under the provisions of the Aviation Safety and Noise Abatement Act and FAA's regulations are in compliance with applicable requirements.

DATES: This notice is effective December 19, 2013, and is applicable beginning December 19, 2013.

FOR FURTHER INFORMATION CONTACT: Allan Nagy, Federal Aviation Administration, Orlando Airports District Office, 5950 Hazeltine National Drive Citadel International Building, Suite 400, Orlando, FL 32822, 407–812–6331.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the Noise Exposure Maps submitted for the Key West International Airport are in compliance with applicable requirements of Title 14 Code of Federal Regulations (CFR) part 150, effective December 19, 2013. Under 49 U.S.C. section 47503 of the Aviation Safety and Noise Abatement Act (the Act), an airport operator may submit to the FAA Noise Exposure Maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted Noise Exposure Maps that are found by FAA to be in compliance with the requirements of 14 CFR part 150, promulgated pursuant to the Act, may submit a Noise Compatibility Program for FAA approval which sets forth the measures the airport operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has completed its review of the Noise Exposure Maps and accompanying documentation submitted by Monroe County. The documentation that constitutes the "Noise Exposure Maps" as defined in Section 150.7 of 14 CFR part 150 includes: Table 4–1, 2013 FAA ATADS and Part 150 Aircraft Operations; Table 4–2, Flight Track Utilization by Aircraft Category for East Flow Operations; Table 4–3, Flight Track Utilization by Aircraft Category for West Flow Operations; Table 4–4, 2013 Air Carrier Flight Operations; Table 4–5, 2013 Commuter and Air Taxi Flight Operations; Table 4–6, 2013 Average Daily Engine Run-Up Operations; Table 4–7, 2013 General Aviation Flight Operations; Table 4–8, 2013 Military Aircraft Flight Operations; Table 4–9, Summary of 2013 Flight Operations; Table 4–10, 2013 Existing Condition Noise Exposure Estimates; Table 5–1, 2018 FAA TAF and Part 150 Aircraft Operations; Table 5–2, 2018 Air Carrier Flight Operations; Table 5–3, 2018 Commuter and Air Taxi Flight Operations; Table 5–4, 2018 Average Daily Engine Run-Up Operations, Table 5–5, 2018 General Aviation Flight Operations; Table 5–6, 2018 Military Aircraft Operations; Table 5–7, Summary of 2018 Flight Operations; Table 5–8, 2018 Future Condition Noise Exposure Estimates; Figure 1–5, Designated Aircraft Warm-Up Circle Location; Figure 2–1, General Study Area; Figure 2–2, Existing Generalized Land Use; Figure 2–3, Community and Recreational Facilities; Figure 2–4, City of Key West Future Land Use and Zoning Map; Figure 3–1, Key West Airspace; Figure 3–2, Key West All Weather Wind Rose; Figure 4–1, Radar Flight Tracks—Arrivals; Figure 4–2, Radar Flight Tracks—Departures; Figure 4–3, East Flow Flight Tracks; Figure 4–4, West Flow Flight Tracks; Figure 4–5, Touch and Go and Helicopter Flight Tracks; Figure 4–6, Aircraft Run-Up and Spool-Up Locations; Figure 4–8, 2013 Existing Condition Noise Exposure Map; Figure 4–9, Noise Monitoring Locations; Figure 5–1, 2018 Future Condition Noise Exposure Map; Figure 5–2, Comparison of Existing Condition and Future Condition Noise Exposure Maps; Figure 6–1, Airport Transmittal Letter; Figure 6–2, Sponsor's Certification.

The FAA has determined that these Noise Exposure Maps and accompanying documentation are in compliance with applicable requirements. This determination is effective on December 19, 2013.

FAA's determination on the airport operator's Noise Exposure Maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of 14 CFR part 150. Such determination does not constitute approval of the airport operator's data, information or

plans, or a commitment to approve a Noise Compatibility Program or to fund the implementation of that Program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a Noise Exposure Map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise exposure contours, or in interpreting the Noise Exposure Maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under 14 CFR part 150 or through FAA's review of Noise Exposure Maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under Section 150.21 of 14 CFR part 150, that the statutorily required consultation has been accomplished.

Copies of the full Noise Exposure Maps documentation and of the FAA's evaluation of the maps are available for examination at the following locations:

(1) Key West International Airport Administrative Office

(2) Federal Aviation Administration, Orlando Airports District Office, 5950 Hazeltine National Drive, Citadel International Building, Suite 400, Orlando, FL 32822

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT.**

Issued in Orlando, FL on December 19, 2013.

Bart Vernace,

Manager, Orlando Airports District Office, Federal Aviation Administration.

[FR Doc. 2013–31075 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0193]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemption from the diabetes mellitus requirement; request for comments.

SUMMARY: FMCSA announces receipt of applications from 65 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before January 27, 2014.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2013–0193 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow theon-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 65 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

Qualifications of Applicants

Bruce S. Allen

Mr. Allen, 52, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Allen understands diabetes management and monitoring,

has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Allen meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Maine.

David E. Ames

Mr. Ames, 48, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ames understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ames meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Michael R. Boland

Mr. Boland, 47, has had ITDM since 2010. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Boland understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Boland meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Taylor D. Bruce

Mr. Bruce, 21, has had ITDM since 1994. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bruce understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bruce meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Missouri.

Christopher D. Burks

Mr. Burks, 51, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Burks understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Burks meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Massachusetts.

Larry D. Burton

Mr. Burton, 53, has had ITDM since 1974. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Burton understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Burton meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Illinois.

James B. Cameron

Mr. Cameron, 57, has had ITDM since 2012. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Cameron understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Cameron meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

Michael M. Canup

Mr. Canup, 58, has had ITDM since 1968. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Canup understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Canup meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Alabama.

John M. Catron

Mr. Catron, 69, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Catron understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Catron meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Anthony D. Chrisley

Mr. Chrisley, 51, has had ITDM since 1980. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting

in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Chrisley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Chrisley meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from California.

Henry Collins

Mr. Collins, 44, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Collins understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Collins meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Missouri.

John B. Conway, Jr.

Mr. Conway, 60, has had ITDM since 2003. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Conway understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Conway meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he stable nonproliferative diabetic retinopathy. He holds an operator's license from North Carolina.

James V. Davidson, Jr.

Mr. Davidson, 49, has had ITDM since 2010. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Davidson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Davidson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Utah.

Michael A. De La Torre

Mr. De La Torre, 55, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. De La Torre understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. De La Torre meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from California.

Corrado DePalma

Mr. DePalma, 59, has had ITDM since 2012. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. DePalma understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. DePalma meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Eugene J. Dilley

Mr. Dilley, 67, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dilley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dilley meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Scott T. Early

Mr. Early, 51, has had ITDM since 1995. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Early understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Early meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from New York.

Carl Ermentrout

Mr. Ermentrout, 65, has had ITDM since 1988. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ermentrout understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ermentrout meets the

requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Pennsylvania.

Douglas E. Erney

Mr. Erney, 52, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Erney understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Erney meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

William C. Flom

Mr. Flom, 55, has had ITDM since 2010. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Flom understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Flom meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Seth E. Frost

Mr. Frost, 33, has had ITDM since 2010. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Frost understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Frost meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Oregon.

Donald R. Fuller, Jr.

Mr. Fuller, 59, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Fuller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Fuller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Brian A. Griep

Mr. Griep, 54, has had ITDM since 2012. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Griep understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Griep meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

George E. Hagey

Mr. Hagey, 62, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hagey understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hagey meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Ronnie L. Harrington

Mr. Harrington, 55, has had ITDM since 2012. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Harrington understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Harrington meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Mississippi.

Andrew P. Hines

Mr. Hines, 48, has had ITDM since 2012. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hines understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hines meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Arlyn D. Holtrop

Mr. Holtrop, 48, has had ITDM since 2007. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist

certifies that Mr. Holtrop understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Holtrop meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Stephan P. Hyre

Mr. Hyre, 55, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hyre understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hyre meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Delayne B. Irwin

Mr. Irwin, 76, has had ITDM since 1998. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Irwin understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Irwin meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from South Dakota.

Aaron C. Kaplan

Mr. Kaplan, 28, has had ITDM since 1987. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kaplan understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kaplan meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from California.

Sigmund E. Keller

Mr. Keller, 47, has had ITDM since 1998. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Keller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Keller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from New York.

Derl T. Martin

Mr. Martin, 50, has had ITDM since 2012. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Martin understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Martin meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Waymond E. Mayfield, Jr.

Mr. Mayfield, 61, has had ITDM since 1980. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mayfield understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mayfield meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Missouri.

Senad Mehmedovic

Mr. Mehmedovic, 31, has had ITDM since 2001. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mehmedovic understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mehmedovic meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Kentucky.

Ronald E. Mullard

Mr. Mullard, 61, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mullard understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mullard meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable proliferative diabetic retinopathy. He holds a Class A CDL from Alabama.

Francis L. Novotny

Mr. Novotny, 65, has had ITDM since 1975. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting

in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Novotny understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Novotny meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Justin C. Orr

Mr. Orr, 28, has had ITDM since 1999. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Orr understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Orr meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from California.

Kevin L. Otto

Mr. Otto, 55, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Otto understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Otto meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Larry H. Painter

Mr. Painter, 72, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Painter understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Painter meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Robert K. Patterson

Mr. Patterson, 60, has had ITDM since 2008. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Patterson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Patterson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Alan A. Phillips

Mr. Phillips, 69, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Phillips understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Phillips meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Wisconsin.

Randall D. Pierce

Mr. Pierce, 41, has had ITDM since 2012. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pierce understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pierce meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Florida.

Clyde R. Pitt

Mr. Pitt, 75, has had ITDM since 2007. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pitt understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pitt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from New York.

Reynier Prieto

Mr. Prieto, 34, has had ITDM since 1982. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Prieto understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Prieto meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable

proliferative diabetic retinopathy. He holds an operator's license from Florida.

Albert R. Purdy

Mr. Purdy, 66, has had ITDM since 2010. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Purdy understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Purdy meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Adam Razny

Mr. Razny, 46, has had ITDM since 2001. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Razny understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Razny meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Thomas F. Scanlon

Mr. Scanlon, 50, has had ITDM since 1999. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Scanlon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Scanlon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Christopher J. Schmidt

Mr. Schmidt, 24, has had ITDM since 2000. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Schmidt understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Schmidt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Pennsylvania.

Harrison G. Simmons

Mr. Simmons, 62, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Simmons understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Simmons meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Cleo W. Snyder

Mr. Snyder, 75, has had ITDM since 2008. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Snyder understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Snyder meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Illinois.

Daniel E. Staack

Mr. Staack, 48, has had ITDM since 1993. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Staack understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Staack meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Nebraska.

Scott A. Stout

Mr. Stout, 48, has had ITDM since 1990. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stout understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stout meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Florida.

Walter D. Strang, IV

Mr. Strang, 30, has had ITDM since 1998. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Strang understands diabetes management and monitoring,

has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Strang meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Connecticut.

Mark A. Torres

Mr. Torres, 48, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Torres understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Torres meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Massachusetts.

Gerald L. Ulmer, Sr.

Mr. Ulmer, 48, has had ITDM since 1993. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ulmer understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ulmer meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Pennsylvania.

Eric A. Vernon

Mr. Vernon, 52, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Vernon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Vernon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Paul M. Vinacco

Mr. Vinacco, 54, has had ITDM since 2006. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Vinacco understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Vinacco meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from Rhode Island.

Marvin L. Vonk

Mr. Vonk, 69, has had ITDM since 2009. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Vonk understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Vonk meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Kelly J. Walstad

Mr. Walstad, 57, has had ITDM since 2011. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Walstad understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Walstad meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

John R. Wappes

Mr. Wappes, 63, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wappes understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wappes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

James W. Watson

Mr. Watson, 64, has had ITDM since 2007. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Watson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Watson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Gordon E. Williams, Jr.

Mr. Williams, 71, has had ITDM since 2006. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the

past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Williams understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Williams meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Ray C. Williams

Mr. Williams, 50, has had ITDM since 2010. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Williams understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Williams meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2013 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Connecticut.

Ricky A. Wulf

Mr. Wulf, 55, has had ITDM since 2013. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wulf understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wulf meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Brandon S. Yarbrough

Mr. Yarbrough, 29, has had ITDM since 2003. His endocrinologist examined him in 2013 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Yarbrough understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Yarbrough meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2013 and certified that he does not have diabetic retinopathy. He holds an operator's license from North Carolina.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 USC. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2013–0193 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2013–0193 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to the proposed rulemaking.

[1] Section 4129(a) refers to the 2003 notice as a "final rule." However, the 2003 notice did not issue a "final rule" but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

Issued on: December 17, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–30871 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2013–0101]

National Maritime Strategy Symposium: Cargo Opportunities and Sealift Capacity

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: On October 28, 2013, the Maritime Administration (MARAD) published a notice in the **Federal Register** inviting the public and other Marine Transportation System stakeholders to participate in a discussion intended to develop a robust national maritime strategy. Stakeholders were asked to provide their ideas for improving the Nation's cargo opportunities and sealift capacity while ensuring future sustainability. After careful consideration of the views and ideas provided, this notice includes the public meeting agenda along with detailed information for those interested in attending the event in person, via phone, or by Internet connection.

DATES: The public meeting will be held from 9:00 a.m. to 4:30 p.m., on January 14th and 15th, and 9:00 a.m. to 12:00 p.m. on January 16th.

Key Date: The deadline to register to attend or speak at the meeting or to submit presentation materials is January 8, 2014.

The following are other important anticipated dates and deadlines:

Deadline to register to attend the public meeting in person	January 8, 2014.
Deadline to register to speak in person, speak by calling in, or to listen only by phone.	January 8, 2014.
Deadline to submit digital presentation materials	January 8, 2014.
Call-in and listen-only information distributed to registrants	January 10, 2014.
National Maritime Strategy Symposium-Public Meeting	January 14–15, 2014, 9:00 a.m. to 4:30 p.m. January 16, 2014, 9:00 a.m. to12:00 p.m.

ADDRESSES: The public meeting will be held in the U.S. Department of Transportation (DOT) West Atrium, located on the ground floor of 1200 New Jersey Avenue SE., Washington, DC 20590. Overflow seating will be available in adjacent conference rooms.

Note: MARAD has opened a docket to assist the public in obtaining information and in providing comments. For on-line access to the MARAD Docket to read background documents or comments received, go to *http://www.regulations.gov* and query "MARAD–2013–0101" at any time or visit our docket in person at Room W12–140 of the Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. If you have questions on viewing the Docket, call Cheryl Collins, Program Manager, Docket Operations, telephone: (800) 647–5527.

[See also Submitting Your Comments and Ideas section.]

FOR FURTHER INFORMATION CONTACT: Christine S. Gurland, Assistant Chief Counsel for Legislation and Regulations, Office of Chief Counsel, MAR–225, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (202) 366–5157; email: *Christine.Gurland@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Marine Transportation System is a core component of the United States' economic and national security. While it has proven to be strong and resilient, there is a need to improve and grow the industry to ensure the availability and viability of a U.S. merchant marine in the future. The historic strength of the United States as a maritime Nation relies on its global, coastal, and inland commercial fleet, its ports and intermodal facilities, the national security establishment, and the maritime workforce that supports and operates U.S.-flagged vessels. The purpose of this initial public meeting is to generate ideas that will improve, strengthen, and sustain the cargo opportunities and sealift capacity of the U.S.-flagged fleet engaged in international commercial trade. Those ideas will necessarily be focused on the U. S. Marine Transportation System.

Public Meeting Agenda

NATIONAL MARITIME STRATEGY SYMPOSIUM #1—GROWING THE US-FLAG FLEET ENGAGED IN INTERNATIONAL TRADE

14–16 JANUARY 2014

Time	14 January 2014	15 January 2014	16 January 2014
0900–1030	PLENARY: Growing the International Fleet: Opportunities & Challenges.	PLENARY: Shipper's Perspective	PLENARY (1000–1200) Wrap Up & Next Steps
1030–1200	BREAKOUT SESSION #1 The Need for a US-Flag International Fleet-National Security- Economy & Jobs.	BREAKOUT SESSION #2C-Same as #2A	Wrap Up & Next Steps continued.
1200–1330	LUNCH/KEYNOTES	LUNCH/KEYNOTES	
1330–1500	BREAKOUT SESSIONS #2A —Creating Cargo Opportunities —Increasing Competiveness in International Trade. —Tax, Regulation & Finance Reform. —Training & Retaining the Maritime Workforce.	PRESENTATIONS —Open Session (Times will be allotted for individual presentations upon registration.).	

NATIONAL MARITIME STRATEGY SYMPOSIUM #1—GROWING THE US-FLAG FLEET ENGAGED IN INTERNATIONAL TRADE—Continued
14–16 JANUARY 2014

Time	14 January 2014	15 January 2014	16 January 2014
1500–1630	—International Issues and Agreements. BREAKOUT SESSIONS #2B-Same As #2A ..	BREAKOUT SESSION #3 Domestic Policies, Industry & Infrastructure Supporting the International Fleet.	

About the Public Meeting

1. The Acting Maritime Administrator will preside over the public meeting. Senior Department and MARAD officials will also attend this meeting to receive comments from the public. During the meeting, we may ask questions that will clarify statements or gather more information or data to help us understand the issues raised by commenters.

2. The meeting is designed to solicit public views and gather additional information, insights and experience to assist in the development of a National Maritime Strategy. Therefore, the meeting will be conducted in an informal and non-adversarial manner. To allow for more detailed discussion, this initial meeting will focus on the opportunities and challenges of growing the U.S.-flagged international fleet.

3. The public meeting will be broadcast live via web streaming and a listen-only telephone line. The public may access the live web streaming by a link from http://www.marad.dot.gov. Listen-only telephone line participants must register in order to obtain the telephone number.

4. Members of the public are invited to make comments in person at the venue, through a call-in number, or by entry in the MARAD Docket. When registering to speak in person or by telephone, please estimate the amount of time that you would like to use for your presentation; final times will be allotted to participants based on the time available and the issues raised.

5. Comments are welcome at the MARAD Docket leading up to the event as well as during the event or on conclusion of the symposium. If you would like to make a comment to the docket go to *http://www.regulations.gov* and type in the docket number (MARAD–2013–0101) in the "SEARCH" box and then click "SEARCH." Once you arrive at the National Maritime Strategy Symposium docket, click "Submit a Comment" and follow the guidance provided. [See also Submitting Your Comments and Ideas section.]

6. To ensure that comments are most useful in informing the development of the U.S.-flagged international fleet as part of a national maritime strategy, please include the docket number (MARAD–2013–0101), any specific citations, a detailed description of your concerns or ideas, and any supporting information that would assist MARAD in considering the issues raised. [See also Submitting Your Comments and Ideas section.]

7. Those who wish to speak during the meeting are requested to advise, at the time of registration, what topic or topics they would like to comment on; amplifying information will be welcome but is not required. For example, comments may focus on, but are not limited to, the following topics: Creating Cargo Opportunities; Increasing Competitiveness in International Trade; Tax, Regulation & Finance Reform; Training & Retaining the Maritime Workforce; International Issues and Agreements; and Domestic Policies, Industry & Infrastructure Supporting the International Fleet.

8. Any digital presentation materials for the meeting should be submitted to Mickalyn Valentine, Office of the Executive Director, MAR–120, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (202) 366–3907; *mickalyn.valentine@dot.gov* no later than January 8, 2014. [See *Registration* section for contact information.]

9. We hope to be able to accommodate everyone who would like to speak at the meeting, but if there are more interested participants than time available, we will limit participants in order of date and time of registration. If available, time will be allotted to those attending the meeting in person to speak, even if they had not previously registered to speak. For those who wish to make comments, but for whom there is not time available or who do not wish to speak, it will be possible to post comments to the public docket. [See also Submitting Your Comments and Ideas section.]

10. A transcript of the public meeting will be made available on our Web site *http://www.marad.dot.gov* and posted to the docket at *http://www.regulations.gov*.

11. The recorded webcast video will remain available following the meeting via a link from our Web site at *http://www.marad.dot.gov*.

Arrival and Admission Information

1. In-person attendees are encouraged to arrive at least 45 minutes prior to the meeting for processing through building security. All in-person attendees must enter through the New Jersey Avenue entrance (West Building—at the corner of New Jersey Avenue SE. and M Street SE.). Anyone exiting the building for any reason will be required to re-enter through the security checkpoint at the New Jersey Avenue Entrance.

2. Due to security requirements, all in-person attendees must bring a Government-issued form of identification (e.g., driver's license) to ensure access to the building. In-person attendees who have Federal government identification are required to register to attend due to space constraints. Foreign National in-person attendees must bring their passports with them. To facilitate security screening, all in-person attendees are encouraged to limit bags and other items (e.g., mobile phones, laptops, cameras, etc.) they bring into the building.

3. Due to space limitations no outside videotaping will be allowed.

4. The Department of Transportation (DOT) and MARAD are not able to offer visitor parking; we suggest that attendees consider using alternative means of transportation to the building. DOT Headquarters/MARAD is served by Metrorail (Navy Yard station), Metrobus, DC Circulator, and taxi service. There are a number of private parking lots near the DOT building, but MARAD cannot guarantee the availability of parking spaces.

5. For information on facilities or services for persons with disabilities, or to request special assistance at the meeting, contact Mickalyn Valentine, Office of the Executive Director, MAR–120, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (202) 366–3907 as soon as possible.

Registration

All in-person attendees, whether or not they are planning to provide their views to the participants, must register with Mickalyn Valentine, Office of the Executive Director, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (202) 366–3907; mickalyn.valentine@dot.gov no later than January 8, 2014. You may locate the symposium registration form and agenda via a link from MARAD's Web site at *http://www.marad@dot.gov.*

Any person wishing to present an oral statement via telephone, or any person who would like to listen to the meeting over a listen-only telephone line must also register with Ms. Valentine by January 8, 2014. Call-in and listen-only telephone numbers will be distributed to registered participants on January 10, 2014. Foreign National registrants must provide full name, title, country of citizenship, date of birth, passport number, and passport expiration date when registering.

Because seating space is limited, we may have to limit the number of attendees in order of date and time of registration.

Submitting Your Comments and Ideas

To ensure that comments are most useful in informing the development of a national

maritime strategy, you should include the docket number (MARAD–2013–0101), any specific citations, a detailed description of your concerns or ideas, and any supporting information that would assist MARAD in considering the issues raised.

In order to provide the public with alternative means of providing feedback to MARAD in ways that may better suit their needs, we have provided a docket at *http://www.regulations.gov* to allow for submissions to MARAD in a less formal manner. The MARAD Docket provides members of the public who do not wish to make a presentation, cannot make a presentation, or who wish to add other comments an opportunity to submit their ideas.

Comments are welcome at the MARAD Docket leading up to the event as well as during the event or on conclusion of the symposium. If you would like to make a comment on-line, go to *http://www.regulations.gov* and type in the docket number (MARAD–2013–0101) in the "SEARCH" box and then click "SEARCH." Once you arrive at the National Maritime Strategy Symposium Docket, click "Submit a Comment" and follow the guidance provided.

If you submit a comment or idea on-line via www.regulations.gov, please know that comments submitted to www.regulations.gov are not immediately posted to the site. It may take several business days before your submission will be posted on the electronic docket. If you have questions on viewing the Docket, call Cheryl Collins, Program Manager, Docket Operations, telephone: (800) 647–5527.

In addition to providing comments on-line via *www.regulations.gov,* you may submit comments and ideas to DOT Docket Number MARAD–2013–0101 by any of the following methods as well: Fax, Mail or Hand Delivery. However, please use only one means for each submission. Specific instructions follow:

- For submission by facsimile/Fax, transmit your comment or idea to (202) 493–2251. Be sure to identify the submission by DOT Docket Number MARAD–2013–0101.
- Submissions by Mail or Hand Delivery should go to Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on Federal holidays. If you submit your inputs by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

If you Fax, mail or hand deliver your input we recommend that you include your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Note: All comments or ideas submitted for this purpose, including any personal information provided, will be posted without change to *http://www.regulations.gov.*

Follow-Up Action by MARAD

Your comments will provide meaningful and significant information for senior DOT and MARAD officials developing the national maritime strategy. Following the symposium, you will be able to access the event transcript on-line from our docket or from a link on our home page at *http://www.marad@dot.gov.* The transcript of the meeting will be a Maritime Administration posting entitled "National Maritime Strategy Symposium 2014 Transcript." To access the transcript on-line at *www.regulations.gov,* go to "SEARCH" and enter MARAD–2013–0101 and click enter. You will arrive at our docket and the transcript of the meeting will be a Maritime Administration posting entitled "National Maritime Strategy Symposium 2014 Transcript." Go to that posting and click on the attachment. MARAD will host or participate in future forums to discuss the domestic aspects of a national maritime strategy.

Privacy Act Statement

Anyone is able to search all comments entered into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476, 04/11/2011) or at *http://www.dot.gov/privacy.html.*

Authority: 5 U.S.C. 610; E.O., 13563, 76 FR 3821, Jan. 21 2011; E.O. 12866, 58 FR51735, Oct. 4, 1993.

* * *

Dated: December 23, 2013.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Acting Secretary, Maritime Administration.

[FR Doc. 2013–31095 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. DOT–NHTSA–2013–0089]

Request for Comments on a New Information Collection

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments.

DATES: Comments must be submitted on or before January 27, 2014.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW., Washington, DC 20503, Attention: NHTSA Desk Officer.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact James Bean, Office of Data Acquisitions (NVS–410), Room W53–489, 1200 New Jersey Avenue SE., Washington, DC 20590. Mr. Bean's telephone number is (202) 366–2837.

SUPPLEMENTARY INFORMATION: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). In compliance with these requirements, this notice announces that the following information collection request has been forwarded to OMB. A **Federal Register** Notice soliciting comments on the following information collection was published on September 6, 2013 (Volume 78, Number 173; Pages 54954–55). The agency received no comments in response to the **Federal Register** Notice.

Title: National Automotive Sampling System (NASS) Law Enforcement Information.

OMB Control Number: Not assigned.

Type of Request: New Information Collection.

Abstract: This collection of information is part of NHTSA's efforts to upgrade its crash data systems. NHTSA's National Automotive Sampling System (NASS) collects crash data on a nationally representative sample of police-reported traffic crashes and related injuries. NASS data are used by government, industry, and academia in the U.S. and around the world to make informed highway safety decisions.

Recognizing the importance as well as the limitations of the current NASS system, NHTSA is undertaking a modernization effort to upgrade its data systems by improving the information technology (IT) infrastructure, updating the data collected, and reexamining the NASS sample sites and sample size.

The current data system samples crashes through a clustered sample of law enforcement agencies that were selected decades ago. Using updated population and other auxiliary information, NHTSA has identified a new set of probabilistically selected geographic locations around the country that are expected to provide a more accurate traffic safety picture, more precise estimates, and greater insight into new and emerging data needs.

This collection of information will assist NHTSA with the next step in updating the NASS sample design, which is to select a fresh sample of law enforcement agencies within these primary sampling units (PSUs). This requires compiling basic crash count data from every law enforcement agency that responds to motor vehicle crashes in the PSUs. This data would be used to construct a measure of size in order to make informed and efficient choices in the probabilistic selection of the second stage sample units, the law enforcement agencies.

Affected Public: Law Enforcement Agencies.

Estimated Number of Respondents: 1,450 Law Enforcement Agencies.

Estimated Number of Responses: We estimate that 90 percent of the Law Enforcement Agencies will respond so approximately 1,305 responses.

Annual Estimated Total Annual Burden Hours: The annual burden is estimated to be 2,900 hours.

Frequency of Collection: This is a one-time collection.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.95.

Issued in Washington, DC, on December 23, 2013.

Terry T. Shelton,

Associate Administrator, National Center for Statistics and Analysis.

[FR Doc. 2013–30987 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2013–0130]

Technical Report Evaluating Seat Belt Pretensioners and Load Limiters

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Request for comments on technical report.

SUMMARY: This notice announces NHTSA's publication of a technical report evaluating the effectiveness of pretensioners and load limiters for seat belts in the front seats of passenger cars and LTVs. The report's title is: *Effectiveness of Pretensioners and Load Limiters for Enhancing Fatality Reduction by Seat Belts.*

DATES: Comments must be received no later than April 22, 2014.

ADDRESSES:

Report: The technical report is available on the Internet for viewing in PDF format at *http://www-nrd.nhtsa.dot.gov/Pubs/811835.pdf.* You may obtain a copy of the report free of charge by sending a self-addressed mailing label to Charles J. Kahane (NVS–431), National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590.

Comments: You may submit comments [identified by Docket Number NHTSA–2013–0130] by any of the following methods:

- Internet: To submit comments electronically, go to the U.S. Government regulations Web site at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- Fax: Written comments may be faxed to 202–493–2251.
- Mail: Send comments to Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- Hand Delivery: If you plan to submit written comments by hand or courier, please do so at 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except federal holidays
- You may call Docket Management at 1–800–647–5527.

Instructions: For detailed instructions on submitting comments and additional information see the Comments heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Charles J. Kahane, Chief, Evaluation Division, NVS–431, National Center for Statistics and Analysis, National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: 202–366–2560. Email: *chuck.kahane@dot.gov.*

SUPPLEMENTARY INFORMATION: Pretensioners and load limiters are

technologies designed to make seat belts more effective. Pretensioners retract the seat belt to remove excess slack almost instantly upon sensing the vehicle has crashed. Load limiters allow the belt to "give" or yield when forces on the belt rise above a predetermined level. NHTSA has long encouraged—but never required—installation of these technologies in the front seats of vehicles. By model year 2008, all new cars and LTVs sold in the United States were equipped with pretensioners and load limiters at the driver's and right-front passenger's seats. Double-pair comparison analyses of FARS data for 1986 to 2011 compare the fatality-reducing effectiveness of seat belts with and without pretensioners and load limiters at those seats. In passenger cars, CUVs, and minivans, a belted driver or right-front passenger has an estimated 12.8 percent lower fatality risk if the belt is equipped with a pretensioner and a load limiter than if it is not equipped with either (95% confidence bounds: 2.6% to 23.0%). By contrast, the analyses of the currently available data do not yet show a significant effect for pretensioners and load limiters in truck-based LTVs (pickup trucks, SUVs with body-and-frame construction, and full-sized vans); it may be advisable to rerun the analyses in about 4 or 5 years when more data will be available.

Comments:

How can I influence NHTSA's thinking on this subject?

NHTSA welcomes public review of the technical report. NHTSA will submit to the Docket a response to the comments and, if appropriate, will supplement or revise the report.

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the Docket number of this document (NHTSA–2013–0130) in your comments.

Your primary comments must not be more than 15 pages long (49 CFR 553.21). However, you may attach additional documents to your primary comments. There is no limit on the length of the attachments.

Please submit one copy of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *http://www.whitehouse.gov/omb/fedreg_reproducible*. DOT's guidelines may be accessed at *http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject_areas/statistical_policy_and_research/data_quality_guidelines/index.html*.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://www.regulations.gov*.

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail. You may also periodically access *http://www.regulations.gov* and enter the number for this docket (NHTSA–2013–0130) to see if your comments are on line.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. In addition, you should submit a copy, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR Part 512.)

Will the agency consider late comments?

In our response, we will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under DATES. To the extent possible, we will also consider comments that Docket Management receives after that date.

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also see the comments on the Internet. To read the comments on the Internet, take the following steps:

(1) Go to the Federal Docket Management System (FDMS) at *http://www.regulations.gov*.

(2) FDMS provides two basic methods of searching to retrieve dockets and docket materials that are available in the system: (a) "Quick Search" to search using a full-text search engine, or (b) "Advanced Search," which displays various indexed fields such as the docket name, docket identification number, phase of the action, initiating office, date of issuance, document title, document identification number, type of document, **Federal Register** reference, CFR citation, etc. Each data field in the advanced search may be searched independently or in combination with other fields, as desired. Each search yields a simultaneous display of all available information found in FDMS that is relevant to the requested subject or topic.

(3) You may download the comments. However, since the comments are imaged documents, instead of word processing documents, the "pdf" versions of the documents are word searchable.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

Authority: 49 U.S.C. 30111, 30181–83 delegation of authority at 49 CFR 1.95 and 501.8.

Issued in Washington, DC, on December 23, 2013.

James F. Simons,

Director, Office of Regulatory Analysis and Evaluation.

[FR Doc. 2013–31024 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 23, 2013.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before January 27, 2014 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov*.

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov*, or the entire information collection request maybe found at *www.reginfo.gov*.

Community Development Financial Institutions (CDFI) Fund

OMB Number: 1559–0044.

Type of Review: Revision of a currently approved collection.

Title: Bond Guarantee Program.

Abstract: The purpose of the Community Development Financial Institutions (CDFI) Bond Guarantee Program (BG Program) is to support CDFI lending by providing Guarantees for Bonds issued by Qualified Issuers as part of a Bond Issue for Eligible Community or Economic Development Purposes.

Affected Public: Private Sector: Businesses or other for-profits, Not-for-profit institutions.

Estimated Annual Burden Hours: 83,000.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013–31004 Filed 12–26–13; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Currently Approved Information Collection: Comment Request for Generic Clearance for the Collection or Qualitative Feedback on Agency Service Delivery

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Generic Clearance for the Collection or Qualitative Feedback on Agency Service Delivery.

DATES: Written comments should be received on or before February 27, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Fiscal Service, Bruce A. Sharp, 200 Third Street A4–A, Parkersburg, WV 26106–1328, or *bruce.sharp@bpd.treas.gov*. The opportunity to make comments online is also available at *www.pracomment.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies should be directed to Bruce A. Sharp, Bureau of the Fiscal Service, 200 Third Street A4–A, Parkersburg, WV 26106–1328, (304) 480–8150.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection or Qualitative Feedback on Agency Service Delivery.

OMB Number: 1535–0143.

Abstract: The Bureau of the Fiscal Service conducts various surveys, focus groups, and interviews to assess the effectiveness and efficiency of existing products and services; to obtain knowledge about the potential public audiences attracted to new products are introduced; and to measure awareness and appeal of efforts to reach audiences and customers.

Current Actions: None.

Type of Review: Extension.

Affected Public: Individuals or households; Business and other for-profit.

Estimated Number of Respondents: 10,000.

Estimated Time Per Respondent: 60 minutes.

Estimated Total Annual Burden Hours: 10,000.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: December 23, 2013.

Bruce A. Sharp,

Bureau Clearance Officer.

[FR Doc. 2013–31045 Filed 12–26–13; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2013–0025]

Minority Depository Institutions Advisory Committee; Meeting

AGENCY: Office of the Comptroller of the Currency, Department of the Treasury.

ACTION: Notice of federal advisory committee meeting.

SUMMARY: The Office of the Comptroller of the Currency (OCC) announces a meeting of the Minority Depository Institutions Advisory Committee (MDIAC).

DATES: The OCC MDIAC will hold a public meeting on Tuesday, January 28, 2014, beginning at 8:30 a.m. Eastern Standard Time (EST).

ADDRESSES: The OCC will hold the January 28, 2014, meeting of the MDIAC at 400 7th Street SW., Washington, DC 20219.

FOR FURTHER INFORMATION CONTACT: Beverly Cole, Senior Advisor to the Senior Deputy Comptroller for Midsize and Community Bank Supervision, (202) 649–5420, Office of the

Comptroller of the Currency, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: By this notice, the OCC is announcing that the OCC MDIAC will convene a meeting at 8:30 a.m. EST on Tuesday, January 28, 2014, at the OCC's headquarters at 400 7th Street SW., Washington, DC 20219. Agenda items include a discussion of the status of the minority depository institution industry and current topics of interest to the industry. The purpose of the meeting is for the MDIAC to advise the OCC on steps the OCC may be able to take to ensure the continued health and viability of minority depository institutions and other issues of concern to minority depository institutions. Members of the public may submit written statements to the MDIAC by any one of the following methods:

- Email to *MDIAC@occ.treas.gov;* or
- Mail in triplicate to: Beverly Cole, Designated Federal Official, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

The OCC must receive written statements no later than Friday, January 17, 2014. Members of the public who plan to attend the meeting and members of the public who require auxiliary aid should contact the OCC by 5:00 p.m. EST on Tuesday, January 21, 2014, to inform the OCC of their desire to attend the meeting and to provide the information that will be required to facilitate entry into the OCC building. Attendees should provide their full name, email address, and organization, if any. Members of the public may contact the OCC via email at *MDIAC@occ.treas.gov* or by telephone at 202–649–5420. On the day of the meeting, attendees will be required to present proof of identification (a driver's license or other government issued photo identification) upon arrival at the OCC in order to gain entrance to the meeting.

Dated: December 19, 2013.

Thomas J. Curry,

Comptroller of the Currency.

[FR Doc. 2013–31010 Filed 12–26–13; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Supplemental Identification Information for Four Individuals Designated Pursuant to Executive Order 13224

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control ("OFAC") is publishing supplemental information for the names of four individuals whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism."

DATES: The publishing of updated identification information by the Director of OFAC of the four individuals in this notice, pursuant to Executive Order 13224, is effective on December 18, 2013.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On September 23, 2001, the President issued Executive Order 13224 (the "Order") pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, and the United Nations Participation Act of 1945, 22 U.S.C. 287c. In the Order, the President declared a national emergency to address grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the September 11, 2001 terrorist attacks in New York, Pennsylvania, and at the Pentagon. The Order imposes economic sanctions on persons who have committed, pose a significant risk of committing, or support acts of terrorism. The President identified in the Annex to the Order, as amended by Executive Order 13268 of July 2, 2002, 13 individuals and 16 entities as subject to the economic sanctions. The Order was further amended by Executive Order 13284 of January 23, 2003, to reflect the creation of the Department of Homeland Security.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in or hereafter come within the United States or the possession or control of United States persons, of: (1) Foreign persons listed in the Annex to the Order; (2) foreign persons determined by the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, to have committed, or to pose a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States; (3) persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to be owned or controlled by, or to act for or on behalf of those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order; and (4) except as provided in section 5 of the Order and after such consultation, if any, with foreign authorities as the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, deems appropriate in the exercise of his discretion, persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to assist in, sponsor, or provide financial, material, or technological support for, or financial or other services to or in support of, such acts of terrorism or those persons listed in the Annex to the Order or determined to be subject to the Order or to be otherwise associated with those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order.

On December 18, 2013 the Director of OFAC supplemented the identification information for four individuals whose property and interests in property are blocked pursuant to Executive Order 13224.

The supplemental identification information for the four individuals is as follows:

Individuals

1. UTHMAN, Omar Mahmoud (a.k.a. ABU UMAR, Abu Omar; a.k.a. AL–FILISTINI, Abu Qatada; a.k.a. TAKFIRI, Abu Umr; a.k.a. UMAR, Abu Umar; a.k.a. UTHMAN, Al-Samman; a.k.a. UTHMAN, Umar; a.k.a. "ABU ISMAIL"), London, United Kingdom; Jordan; DOB 30 Dec 1960; alt. DOB 13 Dec 1960; POB Bethlehem, West Bank, Palestinian Territories; nationality Jordan (individual) [SDGT].

2. ABD AL–KHALIQ, Adil Muhammad Mahmud (a.k.a. ABDUL KHALED, Adel Mohamed Mahmood; a.k.a. ABDUL KHALIQ, Adel Mohamed Mahmoud); DOB 02 Mar 1984; POB Bahrain; nationality Bahrain; Passport 1632207 (Bahrain) (individual) [SDGT].

3. KHALIL, Ibrahim Mohamed (a.k.a. AL ZAFIRI, Khalil Ibrahim; a.k.a. JASSEM,

Khalil Ibrahim; a.k.a. MOHAMMAD, Khalil Ibrahim), Refugee shelter Alte Ziegelei, Mainz 55128, Germany; DOB 02 Jul 1975; alt. DOB 02 May 1972; alt. DOB 03 Jul 1975; alt. DOB 1972; POB Dayr Az-Zawr, Syria; alt. POB Baghdad, Iraq; nationality Syria; Travel Document Number A0003900 (Germany); Temporary suspension of deportation No. T04338017, expired 08 May 2013, issued by Alien's Office of the city of Mainz (individual) [SDGT].

4. AL–SUBAIY, Khalifa Muhammad Turki (a.k.a. ALSUBAIE, Khalifa Mohd Turki; a.k.a. AL–SUBAIE, Khalifa Mohd Turki; a.k.a. AL–SUBAYI, Khalifa; a.k.a. BIN AL–SUAIY, Khalifa Turki bin Muhammad); DOB 01 Jan 1965; POB Doha, Qatar; citizen Qatar; Passport 00685868 (Qatar); National ID No. 26563400140 (Qatar) (individual) [SDGT].

Dated: December 18, 2013.

Barbara C. Hammerle,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2013–30808 Filed 12–26–13; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of One Individual Pursuant to Executive Order 13224

AGENCY: Office of Foreign Assets Control, Treasury

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control ("OFAC") is removing the name of one individual, whose property and interests in property have been blocked pursuant to Executive Order 13224 of September 23, 2001, Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism, from the list of Specially Designated Nationals and Blocked Persons ("SDN List").

DATES: The removal of this individual from the SDN List is effective as of December 18, 2013.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On September 23, 2001, the President issued Executive Order 13224 (the "Order") pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, and the United Nations Participation Act of 1945, 22 U.S.C. 287c, imposing economic sanctions on persons who commit, threaten to commit, or support acts of terrorism. The President identified in the Annex to the Order various individuals and entities as subject to the economic sanctions. The Order authorizes the Secretary of the Treasury, in consultation with the Secretary of State, the Attorney General, and (pursuant to Executive Order 13284) the Secretary of the Department of Homeland Security, to designate additional persons or entities determined to meet certain criteria set forth in Executive Order 13224.

The Department of the Treasury's Office of Foreign Assets Control has determined that this individual should be removed from the SDN List.

The following designation is removed from the SDN List:

Individual

1. ABDELHEDI, Mohamed Ben Mohamed (a.k.a. ABDELHEDI, Mohamed Ben Mohamed Ben Khalifa), via Catalani, n. 1, Varese, Italy; DOB 10 Aug 1965; POB Sfax, Tunisia; nationality Tunisia; Passport L965734 issued 06 Feb 1999 expires 05 Feb 2004; Italian Fiscal Code BDLMMD65M10Z352S (individual) [SDGT].

The removal of this individual name from the SDN List is effective as of December 18, 2013. All property and interests in property of the individual that are in or hereafter come within the United States or the possession or control of United States persons are now unblocked.

Dated: December 18, 2013.

Barbara C. Hammerle,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2013–30811 Filed 12–26–13; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Designation of 2 individuals Pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism"

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control ("OFAC") is publishing the names of 2 individuals whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism."

DATES: The designations by the Director of OFAC of the 2 individual(s) and 0 entit(ies) in this notice, pursuant to Executive Order 13224, are effective on December 18, 2013.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On September 23, 2001, the President issued Executive Order 13224 (the "Order") pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, and the United Nations Participation Act of 1945, 22 U.S.C. 287c. In the Order, the President declared a national emergency to address grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the September 11, 2001 terrorist attacks in New York, Pennsylvania, and at the Pentagon. The Order imposes economic sanctions on persons who have committed, pose a significant risk of committing, or support acts of terrorism. The President identified in the Annex to the Order, as amended by Executive Order 13268 of July 2, 2002, 13 individuals and 16 entities as subject to the economic sanctions. The Order was further amended by Executive Order 13284 of January 23, 2003, to reflect the creation of the Department of Homeland Security.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in or hereafter come within the United States or the possession or control of United States persons, of: (1) foreign persons listed in the Annex to the Order; (2) foreign persons determined by the Secretary of State, in consultation with the Secretary of the Treasury, the

Secretary of the Department of Homeland Security and the Attorney General, to have committed, or to pose a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States; (3) persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to be owned or controlled by, or to act for or on behalf of those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order; and (4) except as provided in section 5 of the Order and after such consultation, if any, with foreign authorities as the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, deems appropriate in the exercise of his discretion, persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to assist in, sponsor, or provide financial, material, or technological support for, or financial or other services to or in support of, such acts of terrorism or those persons listed in the Annex to the Order or determined to be subject to the Order or to be otherwise associated with those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order.

On December 18, 2013 the Director of OFAC, in consultation with the Departments of State, Homeland Security, Justice and other relevant agencies, designated, pursuant to one or more of the criteria set forth in subsections 1(b), 1(c) or 1(d) of the Order, 2 individuals whose property and interests in property are blocked pursuant to Executive Order 13224.

The listings for these individuals on OFAC's list of Specially Designated Nationals and Blocked Persons appear as follows:

Individuals

1. AL–HUMAYQANI, 'Abd al-Wahhab Muhammad 'Abd al-Rahman (a.k.a. AL–HAMAYQANI, 'Abd al-Wahab; a.k.a. AL–HAMAYQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HAMIQANI, 'Abd al-Wahab; a.k.a. AL–HAMIQANI, 'Abd al-Wahab al-Qawi; a.k.a. AL–HAMIQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HAMIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAIKANI, Abdul-Wahab Mohammed Abdul Rahman; a.k.a. AL–HUMAIKANI, Abdulwahhab Mohammed Abdulrahman; a.k.a. AL–HUMAIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAYQANI, Abd al-Wahab; a.k.a. AL–HUMAYQANI, 'Abd al-Wahab al-Qawi; a.k.a. AL–HUMAYQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HUMAYQANI, 'Abd al-Wahhab Muhammad 'Abd al-Rahim; a.k.a. AL–HUMAYQANI, Abdul Wahab; a.k.a. AL–HUMAYQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMIQANI, 'Abd al-Wahab; a.k.a. "ABU AYED"; a.k.a. "ABU AYID"), Yemen; DOB 04 Aug 1972; POB al-Zahir, al-Bayda', Yemen; Passport 03902409 (Yemen) issued 13 Jun 2010 expires 13 Jun 2016; alt. Passport 01772281 (Yemen); Personal ID Card 1987853 (Yemen) (individual) [SDGT].

2. AL–NU'AYMI, 'Abd al-Rahman bin 'Umayr (a.k.a. AL NAIMEH, Abdelrahman Imer al Jaber; a.k.a. AL NEAIMI, Abdulrahman Omair; a.k.a. AL–NAIMI, A. Rahman; a.k.a. ALNAIMI, A. Rahman Omair J; a.k.a. AL–NA'IMI, Abd al-Rahman bin 'Amir; a.k.a. AL–NU'AIMI, 'Abd al-Rahman; a.k.a. AL–NUA'YMI, 'Abd al-Rahman; a.k.a. AL–NU'AYMI, 'Abd al-Rahman bin 'Amir; a.k.a. AL–NU'AYMI, 'Abdallah Muhammad; a.k.a. AL–NU'IMI, 'Abd al-Rahman bin 'Amir), Qatar; DOB 1954; Passport 00868774 (Qatar) expires 27 Apr 2014; Personal ID Card 25463401784 (Qatar) expires 06 Dec 2019 (individual) [SDGT].

Dated: December 18, 2013.

Barbara C. Hammerle,

Deputy Director, Office of Foreign Assets Control.

[FR Doc. 2013–30803 Filed 12–26–13; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0764]

Agency Information Collection (Dental Patient Satisfaction Survey); Activities under OMB Review

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

DATES: Comments must be submitted on or before January 27, 2014.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov*. Please refer to "OMB Control No. 2900–0764 (Dental Patient Satisfaction Survey)" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov*. Please refer to "OMB Control No. 2900–0764 (Dental Patient Satisfaction Survey)" in any correspondence).''

SUPPLEMENTARY INFORMATION:

Title: Survey of Healthcare Experiences, Dental Patient Satisfaction Survey, VA Form 10–10070.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 10–10070 will be used to systematically obtain information from patients that can be used to identify problems or complaints that need attention and to improve the quality of dental health care services delivered to Veterans. The goal of the Veterans Health Administration (VHA) is to provide high quality medical and dental care to eligible veterans.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on (*Tuesday, August 28, 2013*), Vol. 78, No. 167, on page 53195.

Affected Public: Individuals or households.

Estimated Annual Burden: 36,585 burden hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 9,146.

Dated: December 23, 2013.

By direction of the Secretary.

Crystal Rennie,

VA Clearance Officer, U.S. Department of Veterans Affairs.

[FR Doc. 2013–31057 Filed 12–26–13; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 249 December 27, 2013

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, et al.
Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, and 494

[CMS–3178–P]

RIN 0938–AO91

Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It would also ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

We are proposing emergency preparedness requirements that 17 provider and supplier types must meet to participate in the Medicare and Medicaid programs. Since existing Medicare and Medicaid requirements vary across the types of providers and suppliers, we are also proposing variations in these requirements. These variations are based on existing statutory and regulatory policies and differing needs of each provider or supplier type and the individuals to whom they provide health care services. Despite these variations, our proposed regulations would provide generally consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 25, 2014.

ADDRESSES: In commenting, please refer to file code CMS–3178–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3178–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Janice Graham, (410) 786–8020.
Mary Collins, (410) 786–3189.
Diane Corning, (410) 786–8486.
Ronisha Davis, (410) 786–6882.
Lisa Parker, (410) 786–4665.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

AAAHC Accreditation Association for Ambulatory Health Care, Inc.
AAAASF American Association for Accreditation for Ambulatory Surgery Facilities, Inc.
AAR/IP After Action Report/Improvement Plan
ACHC Accreditation Commission for Health Care, Inc.
ACHE American College of Healthcare Executives
AHA American Hospital Association
AO Accrediting Organization
AOA American Osteopathic Association
ASC Ambulatory Surgical Center
ARCAH Accreditation Requirements for Critical Access Hospitals
ASPR Assistant Secretary for Preparedness and Response
BLS Bureau of Labor Statistics
BTCDP Bioterrorism Training and Curriculum Development Program
CAH Critical Access Hospital
CAMCAH Comprehensive Accreditation Manual for Critical Access Hospitals
CAMH Comprehensive Accreditation Manual for Hospitals
CASPER Certification and the Survey Provider Enhanced Reporting
CDC Centers for Disease Control and Prevention
CFC Conditions for Coverage
CHAP Community Health Accreditation Program
CMHC Community Mental Health Center
COI Collection of Information
COP Conditions of Participation
CORF Comprehensive Outpatient Rehabilitation Facilities
CPHP Centers for Public Health Preparedness
CRI Cities Readiness Initiative

DHS Department of Homeland Security
DHHS Department of Health and Human Services
DOL Department of Labor
DPU Distinct Part Units
DSA Donation Service Area
EOP Emergency Operations Plans
EC Environment of Care
EMP Emergency Management Plan
EP Emergency Preparedness
ESF Emergency Support Function
ESRD End-Stage Renal Disease
FEMA Federal Emergency Management Agency
FDA Food and Drug Administration
FQHC Federally Qualified Health Clinic
GAO Government Accountability Office
HFAP Healthcare Facilities Accreditation Program
HHA Home Health Agencies
HPP Hospital Preparedness Program
HRSA Health Resources and Services Administration
HSC Homeland Security Council
HSEEP Homeland Security Exercise and Evaluation Program
HSPD Homeland Security Presidential Directive
HVA Hazard Vulnerability Analysis
ICFs/IID Intermediate Care Facilities for Individuals with Intellectual Disabilities
ICR Information Collection Requirements
IDG Interdisciplinary Group
IOM Institute of Medicine
JCAHO Joint Commission on the Accreditation of Healthcare Organizations
JPATS Joint Patient Assessment and Tracking System
LD Leadership
LPHA Local Public Health Agencies
LSC Life Safety Code
LTC Long Term Care
MMRS Metropolitan Medical Response System
MS Medical Staff
NDMS National Disaster Medical System
NF Nursing Facilities
NFPA National Fire Protection Association
NIMS National Incident Management System
NIOSH National Institute for Occupational Safety and Health
NLTN National Laboratory Training Network
NRP National Response Plan
NRF National Response Framework
NSS National Security Staff
OBRA Omnibus Budget Reconciliation Act
OIG Office of the Inspector General
OPHPR Office of Public Health Preparedness and Response
OPO Organ Procurement Organization
OPT Outpatient Physical Therapy
OPTN Organ Procurement and Transplantation Network
OSHA Occupational Safety and Health Administration
ORHP Office of Rural Health Policy
PACE Program for the All-Inclusive Care for the Elderly
PAHPA Pandemic and All-Hazards Preparedness Act
PHEP Public Health Emergency Preparedness
PIN Policy Information Notice
PPD Presidential Policy Directive
PRTF Psychiatric Residential Treatment Facilities
QAPI Quality Assessment and Performance Improvement
QIES Quality Improvement and Evaluation System
RFA Regulatory Flexibility Act
RNHCI Religious Nonmedical Health Care Institutions
RHC Rural Health Clinic
SAMHSA Substance Abuse and Mental Health Services Administration
SLP Speech Language Pathology
SNF Skilled Nursing Facility
SNS Strategic National Stockpile
TEFRA Tax Equity and Fiscal Responsibility Act
TFAH Trust for America's Health
TJC The Joint Commission
TTX Tabletop Exercise
UMRA Unfunded Mandates Reform Act
UPMC University of Pittsburgh Medical Center
WHO World Health Organization

Table of Contents

I. Overview

A. Executive Summary

1. Purpose

Over the past several years, the United States has been challenged by several natural and man-made disasters. As a result of the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, the catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, tornadoes and floods in the spring of 2011, the 2009 H1N1 influenza pandemic, and Hurricane Sandy in 2012, readiness for public health emergencies has been put on the national agenda. For the purpose of this proposed regulation, "emergency" or "disaster" can be defined as an event affecting the overall target population or the community at large that precipitates the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a governor, the Secretary of the Department of Health and Human Services (HHS), or the President of the United States. (See Health Resources and Services Administration (HRSA) Policy Information notice entitled, "Health Center Emergency Management Program Expectations," (Document No. 2007–15, dated August 22, 2007, found at *http://www.hsdl.org/?view&did=478559*). Disasters can disrupt the environment of health care and change the demand for health care services. This makes it essential that health care providers and suppliers ensure that emergency management is integrated into their daily functions and values.

In preparing this proposed rule, we reviewed the guidance, developed by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Office of the Assistant Secretary for Preparedness and Response (ASPR). Additionally, we held regular meetings with these agencies and ASPR to collaborate on federal emergency preparedness requirements. To guide us in the development of this rule, we also reviewed several other sources to find the most current best practices in the health care industry. These sources included other federal agencies; The Joint Commission (TJC) standards for emergency preparedness; the American Osteopathic Association (AOA) standards for disaster preparedness (currently written for Critical Access Hospitals (CAHs) only); the National Fire Protection Association (NFPA) standards in NFPA 101 Life Safety Code and NFPA 1600: "Standard on Disaster/Emergency Management and Business Continuity Programs," 2007 Edition; state-level requirements for some states, including those for California and Maryland; and policy guidance from the American College of Healthcare Executives (ACHE), entitled the "Healthcare Executives' Role in Emergency Preparedness," which reinforces our position regarding the necessity of this proposed rule. Many of the resources we reviewed in the development of this proposed rule are listed in the APPENDIX—"Emergency Preparedness Resource Documents and Sites." We encourage providers and suppliers to use these resources to develop and maintain their emergency preparedness plans.

We also reviewed existing Medicare emergency preparedness requirements for both providers and suppliers. We concluded that current emergency preparedness regulatory requirements are not comprehensive enough to address the complexities of actual emergencies. Specifically, the requirements do not address the need for: (1) Communication to coordinate with other systems of care within local jurisdictions (for example. cities, counties) or states; (2) contingency planning; and (3) training of personnel.

Based on our analysis of the written reports, articles, and studies, as well as on our ongoing dialogue with representatives from the federal, state, and local levels and with various stakeholders, we believe that, currently, in the event of a disaster, health care providers and suppliers across the nation would not have the necessary emergency planning and preparation in place to adequately protect the health and safety of their patients. Underlying this problem is the pressing need for a more consistent regulatory approach that would ensure that providers and suppliers nationwide are required to plan for and respond to emergencies and disasters that directly impact patients, residents, clients, participants, and their communities. As we have learned from past events and disasters, the current regulatory patchwork of federal, state, and local laws and guidelines, combined with the various accrediting organization emergency preparedness standards, falls far short of what is needed to require that health care providers and suppliers be adequately prepared for a disaster. Thus, we are proposing these emergency preparedness requirements to establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness and response that incorporates the lessons learned

from the past, combined with the proven best practices of the present. We recognize that central to this approach is to develop and guide emergency preparedness and response within the framework of our national health care system. To this end, these proposed regulations would also encourage providers and suppliers to coordinate their preparedness efforts within their own communities and states as well as across state lines, as necessary to achieve their goals. We are soliciting comments on whether certain requirements should be implemented on a staggered basis.

2. Summary of the Major Provisions

We are proposing emergency preparedness requirements that will be consistent and enforceable for all affected Medicare and Medicaid providers and suppliers. This proposed rule addresses the three key essentials needed to ensure that health care is available during emergencies: safeguarding human resources, ensuring business continuity, and protecting physical resources. Current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

Based on our research and consultation with stakeholders, we have identified four core elements that are central to an effective and comprehensive framework of emergency preparedness requirements for the various Medicare and Medicaid participating providers and suppliers. The four elements of the emergency preparedness program are as follows:

- Risk assessment and planning: This proposed rule would propose that prior to establishing an emergency plan, a risk assessment would be performed based on utilizing an "all-hazards" approach. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the provider and supplier considering the particular types of hazards which may most likely occur in their area.
- Policies and procedures: We are proposing that facilities be required to develop and implement policies and procedures based on the emergency plan and risk assessment.
- Communication plan: This proposed rule would require a facility to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. Patient care must be well-coordinated within the facility, across health care providers, and with state and local public health departments and emergency systems to protect patient health and safety in the event of a disaster.
- Training and testing: We are proposing that a facility develop and maintain an emergency preparedness training and testing program. A well-organized, effective training program must include providing initial training in emergency preparedness policies and procedures. We propose that the facility ensure that staff can demonstrate knowledge of emergency procedures and provide this training at least annually. We would require that facilities conduct drills and exercises to test the emergency plan.

We are seeking public comments on when these CoPs should be implemented.

B. Current State of Emergency Preparedness

1. Federal Emergency Preparedness

In response to the September 11, 2001 terrorist attacks and the subsequent national need to refine the nation's strategy to handle emergency situations, there have been numerous efforts across federal agencies to establish a foundation for development and expansion of emergency preparedness systems. The following is a brief overview of some emergency preparedness activities at the federal level. Additional information is included in the appendix to this proposed rule.

a. Presidential Directives

Three Presidential Directives HSPD–5, HSPD–21 and PPD–8, require agencies to coordinate their emergency preparedness activities with each other and across federal, state, local, tribal, and territorial governments. Although these directives do not specifically require Medicare providers and suppliers to adopt such measures, they have set the stage for what we expect from our providers and suppliers in regard to their roles in a more unified emergency preparedness system. The Homeland Security Presidential Directive (HSPD–5), "Management of Domestic Incidents," was issued on February 28, 2003. This directive authorizes the Department of Homeland Security to develop and administer the National Incident Management System (NIMS). The NIMS provides a consistent national template that enables federal, state, local, and tribal governments, as well as private-sector and nongovernmental organizations, to work together effectively and efficiently to prepare for, prevent, respond to, and recover from domestic incidents, regardless of cause, size, or complexity, including acts of catastrophic terrorism. The Presidential Policy Directive (PPD–8 focuses on strengthening the security and resilience of the nation through systematic preparation for the full range of 21st century hazards that threaten the security of the nation, including acts of terrorism, cyber attacks, pandemics, and catastrophic natural disasters. The directive is founded by 3 key principles which include: (1) employ an all-of-nation/whole community approach, integrate efforts across federal, state, local, tribal and territorial governments; (2) build key capabilities to confront any challenge; and (3) utilize an assessment system focused on outcomes to measure and track progress. Finally, the Presidential directive published on October 18, 2007, entitled, "Homeland Security Presidential Directive/HSPD–21," addresses public health and medical preparedness. The directive, found at *http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm*, establishes a National Strategy for Public Health and Medical Preparedness (Strategy), which aims to transform our national approach to protecting the health of the American people against all disasters. HSPD–21 summarizes implementation actions that are the four most critical components of public health and medical preparedness: biosurveillance, countermeasure stockpiling and distribution, mass casualty care, and community resilience. The directive states that these components will receive the highest priority in public health and medical preparedness efforts.

b. Assistant Secretary for Preparedness and Response

In December 2006, the President signed the Pandemic and All-Hazards Preparedness Act (PAHPA) (Pub. L. 109–417). The purpose of the Pandemic and All-Hazards Preparedness Act is "to improve the Nation's public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural." The Office of the Assistant Secretary for Preparedness and Response (ASPR) was created under the PAHPA Act in the wake of Katrina to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. The Secretary of HHS delegates to ASPR the leadership role for all health and medical services support functions in a health emergency or public health event. ASPR also serves as the senior advisor to the HHS

Secretary on public health and medical preparedness and provides, at a minimum, support for; building federal emergency medical operational response and recovery capabilities; countermeasures research, advance development, and procurement; and grants to strengthen the capabilities of healthcare preparedness at the state, regional, local and healthcare coalition levels for public health emergencies and medical disasters. The office provides federal support, including medical professionals through ASPR's National Disaster Medical System (NDMS), to augment state and local capabilities during an emergency or disaster. The purpose of the NDMS is to establish a single, integrated, and national medical response capability to assist state and local authorities in dealing with the medical impacts of major peacetime disasters and to provide support to the military and the Department of Veterans Affairs medical systems in caring for casualties evacuated back to the U.S. from overseas conflicts. The NDMS, as part of the HHS, led by ASPR, supports federal agencies in the management and coordination of the federal medical response to major emergencies and federally declared disasters including natural disasters, technological disasters, major transportation accidents, and acts of terrorism, including weapons of mass destruction events. Additional information can be found at: *http://www.phe.gov/preparedness/responders/ndms/Pages/default.aspx*.

ASPR also administers the Hospital Preparedness Program (HPP), which provides leadership and funding through grants and cooperative agreements to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Through the work of its state partners, HPP has advanced the preparedness of hospitals and communities in numerous ways, including building healthcare coalitions, planning for all hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners.

The first response in a disaster is always local, and comprised of local government emergency services supplemented by state and volunteer organizations. This aspect of the "disaster response" is specifically coordinated by state and local authorities. When an incident overwhelms or is anticipated to overwhelm state resources, the Governor of a state or chief executive of a tribe may request federal assistance. In such cases, the affected local jurisdiction, tribe, state, and the federal government will collaborate to provide that necessary assistance. When it is clear that state capabilities will be exceeded, the Governor or the tribal executive can request federal assistance, including assistance under the *Robert Stafford Disaster Relief and Emergency Assistance Act (Stafford Act)*. The Stafford Act authorizes the President to provide financial and other assistance to state and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts following Presidential emergency or major disaster declarations.

The National Response Framework (NRF), a guide to how the nation should conduct all hazards responses, includes 15 Emergency Support Functions (ESFs), which are groupings of governmental and certain private sector capabilities into an organizational structure. The purpose of the ESFs is to provide support, resources, program implementation, and services that are most likely needed to save lives, protect property and the environment, restore essential services and critical infrastructure, and help victims and communities return to normal following domestic incidents. HHS is the primary agency responsible for ESF 8—Public Health and Medical Services.

The Secretary of HHS leads all federal public health and medical response to public health and medical emergencies and incidents that are covered by the Stafford Act, via NRF, or the Public Health Service Act. Under the NRF, ESF 8 is coordinated by the Secretary of HHS principally through the Assistant Secretary for Preparedness and Response (ASPR). ESF 8—Public Health and Medical Services provides the mechanism for coordinated federal assistance to supplement state, tribal, and local jurisdictional resources in response to a public health and medical disaster, potential or actual incidents requiring a coordinated federal response, or during a developing potential health and medical emergency.

c. Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) Office of Public Health Preparedness and Response (OPHPR) leads the agency's preparedness and response activities by providing strategic direction, support, and coordination for activities across CDC as well as with local, state, tribal, national, territorial, and international public health partners. CDC provides funding and technical assistance to states to build and strengthen public health capabilities. Ensuring that states can adequately respond to threats will result in greater health security; a critical component of overall U.S. national security. Additional information can be found at: *http://www.cdc.gov/phpr/*. The CDC Public Health Emergency Preparedness (PHEP) cooperative agreement, led by OPHPR, is a critical source of funding for state, local, tribal, and territorial public health departments. Since 2002, the PHEP cooperative agreement has provided nearly $9 billion to public health departments across the nation to upgrade their ability to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events. Preparedness activities funded by the PHEP cooperative agreement are targeted specifically for the development of emergency-ready public health departments that are flexible and adaptable. The Strategic National Stockpile (SNS), administered by the CDC, is a stockpile of pharmaceuticals and medical supplies. The SNS program was created to assist states and local communities in responding to public health emergencies, including those resulting from terrorist attacks and natural disasters. The SNS program ensures the availability of necessary medicines, antidotes, medical supplies, and medical equipment for states and local communities, to counter the effects of biological pathogens and chemical and nerve agents. (*http://www.cdc.gov/phpr/stockpile/stockpile.htm*).

The Cities Readiness Initiative (CRI), led by CDC, is a federally funded pilot program to help cities increase their capacity to deliver medicines and medical supplies within 48 hours after recognition of a large-scale public health emergency such as a bioterrorism attack or a nuclear accident. More information on this effort can be found at: *http://www.bt.cdc.gov/cri/*. An evaluative report of this program since its inception, requested by the CDC, performed by the RAND Corporation, and published in 2009, entitled, "Initial Evaluation of the Cities Readiness Initiative" can be found at *http://www.rand.org/pubs/technical_reports/2009/RAND_TR640.pdf*.

Given the heightened concern regarding the impact of various influenza outbreaks in recent years, the federal government has created a Web site with "one-step access to U.S.

Government H1N1, Avian, and Pandemic Flu Information" at *www.flu.gov*. The Web site provides links to influenza guidance and information from federal agencies, such as the CDC, as well as checklists for pandemic preparedness. The information and links are found at *http://www.flu.gov/professional/index.html*. This Web site includes information for hospitals, long term care facilities, outpatient facilities, home health agencies, other health care providers, and clinicians. For example, the "Hospital Pandemic Influenza Planning Checklist" provides guidance on structure for planning and decision making; development of a written pandemic influenza plan; and elements of an influenza pandemic plan. The checklist is comprehensive and lists everything a hospital should do to prepare for a pandemic, from planning for coordination with local and regional planning and response groups to infection control.

2. State and Local Preparedness

A review of studies and articles regarding readiness of state and local jurisdictions reveals that there is inconsistency in the level of emergency preparedness amongst states and need for improvement in certain areas. In a report by the Trust for America's Health (TFAH) (December 2012, *http://www.healthyamericans.org/report/101/*) entitled, "Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism" the authors assessed state-by-state public health preparedness nearly 10 years after the September 11th and anthrax tragedies. Using 10 key indicators to rate levels of public health preparedness, some key findings included: (1) 29 states cut public health funding from fiscal years (FY) 2010 through 2012, with 2 of these states cutting funds for a second year in a row and 14 for 3 consecutive years, and that federal funds for state and local preparedness have decreased by 38 percent from FY 2005 through 2012 and (2) 35 states and Washington DC do not currently have complete climate change adaption plans, which include planning for health threats posed by extreme weather events.

An article entitled, "Public Health Response to Urgent Case Reports," published in Health Affairs (August 30, 2005), Dausey, D., Lurie, N., and Diamond, A.) evaluated the ability of local public health agencies (LPHAs) to adequately meet "a preparedness standard" set by the CDC. The standard was for the LPHAs "to receive and respond to urgent case reports of communicable diseases 24 hours a day, 7 days a week." Using 18 metropolitan area LPHAs that were roughly evenly distributed by agency size, structure, and region of the country, the goal of the test was to contact an "action officer" (that is, physician, nurse, epidemiologist, bioterrorism coordinator, or infection control practitioner) responsible for responding to urgent case reports.

During a 4-month period of time, each LPHA was contacted several times and asked questions regarding triage procedures, what questions would be asked in the event of an urgent case being filed, next steps taken after receiving such a report, and who would be contacted. Although the LPHAs had a substantial role in community public health through prevention and treatment efforts, the authors found significant variation in performance and the systems in place to respond to such reports.

We also reviewed an article published in June 2004 by Lurie, N., Wasserman, J., Stoto, M., Myers, S., Namkung, P., Fielding, J., and Valdez, R. B., entitled, "Local Variations in Public Health Preparedness: Lessons from California" found at *http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.341/DC1*. The authors stated that "evidence-based measures to assess public health preparedness are lacking in California." Using an "expert-panel process," the researchers developed performance measures based on ten identified essential public health services. They performed site visits and tabletop exercises to evaluate preparedness across the state in geographic locations identified as urban, rural, and border status to detect and respond to a hypothetical smallpox outbreak based on the different measures of preparedness. Overall, the researchers found that there was a lack of consensus regarding what "emergency preparedness" encompassed and a wide variation in what various governmental agencies deemed to be adequate emergency preparedness "readiness" in California. They noted that gaps in the infrastructure were common.

Throughout the jurisdictions investigated, there were similarities noted in the shortage of nurses, the number of essential workers nearing retirement age, and the lack of epidemiologists, lab personnel, and public health nurses to meet potential needs. Such gaps in personnel infrastructure were found in many jurisdictions. In some jurisdictions, there was incomplete information regarding the demographics of persons who could be considered potentially vulnerable or part of an underserved population.

In one situation, there was also great variability in the length of time it took to bring three suspicious cases to public health officers' attention and for these officers to realize that these cases were related. There was great variation in the public health officers' ability to rapidly alert the physician and hospital community of an outbreak. There was a lack of consensus regarding when to report a potential outbreak to the public. There also was wide variation in knowledge of public health legal authority, specifically, in regard to quarantine and its enforcement. We believe these findings to be typical of most states.

3. Hospital Preparedness

Hospitals are the focal points for health care in their respective communities; thus, it is essential that hospitals have the capacity to respond in a timely and appropriate manner in the event of a natural or man-made disaster. Additionally, since Medicare-participating hospitals are required to evaluate and stabilize every patient seen in the emergency department and to evaluate every inpatient at discharge to determine his or her needs and to arrange for post-discharge care as needed, hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities. We would expect hospitals to be prepared to provide care to the greatest number of disaster victims for which they have the capacity, while meeting at least minimal obligations for care to all who are in need.

In 2007, ASPR contracted with the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) (the Center) to conduct an assessment of U.S. hospital preparedness and to develop recommendations for evaluating and improving future hospital preparedness efforts. The Center's assessment, entitled "Hospitals Rising to the Challenge: The First Five Years of the U.S. Hospital Preparedness Program and Priorities Going Forward" describes the most important components of preparedness for mass casualty response at the local and regional hospital and healthcare system levels. This evaluation report was based on extensive analyses of the published literature, government reports, and HPP program assessments, as well as on detailed conversations with 133 health officials and hospital professionals representing every state, the largest cities, and major territories of the U.S.

The authors stated that major disasters can severely challenge the ability of healthcare systems to adequately care for large numbers of patients (surge capacity) or victims with unusual or highly specialized medical needs (surge capability) such as occurred with Hurricane Katrina. The authors further stated that addressing medical surge and medical system resilience requires implementing systems that can effectively manage medical and health responses, as well as developing and maintaining preparedness programs. There were numerous findings and conclusions in the 2007 report. The researchers found that since the start of the HPP in 2002, individual hospitals' disaster preparedness has improved significantly. The report found that hospital senior leadership is actively supporting and participating in preparedness activities, and disaster coordinators within hospitals have given sustained attention to preparedness and response planning efforts. Hospital emergency operations plans (EOPs) have become more comprehensive and, in many locations, are coordinated with community emergency plans and local hazards. Disaster training has become more rigorous and standardized; hospitals have stockpiled emergency supplies and medicines; situational awareness and communications are improving; and exercises are more frequent and of higher quality. The researchers also found improved collaboration and networking among and between hospitals, public health departments, and emergency management and response agencies. These coalitions are believed to represent the beginning of a coordinated community-wide approach to medical disaster response.

However, ASPR Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness (2012) and CDC Public Health Preparedness Capabilities: National Standards for State and Local Planning (March 2011) notes numerous federal directives that recognize the need for a consistent approach to preparedness planning across the nation so as to ensure an effective response.. The 2010 IOM report also notes that direction at the federal level is essential in order to ensure a coordinated, interoperable disaster response. (IOM Medical Surge Capacity. 2009 Forum on Medical and Public Health Preparedness for Catastrophic Events, 2010)"

4. OIG and GAO Reports

Since Katrina, several studies regarding the preparedness of health care providers have been published. In general, these reports and studies point to a need for improved requirements to ensure that providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

In response to a request from the U.S. Senate Special Committee on Aging calling for an examination of nursing home emergency preparedness, the Office of the Inspector General (OIG) conducted a study during 2004 through 2005 entitled, "Nursing Home Emergency Preparedness and Responses During Recent Hurricanes," (OEI–06–06–00020) *http://oig.hhs.gov/oei/reports/oei-06-06-00020.pdf*). The OIG reviewed state survey data for emergency preparedness measures both for the nation in general and for the Gulf States (Alabama, Florida, Louisiana, Mississippi, and Texas). The study indicated that in 2004 through 2005, 94 percent of nursing homes nationwide met the limited federal regulations for emergency plans then in existence, while only 80 percent met the federal standards for emergency training. Similar compliance rates were noted in the Gulf states. However, the OIG found that nursing homes in the Gulf states experienced problems even though they were in compliance with federal interpretive guidelines. Further, they experienced problems whether they evacuated residents or sheltered them in place. The OIG listed the problems encountered by Gulf state nursing homes including, transportation contracts that were not honored; lengthy travel times for residents; insufficient food and water for residents and staff; complicated resident medication needs; host facilities that were unavailable or that were inadequately prepared, provisioned, or staffed for the transfer of residents; and difficulty re-entering their own facilities. As further detailed in the OIG report, the main reasons for these problems were lack of effective planning; failure to properly execute emergency plans; failure to anticipate the specific problems encountered; and failure to adjust decisions and actions to specific situations.

The OIG also found that some facility administrators deviated, many significantly, from their emergency plans or worked beyond the plans, either because the plans were not updated or plans did not include instructions for certain circumstances. The report goes on to note that many of the nursing home emergency preparedness plans did not consider the following factors: the need to evacuate residents to alternate sites as evidenced by a formal agreement with a host facility; criteria to determine whether to evacuate residents or shelter them in place; a means by which an individual resident's care needs would be identified and met; and re-entry into the facility following an evacuation.

Although some local communities were directly involved in the evacuation of their nursing home residents, other nursing homes received assistance with evacuation from resident and staff family members, parent corporations, and "sister facilities," according to the OIG report. A few nursing homes reported that problems with state and local government coordination during the hurricanes contributed to the problems they encountered.

Based on this study, the OIG had two recommendations for CMS: (1) Strengthen federal certification standards for nursing home emergency plans by including requirements for specific elements of emergency planning; and (2) encourage communication and collaboration between state and local emergency entities and nursing homes. As a result of the OIG's recommendations, the Secretary initiated an emergency preparedness improvement effort to be coordinated across all HHS agencies. Our development of this proposed rule is an important part of HHS-wide efforts to meet the Department's overall emergency preparedness goals and objectives by directly addressing the OIG recommendations. In April 2012, the OIG issued a subsequent report entitled, "Gaps Continue to Exist in Nursing Home Emergency Preparedness and response During Disasters: 2007–2010," (OEI–06–09–00270 *http://oig.hhs.gov/oei/reports/oei-06-09-00270.pdf*). This report notes that many of the gaps in nursing home preparedness and response identified in the 2006 report still exist.

We also reviewed several Government Accountability Office (GAO) reports on emergency preparedness. One such report is entitled, "Disaster Preparedness: Preliminary Observations on the Evacuation of Hospitals and Nursing Homes Due to Hurricanes" (GAO–06–443R), was published on February 16, 2006, and can be found at *http://www.gao.gov/new.items/d06443r.pdf*). This report discusses the GAO's findings regarding—(1) Responsibility for the decision to evacuate hospitals and nursing homes; (2) the issues administrators consider when deciding to evacuate hospitals and nursing homes; and (3) the federal response capabilities that support evacuation of hospitals and nursing homes.

The GAO found that "hospital and nursing home administrators are often responsible for deciding whether to evacuate patients from their facilities due to disasters, including hurricanes or other natural disasters. State and local governments can order evacuations of the population or segments of the population during emergencies, but health care facilities may be exempt from these orders." The GAO found that hospitals and nursing home administrators evacuate only as a last resort and that these facilities' emergency plans are designed primarily to shelter in place. The GAO also found that administrators considered the availability of adequate resources to shelter in place, the risks to patients in deciding when to evacuate, the availability of transportation to move patients, the availability of receiving facilities to accept patients, and the destruction of the facility's or community's infrastructure.

The GAO noted that nursing home administrators also must consider the fact that nursing home residents cannot care for themselves and generally have no home and no place to live other than the nursing home. Therefore, in the event of an evacuation, nursing homes also need to consider the necessity of locating facilities that can accommodate their residents for a long period of time.

A second report from the GAO about the hurricanes' impact entitled, "Disaster Preparedness: Limitations in Federal Evacuation Assistance for Health Facilities Should be Addressed," (GAO–06–826) July, 2006, *www.gao.gov/cgi-bin/getrpt?GAO–06–826*), supports the findings noted in the first GAO report on the disasters. In addition, the GAO noted that the evacuation issues that facilities faced during and after the hurricanes occurred due to their inability to secure transportation when needed. Despite previously established contracts with transportation companies, demand for this assistance overwhelmed the supply of vehicles in the community.

A third report, an after-event analysis entitled, "Hurricane Katrina: Status of Hospital Inpatient and Emergency Departments in the Greater New Orleans Area," (GAO–06–1003) September 29, 2006, *http://www.gao.gov/docdblite/details.php?rptno=GAO-06-1003*) revealed that, as of April 2006: (1) Emergency departments were experiencing overcrowding; but that (2) the number of staffed inpatient beds per 1,000 population was greater than that of the national average and expected to increase further. However, the study found that the number of staffed inpatient beds was not available in psychiatric care settings. In fact, some persons with mental health needs had to be transferred out of the area due to a lack of beds. Attracting and retaining nursing and support staff were two problems that were identified as hindering efforts to maintain an adequate supply of staffed beds for psychiatric patients.

While this study focused specifically on patient care issues in the New Orleans area, the same issues are common to hospitals in any major metropolitan area. Given the vulnerability of persons with mental illness and the tremendous stress a man-made or natural disaster can put on the entire general population, an increase in the number of persons who seek mental health services and require inpatient psychiatric care can be expected following any natural or man-made disaster.

In another report from the GAO, an after-event analysis entitled, "Disaster Recovery: Past Experiences Offer Recovery Lessons for Hurricane Ike and Gustav and Future Disasters," (GAO–09–437T March 3, 2009, *http://www.gao.gov/products/GAO-09-437T*) the GAO concluded that recovery from major disasters is a complex undertaking that involves the combined efforts of federal, state, and local government in order to succeed. The GAO stated that while the federal government provides a significant amount of financial and technical assistance for recovery, state and local jurisdictions should work closely with federal agencies to secure and make use of those resources.

In a report from the GAO, entitled, "Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed," (GAO–09–909T July 29, 2009; *http://www.gao.gov/new.items/d09909t.pdf*), the GAO expressed its concern that, despite a number of actions having been taken to plan for a pandemic, including developing a National Strategy and Implementation Plan, many gaps in pandemic planning and preparedness still existed in the presence of a potential pandemic influenza outbreak.

In November 2009, the GAO published an additional report entitled, "Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement," (GAO–10–73) (*http://www.gao.gov/new.items/d1073.pdf*). In this report, the GAO assessed the progress of the responsible federal agencies (including HHS) in implementing the action items set forth in the "National Strategy for Pandemic Influenza: Implementation Plan" (the Plan) (*http://georgewbush-whitehouse.archives.gov/homeland/pandemic-influenza-implementation.html*). Specifically, the researchers were interested in determining how the Homeland Security Council (HSC) and the responsible federal agencies were monitoring the progress and completion of the Plan's 342 action items, and assessing the extent to which selected action items were completed, whether activity had continued on the selected action items reported as complete, and the nature of that work. Having conducted an in-depth analysis of a random sample of 60 action items, the GAO found the status of selected action items considered complete was difficult to determine. Specifically, the GAO found that: (1) Measures of performance used to determine status did not always fully reflect the descriptions of the action items; (2) some selected action items were designated as complete despite requiring actions outside the authority of the responsible entities; and (3) additional work was conducted on some selected action items designated as complete. Ultimately, the GAO recommended that, in order to improve how progress is monitored and completion is assessed under the Plan and subsequent updates of the Plan, the HSC should instruct the White House National Security Staff (NSS) to work with responsible federal agencies to: (1) Develop a monitoring and reporting process for action items that are intended for nonfederal entities, such as state and local governments; (2) identify the types of information needed to decide whether to carry out the response-related action items; and (3) develop measures of performance that are more consistent with the descriptions of the action items.

C. Statutory and Regulatory Background

Various sections of the Social Security Act (the Act) define the terms Medicare uses for each provider and supplier type and list the requirements that each provider and supplier must meet to be eligible for Medicare and Medicaid participation. Each statutory provision also specifies that the Secretary may establish other requirements as the Secretary finds necessary in the interest of the health and safety of patients, although the exact wording of such authority may differ slightly between different provider and supplier types. These requirements are called the Conditions of Participation (CoPs) for providers and the Conditions for Coverage (CfCs) for suppliers. The CoPs and CfCs are intended to protect public health and safety and ensure that high

quality care is provided to all persons. Further, the Public Health Service (PHS) Act sets forth additional requirements that certain Medicare providers and suppliers must meet to participate.

The following are the statutory and regulatory citations for the providers and suppliers for which we intend to propose emergency preparedness regulations:

- Religious Nonmedical Health Care Institutions (RNHCIs)—section 1821 of the Act and 42 CFR 403.700 through 403.756.
- Ambulatory Surgical Centers (ASCs)—section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.40 through 416.49.
- Hospices—section 1861(dd)(1) of the Act and 42 CFR 418.52 through 418.116.
- Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs (PRTFs)—sections 1905(a) and 1905(h) of the Act and 42 CFR 441.150 through 441.182 and 42 CFR 483.350 through 483.376.
- Programs of All-Inclusive Care for the Elderly (PACE)—sections 1894, 1905(a), and 1934 of the Act and 42 CFR 460.2 through 460.210.
- Hospitals—section 1861(e)(9) of the Act and 42 CFR 482.1 through 482.66.
- Transplant Centers—sections 1861(e)(9) and 1881(b)(1) of the Act and 42 CFR 482.68 through 482.104.
- Long Term Care (LTC) Facilities –Skilled Nursing Facilities (SNFs) –under section 1819 of the Act, Nursing Facilities (NFs)—under section 1919 of the Act, and 42 CFR 483.1 through 483.180.
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)—section 1905(d) of the Act and 42 CFR 483.400 through 483.480.
- Home Health Agencies (HHAs)—sections 1861(o), 1891 of the Act and 42 CFR 484.1 through 484.55.
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)—section 1861(cc)(2) of the Act and 42 CFR 485.50 through 485.74.
- Critical Access Hospitals (CAHs)—sections 1820 and 1861(mm) of the Act and 42 CFR 485.601 through 485.647.
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services—section 1861(p) of the Act and 42 CFR 485.701 through 485.729.
- Community Mental Health Centers (CMHCs)—section 1861(ff)(3)(B)(i)(ii) of the Act, section 1913(c)(1) of the PHS Act, and 42 CFR 410.110.
- Organ Procurement Organizations (OPOs)—section 1138 of the Act and section 371 of the PHS Act and 42 CFR 486.301 through 486.348.
- Rural Health Clinics (RHCs)—section 1861(aa) of the Act and 42 CFR 491.1 through 491.11; Federally Qualified Health Centers (FQHCs)—section 1861(aa) of the Act and 42 CFR 491.1 through 491.11, except 491.3.
- End-Stage Renal Disease (ESRD) Facilities—sections 1881(b), 1881(c), 1881(f)(7) of the Act and 42 CFR 494.1 through 494.180.

We considered proposing these regulations for each provider and supplier type individually, as we updated their CoPs or CfCs over time. However, for the reasons we have already discussed, we believe the most prudent course of action is to publish emergency preparedness requirements for Medicare and Medicaid providers and suppliers in a single proposed rule. Thus, we are proposing regulatory language for 17 Medicare and Medicaid providers and suppliers to address the four main aspects of emergency preparedness: (1) Risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training.

II. Provisions of the Proposed Regulations

This proposed rule responds to concerns from the Congress, the health care community, and the public regarding the ability of health care providers and suppliers to plan and execute appropriate emergency response procedures for disasters. We developed this proposed rule taking into consideration the extent of regulatory oversight that is currently in existence.

We are proposing requirements for facilities to ensure the continued provision of necessary care at the facility or, if needed, the evacuation and transfer of patients to a location that can supply necessary care. Regulations that address these functions too specifically may become outdated over time as technology and the nature of threats change. However, as our analysis of existing regulations, and the OIG and GAO reports discussed in section I. of this proposed rule, indicate regulations that are too broad may be ineffective. Our challenge is to develop core components that can be used across provider and supplier types as diverse as hospitals, organ procurement organizations, and home health agencies, while tailoring requirements for individual provider and supplier types to their specific needs and circumstances, as well as the needs of their patients, residents, clients, and participants.

We have identified four core elements that we believe are central to an effective emergency preparedness system and must be addressed to offer a more comprehensive framework of emergency preparedness requirements for the various Medicare- and Medicaid-participating providers and suppliers. The four elements are—(1) risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training and testing. We have also proposed an additional requirement for OPOs entitled "Agreements with other OPOs and hospitals."

We believe many of the proposed elements of an emergency preparedness plan need to be conducted at the level of an individual facility. However, other elements may be addressed as effectively, and more efficiently, at a broader organizational level, for example, a system for preserving medical documentation. Our regulatory requirements for each provider and supplier type are based on the comprehensive emergency preparedness requirements that we are proposing for hospitals. Since we are aware that the application of the proposed regulatory language for hospitals may be inappropriate or overly burdensome for some providers and suppliers, we have used the proposed hospital requirements as a template for our proposed emergency preparedness regulations for other providers and suppliers but have specific proposed requirements tailored to each providers' and suppliers' unique needs. Any contracted services furnished to patients must be in compliance with all the facilities' CoPs and standards of this rule, and all services must be provided in a safe and effective manner.

All providers and suppliers would be required to establish an emergency preparedness plan that addressed the four core elements noted previously. The proposed requirements vary based on the type of provider. We discuss the hospital requirements in detail at the beginning of this section. The subsequent discussion of the proposed requirements for all remaining providers and suppliers focuses on how the requirements differ from those proposed for hospitals and why.

For example, because they are inpatient facilities, religious nonmedical health care institutions (RNHCIs), psychiatric residential treatment facilities (PRTFs), skilled nursing facilities and nursing homes (referred to in this document as long term care (LTC) facilities), intermediate care facilities individuals with intellectual disabilities (ICFs/IID), and critical access hospitals (CAHs) may have greater responsibility than outpatient facilities during an emergency for ensuring the health and safety of persons for whom they provide care,

their employees, and volunteers. Thus, proposed requirements for RNHCIs, PRTFs, ICFs/IID, LTC facilities, and CAHs are similar to those proposed for hospitals.

In the event of a natural or man-made disaster, providers and suppliers of outpatient services, such as ambulatory surgical centers (ASCs), programs of all-inclusive care for the elderly (PACE) organizations, home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), rural health clinics (RHCs), federally qualified health centers (FQHCs), and end stage renal disease (ESRD) facilities, may not open their facilities or may close them, sending patients and staff home or to a place where they can safely shelter in place. However, we recognize that outpatient facilities may find it necessary to shelter their patients until they can be evacuated or may be called upon to provide some level of care for community residents in the event of an emergency. For example, a CORF that is housed in a large building may open its doors to persons in the community who would otherwise have no place to go. The CORF may provide only shelter from the elements or may provide water, food, and basic self-care items, if available.

Finally, given that some hospice facilities provide both inpatient and home based services, and that transplant centers and OPOs are unique in their provision of health care, our proposed requirements are tailored even more specifically to address the circumstances of these entities. We believe lessons learned following the 2005 hurricanes and subsequent disasters, such as the flooding in the Midwest in 2008, and the tornadoes and flooding in 2011 and 2012, have provided us with an opportunity to work collaboratively with the health care community to ensure best practices in emergency preparedness across providers and suppliers.

It is important to point out that we expect that implementation of certain requirements that we propose for providers and suppliers would be different, based on the category of the provider or supplier. For example, we propose that nearly all providers and suppliers would be required to have policies and procedures to provide subsistence needs to staff and patients during an emergency. However, a small RHC's implementation of this requirement would be quite different from a large metropolitan hospital's implementation. Specifically, with respect the proposed requirement that hospitals, CAHs, inpatient hospice facilities, PRTFs, LTC facilities, ICFs/IID, and RNHCIs would be required to maintain various subsistence needs, we are requesting public comment regarding whether this should be a requirement and in what quantities and for what time period these subsistence needs would be maintained. Nevertheless, we expect that each facility would determine how to implement a requirement considering similar variables such as whether the provider might have the option of notifying staff and patients not to come to the facility due to an emergency; the number of staff and patients likely to be in the facility at the time of an emergency; whether the provider would have the capability of providing shelter, provisions, and health care to members of the community; and the amount of space within the facility available for storing provisions. Although various providers and suppliers utilize different nomenclature to describe the individuals for whom they provide care (patient, resident, client, or participant), unless otherwise indicated, we will use the term "patients" to refer to the individuals for whom the provider or supplier under discussion provides care.

Data regarding the number of providers cited in this proposed rule were obtained from a variety of different CMS databases. The number of providers and suppliers deemed by accrediting organizations to meet the Medicare conditions of participation are from CMS's second quarter fiscal year 2010 Accrediting Organization System for Storing User Recorded Experiences (ASSURE) database. Currently, there are accrediting organizations with Medicare deeming authority for hospitals, critical access hospitals, HHAs, hospices, and ASCs.

Data for CAHs that report having psychiatric and rehabilitation Distinct Part Units (DPUs) are from the Medicare Quality Improvement and Evaluation System (QIES)/Certification and the Survey Provider Enhanced Reporting (CASPER) system as of March 2013. Data for CAHs that do not have DPUs are from the Online Survey, Certification, and Reporting (OSCAR) data system as of March 2013. Data for the number of transplant centers are from the CMS Web site as of March 2013. Data for the total number of accredited and non-accredited hospitals, HHAs, ASCs, hospices, RHNCHIs, PRTFs, SNFs, ICFs/IID, CORFs, OPOs, and RHCs/FQHCs are from the OSCAR data system as of March 2013. We acquired the PACE data from CMS's Health Plan Management System (HPMS), which reports the number of PACE contracts. Given that PACE organizations may have more than one "center," we are using the number of PACE contracts as a reflection of the number of PACE centers under contract with the CMS.

Note that the CMS OSCAR data system is updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited facilities shown may not equal the total number of facilities.

Discussion of the proposed regulatory provisions for each type of provider and supplier follows the discussion in this section of the hospital requirements in the order in which they would appear in the Code of Federal Regulations (CFR). However, our discussion of the hospital requirements includes a general discussion of the differences between our proposed requirements, based on whether providers and suppliers provide outpatient services or inpatient services or both. Thus, we encourage all providers to read the discussion of the proposed hospital emergency preparedness requirements in section II.A. of this proposed rule.

This section also provides detailed discussion of each proposed hospital requirement, offers resources that providers and suppliers can use to meet these proposed requirements, offers a means to establish and maintain emergency preparedness for their facilities, and provides links to guidance materials and toolkits that can be used to help meet these requirements.

A. Emergency Preparedness Regulations for Hospitals (§ 482.15)

Section 1861(e) of the Act defines the term "hospital," and subsections (1) through (8) list requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. Under the authority of 1861(e) of the Act, the Secretary has established in regulations at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare conditions of participation (CoPs) to qualify for participation in Medicaid. The hospital CoPs are found at § 482.1 through § 482.66.

As of September 2012, 4,928 hospitals participated in Medicare. CAHs that have distinct part units (DPUs) must comply with all of the hospital CoPs with respect to those units. There are 1,332 active CAHs. Of these CAHs, there are 95 CAHs with DPUs. The remainder of CAHs (the vast majority) are not subject to hospital CoPs, and must comply with CAH-specific CoPs. Proposed requirements for CAHs are laid out in § 485.625.

Services provided by hospitals encompass inpatient and outpatient care for persons with various acute or chronic medical or psychiatric conditions, including patient care services provided in the emergency department. Hospitals are the focal points for health care in their respective communities; thus, it is essential that hospitals have the capacity to respond in a timely and appropriate manner in the event of a natural or man-made disaster. Additionally, since Medicare-participating hospitals are required to evaluate and stabilize every patient seen in the emergency department and to evaluate every inpatient at discharge to determine his or her needs and to arrange for post-discharge care as needed, hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities.

We are proposing a new requirement under 42 CFR 482.15 that would require that hospitals have both an emergency preparedness program and an emergency preparedness plan. Conceptually, an emergency preparedness program encompasses an approach to emergency preparedness that allows for continuous building of a comprehensive system of health care response to a natural or man-made emergency. We are also proposing that a hospital, and all other providers and suppliers, utilize an "all-hazards" approach in the preparation and delivery of emergency preparedness services in order to meet the health and safety needs of its patient population. The definition of "all hazards" is discussed later in this section under "Emergency Plan."

We would expect that during an emergency, injured and ill individuals would seek health care services at a hospital or CAH, rather than from another provider or supplier. For example, during a pandemic, individuals with influenza-like symptoms are more likely to visit a hospital or CAH emergency department than an ASC. Typically, in the event of a chemical spill, affected individuals would not expect to receive emergency health care services at an LTC facility but would seek health care services at the hospital or CAH in their community. However, we believe it is imperative that each provider think in broader terms than their own facility, and plan for how they would serve similar and other healthcare facilities, as well as the whole community during and surrounding an emergency event. We believe the first step in emergency management is to develop an emergency plan. An emergency plan sets forth the actions for emergency response based on a risk assessment that addresses an "all-hazards approach" to medical and non-medical emergency events. In keeping with the emergency management industry and with strong recommendation from the Department's Assistant Secretary for Preparedness and Response (ASPR), we are proposing that all providers utilize an all-hazards approach to emergency response. We do not specify the quantity or the expected level of detail in which each hazard would be addressed by each provider; however, we do believe it would encourage the adoption of a well thought out, cohesive system of response both within and across provider types.

Analysis of anticipated outcomes to the facility-based and community-based risk assessments would drive revision to the emergency preparedness program, the plan for response, or both. A facility-based risk assessment is contained within the actual facility and carried out by the facility. A community based risk assessment is carried out outside the organization within their defined community.

1. Emergency Plan

a. Emergency Planning Resources

To stimulate and foster improved emergency preparedness continuity of operations, the federal interagency community has developed fifteen all-hazards planning scenarios, entitled the "National Planning Scenarios" for use in federal, state, and local homeland security preparedness activities. These scenarios serve as planning tools for response to the range of man-made and natural disasters the nation could face. The scenarios are: nuclear detonation-improvised nuclear device; biological attack—aerosol anthrax; biological disease outbreak—pandemic influenza; biological attack—plague; chemical attack—blister agent; chemical attack—toxic industrial chemicals; chemical attack—nerve agent; chemical attack—chlorine tank explosion; natural disaster—major earthquake; and natural disaster—major hurricane; radiological attack—radiological dispersal devices; explosive attack—bombing using improvised explosive device; biological attack—food contamination; biological attack—foreign animal disease (foot and mouth disease); and cyber attack. Additional scenarios include volcano preparedness and severe winter weather (snow/ice). Additional information regarding the National Planning Scenarios and how they align to the National Preparedness Goal can be found at: *http://www.fema.gov/preparedness-1/learn-about-presidential-policy-directive-8#MajorElements.*

These planning tools along with other emergency management and business continuity information can be found on HRSA's Web site at: *http://www.hrsa.gov/emergency/* and also in HRSA's, Policy Information Notice entitled, "Health Center Emergency Management Program Expectations," (No. 2007–15), dated August 22, 2007, at: *http://bphc.hrsa.gov/policiesregulations/policies/pin200715expectations.html*). While these materials were developed for health centers, the content is relevant to all health providers. According to the notice emergency management planning is to ensure predictable staff behavior during a crisis, provide specific guidelines and procedures to follow and define specific roles. Also, emergency planning should address the four phases of emergency management that include: mitigation activities to lessen the severity and impact a potential disaster or emergency might have on a health center's operation; preparedness activities to build capacity and identify resources that may be used should a disaster or emergency occur; response to the actual emergency and controls the negative effects of emergency situations; and recovery that begin almost concurrently with response activities and are directed at restoring essential services and resuming normal operations to sustain the long-term viability of the health center. HRSA further states that for FQHCs, this means protecting staff and patients, as well as safeguarding the facility's ability to deliver health care. According to HRSA, the expectations outlined in their guidance are intended to be broad to ensure applicability to the diverse range of centers and to aid integration of the guidance into what centers already are doing related to emergency and risk management. While this guidance is targeted toward centers, we believe hospitals and all other providers and suppliers can use this guidance in the

development of their emergency preparedness plans.

The Agency for Healthcare Research and Quality (AHRQ) released a web-based interactive tool entitled, "Surge Tool Kit and Facility Checklist" (located at: *http://www.cdc.gov/phpr/healthcare/documents/shuttools.pdf* or at: *http://archive.ahrq.gov/research/shuttered/toolkitchecklist/*), which will allow hospitals and emergency planners to estimate the resources needed to treat a surge of patients resulting from a major disaster, such as an influenza pandemic or a terrorist attack. Designed to dovetail with the Homeland Security Council's 15 all-hazards National Planning Scenarios, previously discussed, the AHRQ Hospital Surge Model allows users to select a disaster scenario and estimate the number of patients needing medical attention by arrival condition and day; the number of casualties in the hospital by unit and day; and the cumulative number of both dead or discharged casualties by day. The tool also calculates the level of hospital resources, including personnel, equipment and supplies, needed to treat patients. The model estimates resources for biological, chemical, nuclear or radiological attacks. (For the development of emergency preparedness plans, providers and suppliers may also find the National Fire Protection Association's (NFPA) NFPA 1600: "Standard on Disaster/Emergency Management and Business Continuity Programs, 2013 Edition," particularly helpful. The NFPA document can be found at: *http://www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=1600*. The standard sets forth the basic criteria for a comprehensive program that addresses disaster recovery, emergency management, and business continuity. Under most definitions, the NFPA 1600 is an industry standard for disaster management.

Also of concern when developing an emergency plan is the issue of the allocation of scarce resources during a potentially devastating event. Disasters can create situations where such resources must be distributed in a manner that is different from usual circumstances, but still appropriate to the situation. As discussed in "Providing Mass Medical Care with Scarce Resources: A Community Planning Guide, Publication No. 07–0001, Rockville, MD: Agency for Healthcare Research and Quality," (found at: *http://archive.ahrq.gov/research/mce/*), such resource considerations are part of the impact that natural or man-made disasters have on hospitals. This guide provides information on the circumstances that communities would likely face as a result of a mass casualty event (MCE); key constructs, principles, and structures to be incorporated into the planning for an MCE; approaches and strategies that could be used to provide the most appropriate standards of care possible under the circumstances; examples of tools and resources available to help states and communities in their planning processes; and illustrative examples of how some health systems, communities, or states have approached certain issues as part of their MCE-related planning efforts. Building on the work from 2008, the Institute of Medicine (IOM) released in 2012 a guidance report entitled "The Crisis Standards of Care (CSC): A Systems Framework for Catastrophic Disaster Response" available at: *http://www.iom.edu/Reports/2012/Crisis-Standards-of-Care-A-Systems-Framework-for-Catastrophic-Disaster-Response.aspx*. The guidance report expanding upon prior scarce resources reports and defined crisis standards of care as "the optimal level of health care that can be delivered during a catastrophic event, requiring a substantial change in usual health care operations." The report stated that CSC; provides a mechanism for responding to situations in which the demand on needed resources far exceeds the resource availability (that is, scarce resources); implementation of CSC involves a substantial shift in normal health care activities and reallocation of staff, facilities, and resources; and that to transition quickly and effectively, each organization and agency has a responsibility to plan and identify in advance the core functions it must carry out in a crisis and who will be responsible for each task.

Another resource that would be useful in helping planners address the issues associated with preparing for and responding to an MCE in the context of broader emergency planning processes is the document entitled, "Standing Together: An Emergency Planning Guide for America's Communities" (published by The Joint Commission (TJC), formerly known as the Joint Commission on the Accreditation of Healthcare Organizations, 2006). The document by TJC is a comprehensive resource that offers step-by-step guidance for development of an emergency preparedness plan that is applicable to small, rural, and suburban communities. This document can be found at: *http://www.jointcommission.org/Standing_Together__An_Emergency_Planning_Guide_for_Americas_Communities/*. This document may be particularly useful for small or rural facilities and agencies.

Rural communities face challenges in the delivery of health care that are often very different from those faced by urban and suburban communities. While rural communities depend on public health departments, hospitals, and emergency medical services (EMS) providers just as urban and suburban communities do, rural communities tend to have fewer health care resources overall. A report entitled, "Rural Communities and Emergency Preparedness," (published by the Health Resources and Services Administration's (HRSA) Office of Rural Health Policy, April 2002, found at: *ftp://ftp.hrsa.gov/ruralhealth/RuralPreparedness.pdf*) addresses the issues faced by rural communities with respect to emergency preparedness.

The authors report that there are many factors that limit the ability of rural providers and suppliers to deliver optimal health care services in the event of a natural or man-made disaster. The authors found that geographic isolation is a significant barrier to providing a coordinated emergency response. Rural areas are also more affected by variations in weather conditions and by seasonal variations in populations (for instance, tourism). As reported by the authors, these areas have fewer human and technical resources (that is, health care professionals, medical equipment, and communication systems).

For example, the study found that in 2002, only 20 percent of the 3,000 local public health departments in the United States had developed a plan to deal with a bioterrorism event. The researchers also found that the majority of rural public health agencies are closed evenings and weekends, and are not equipped to respond to an emergency situation on a 24-hour basis. While these factors may not affect a rural hospital directly, as an integral part of the larger system of health care delivery for its community, a hospital must be ready to manage the surge of persons who would seek care at the hospital during and after a disaster when many smaller health care entities may be non-operational.

b. Risk Assessment

To ensure that all hospitals operate as part of a coordinated emergency preparedness system, as outlined in the PPD–8, NIMS, NRF, HSPD–21, and PAHPA/PAHPRA, we are proposing at § 482.15 that all hospitals establish and maintain an emergency preparedness plan that complies with both federal and state requirements. Additionally,

we propose that a hospital would develop and maintain a comprehensive emergency preparedness program, utilizing an "all-hazards" approach. The emergency preparedness plan would have to be reviewed and updated at least annually.

In keeping with the focus of the emergency management field, we propose that prior to establishing an emergency preparedness plan, the hospital and all other providers would first perform a risk assessment based on utilizing an "all-hazards" approach. An all-hazards approach is an integrated approach to emergency preparedness planning. In the abstract of a November 2007 paper entitled, "Universal Design: The All-Hazards Approach to Vulnerable Populations Planning" by Charles K.T. Ishikawa, MSPH, Garrett W. Simonsen, MSPS, Barbara Ceconi, MSW, and Kurt Kuss, MSW, the researchers described an all-hazards planning approach as "a more efficient and effective way to prepare for emergencies. Rather than managing planning initiatives for a multitude of threat scenarios, all-hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters." Thus, all-hazards planning does not specifically address every possible threat but ensures that hospitals and all other providers will have the capacity to address a broad range of related emergencies.

It is imperative that hospitals perform all-hazards risk assessment consistent with the concepts outlined in the National Preparedness Guidelines, the "Guidelines" published by the U.S. Department of Homeland Security that we described in section I.A.3 of this proposed rule. Additional guidance and resources for assistance with designing and performing a hazard vulnerability assessment include: the *Comprehensive Preparedness Guide 201: Threat and Hazard Identification and Risk Assessment Guide* (available at: *http://www.fema.gov/library/viewRecord.do?fromSearch=fromsearch&id=5823*), the *Use of Threat and Hazard Identification and Risk Assessment for Preparedness Grants* (available at: *http://www.fema.gov/library/viewRecord.do?fromSearch=fromsearch&id=5826*), the *Preparedness Guide 201 Supplement 1: Threat and Hazard Identification and Risk Assessment Guide Toolkit* (available at: *http://www.fema.gov/library/viewRecord.do?fromSearch=fromsearch&id=5825*), the *Hazard Risk Assessment Instrument Workbook* (available at: *http://www.cphd.ucla.edu/hrai.html*) and the *Understanding Your Risks: Identifying Hazards and Estimating Losses* document (available at: *http://www.fema.gov/library/viewRecord.do?id=1880*).

Additionally, AHRQ published two additional guides to help hospital planners and administrators make important decisions about how to protect patients and health care workers and assess the physical components of a hospital when a natural or manmade disaster, terrorist attack, or other catastrophic event threatens the soundness of a facility. The guides examine how hospital personnel have coped under emergency situations in the past to better understand what factors should be considered when making evacuation, shelter-in-place, and reoccupation decisions.

The guides entitled, "Hospital Evacuation Decision Guide" and "Hospital Assessment and Recovery Guide" are intended to supplement hospital emergency plans, augment guidance on determining how long a decision to evacuate may be safely deferred, and provide guidance on how to organize an initial assessment of a hospital to determine when it is safe to return after an evacuation.

The evacuation guide distinguishes between "pre-event evacuations" which are undertaken in advance of an impending disaster, such as a storm, when the hospital structure and surrounding environment are not yet significantly compromised and "post-event evacuations," which are carried out after a disaster has damaged a hospital or the surrounding community. It draws upon past events including: the Northridge, CA, earthquake of 1994; the Three Mile Island nuclear reactor incident of 1979; and Hurricanes Katrina and Rita in 2005. The guide offers advice regarding sequence of patient evacuation and factors to consider when a threat looms.

The assessment and recovery guide helps hospitals determine when to get back into a hospital after an evacuation. Comprised primarily of a 45-page checklist, the guide covers 11 separate areas of hospital infrastructure that should be evaluated before determining that it is safe to reoccupy a facility, such as security and fire safety, information technology and communication and biomedical engineering.

The "Hospital Evacuation Decision Guide" can be found at: *http://archive.ahrq.gov/prep/hospevacguide/*) (AHRQ Publication No. 10–0009), and the "Hospital Assessment and Recovery Guide" can be found at (*http://archive.ahrq.gov/prep/hosprecovery/*) (AHRQ Publication No. 10–0081).

Based on the guidance and information in these resources, we would expect a hospital's risk assessment, which we would require at § 482.15(a)(1), to be based on and include a documented, facility-based and community-based risk assessment, utilizing an all hazards approach. In order to meet this requirement, we would expect hospitals to consider, among other things, the following—(1) Identification of all business functions essential to the hospitals operations that should be continued during an emergency; (2) identification of all risks or emergencies that the hospital may reasonably expect to confront; (3) identification of all contingencies for which the hospital should plan; (4) consideration of the hospital's location, including all locations where the hospital delivers patient care or services or has business operations; (5) assessment of the extent to which natural or man-made emergencies may cause the hospital to cease or limit operations; and (6) determination of whether arrangements with other hospitals, other health care providers or suppliers, or other entities might be needed to ensure that essential services could be provided during an emergency.

We propose at § 482.15(a)(2) that the emergency plan include strategies for addressing emergency events identified by the risk assessment. For example, a hospital in a large metropolitan city may plan to utilize the support of other large community hospitals as alternate placement sites for its patients if the hospital needs to be evacuated. However, we would expect the hospital to have back-up evacuation plans for circumstances in which nearby hospitals also were affected by the emergency and were unable to receive patients. We would expect these plans to include consideration for how the hospital would work in collaboration with hospitals and other providers and suppliers across state lines, if applicable. Individuals who live near the border with an adjoining state could use the services of a hospital located in the adjoining state if the hospital was closer or provided more services than the nearest hospital in the state in which the individual resides. Therefore, we would encourage hospitals in adjoining states to work together to formulate plans to provide services across state lines in the event of a natural or man-made disaster to ensure continuity of care during a disaster.

c. Patient Population and Available Services

At § 482.15(a)(3), we propose that a hospital's emergency plan address its patient population, including, but not limited to, persons at-risk. As defined by the PAHPA, members of at-risk populations may have additional needs in one or more of the following functional areas: maintaining independence, communication, transportation, supervision, and medical care. In addition to those individuals specifically recognized as at-risk in the statute (children, senior citizens, and pregnant women), we are proposing to define "at-risk populations" as individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. Also, as discussed in "Providing Mass Medical Care with Scarce Resources: A Community Planning Guide," (*http://archive.ahrq.gov/research/mce/*), at-risk populations would include, but are not limited to, the elderly, persons in hospitals and nursing homes, people with physical and mental disabilities, and infants, and children. Hospitals may find this resource helpful in establishing emergency plans that address the needs of such patients.

We also propose at § 482.15(a)(3) that a hospital's emergency plan address the types of services that the hospital would be able to provide in an emergency. The hospital should base these determinations on factors such as the number of staffed beds, whether the hospital has an emergency department or trauma center, availability of staffing and medical supplies, the hospital's location, and its ability to collaborate with other community resources during an emergency.

d. Succession Planning and Cooperative Efforts

In regard to emergency preparedness planning, we are also proposing at § 482.15(a)(3) that all hospitals include delegations and succession planning in their emergency plan to ensure that the lines of authority during an emergency are clear and that the plan is implemented promptly and appropriately.

Finally, at § 482.15(a)(4), we propose that a hospital have a process for ensuring cooperation and collaboration with local, tribal, regional, state, or federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. We believe that planning with officials in advance of an emergency to determine how such collaborative and cooperative efforts will be achieved will foster a smoother, more effective, and more efficient response in the event of a disaster.

While we are aware that the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the hospital would need to document its efforts to contact these officials and inform them of the hospital's participation in the coordinated emergency response. Although we propose to require the same efforts for all providers and suppliers as we propose for hospitals, we realize that federal, state, and local officials may not elect to collaborate with some providers and suppliers due to their size and role in the community. For example, a RNHCI, by the limited nature of its service within the community, may not be called upon to participate in such collaborative and cooperative planning efforts. In this instance, we are proposing that such a provider or supplier would only need to provide documentation of its efforts to contact such officials and, when applicable, its participation.

Through the work of its state partners, the ASPR Hospital Preparedness Program (HPP) has advanced the preparedness of hospitals and communities in numerous ways, including building healthcare coalitions, planning for all hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners. Many more community healthcare facilities have equipment to protect healthcare workers and decontaminate patients in chemical, biological, radiological, or nuclear emergencies.

While the HPP program continues to encourage preparedness at the hospital level, evidence and real-world events have illustrated that hospitals cannot be successful in response without robust community healthcare coalition preparedness—engaging critical partners. Critical partners include emergency management, public health, mental/behavioral health providers, as well as community and faith-based partners. Together these partners make up a community's Healthcare Coalition (HCC). A key goal of HPP moving forward is to strengthen the capabilities of the HCC, not just the individual hospital. HCCs are a cornerstone for the HPP and an integral component for community-wide planning for healthcare resiliency.

We are aware that, among some emergency management leaders, healthcare coalitions are viewed as a valued and essential component of a coordinated system of response and that many providers now participate in such coalitions. While we are not requiring that providers participate in coalitions, we do recognize and support their value in the well-coordinated emergency response system and encourage providers of all types and sizes to engage in such collaborations, where possible, to ensure better coordination in planning, including the assessment of risk, surrounding an emergency event. The primary goal of health care coalitions is to foster collaboration amongst provider types in order to strengthen the overall health system by leveraging expertise, sharing resources, and increasing capacity to respond; thus reducing potential administrative burden for emergency preparedness, while similarly enabling easier emergency response integration and coordination during an emergency. Healthcare coalition activities provide, at a minimum, an optimal forum for: Leveraging leadership and operational expertise (health, public health, emergency management, public works, public safety, etc.) within a community; conducting mutual hazard vulnerability/risk assessments to identify community health gaps and develop plans and strategies to address them; developing standardized tools, emergency plans, processes and protocols, training and exercises to support the community and support ease of integration; and facilitating timely and/or shared resource management and coordination of communications and information during an emergency

2. Policies and Procedures

We are proposing at § 482.15(b) that a hospital be required to develop and implement emergency preparedness policies and procedures based on the emergency plan proposed at § 482.15(a), the risk assessment proposed at § 482.15(a)(1), and the communication plan proposed at § 482.15(c). These policies and procedures would be reviewed and updated at least annually. We are soliciting public comment on the timing of the updates.

We propose at § 482.15(b)(1) that a hospital's policies and procedures would have to address the provision of subsistence needs for staff and patients, whether they evacuated or sheltered in place, including, but not limited to, at (b)(1)(i), food, water, and medical supplies. Analysis of the disaster caused by the hurricanes in the Gulf states in 2005 revealed that hospitals were forced to meet basic subsistence needs for community evacuees, including visitors and volunteers who sheltered in place, resulting in the rapid depletion of subsistence items and considerable difficulty in meeting the subsistence needs of patients and staff. Therefore, we are proposing that a hospital's policies and procedures also address how the subsistence needs of patients and staff who were evacuated would be met during an emergency. For example, a hospital might arrange for storage of supplies outside the facility, have contracts with suppliers for the acquisition of supplies during an emergency, or address subsistence needs for evacuees in an agreement with a facility that was willing to accept the hospital's patients during an emergency.

Based on our experience with hospitals, most hospitals do maintain subsistence supplies in the event of an emergency. Thus, we believe it would be overly prescriptive to require hospitals to maintain a defined quantity of subsistence needs for a defined period of time. We believe hospitals and other inpatient providers should have the flexibility to determine what is adequate based on the location and individual characteristics of the facility. Although we propose requiring only that each hospital addresses subsistence needs for staff and patients, we recommend that hospitals keep in mind that volunteers, visitors, and individuals from the community may arrive at the hospital to offer assistance or seek shelter and consider whether the hospital needs to maintain a store of extra provisions. We are soliciting public comment on this proposed requirement.

As stated earlier, we also have learned from attendance in the Hurricane Katrina Sharing Information During Emergencies (SIDE) conference held in July of 2006, and from on-going participation in the CMS Survey & Certification (S&C) Emergency Preparedness Stakeholder Communication Forum, that many facilities placed back-up generators in basements that subsequently became inoperable due to water damage. In turn, this led to possible unsafe conditions for their patients and other persons sheltered in the facility. We note that existing regulations at § 482.41 require hospitals to have emergency power and lighting in certain areas (operating, recovery, intensive care, emergency rooms, and stairwells). Emergency lighting only in these areas will not assist staff if there is a requirement to continue operations for long periods of time with no power (for example, in the wards). Power outages lasted several days after Hurricane Sandy in some areas of the northeast. Similarly, should a large-scale evacuation be required, a lack of emergency lighting in general areas of the hospital such as wards and corridors would greatly hinder this process. This was of particular concern in impacted healthcare facilities during Hurricane Sandy (Redlener I, Reilly M, Lessons from Sandy—Preparing Health Systems for Future Disasters. N ENGL J MED. 367;24:2269–2271.) Thus, as previously stated, at § 482.15(b)(1)(ii) we also propose that the hospital have policies and procedures that address the provision of alternate sources of energy to maintain: (1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; (2) emergency lighting; (3) fire detection, extinguishing, and alarm systems. We are also proposing at § 482.15(b)(1)(ii)(D) that the hospital develop policies and procedures to address provision of sewage and waste disposal. We are proposing to define the term "waste" as including all wastes including solid waste, recyclables, chemical, biomedical waste and wastewater, including sewage. These proposed requirements concern assuring the continuity of the power source for the fire detection, extinguishing and alarm systems and are an essential prerequisite for successful implementation of existing requirements during emergencies that result in loss of regular power. These proposed requirements are more in line with best practice rather than mere sufficiency.

We are proposing at § 482.15(b)(2) that the hospital develop policies and procedures regarding a system to track the location of staff and patients in the hospital's care both during and after an emergency. We believe it is imperative that the hospital be able to track a patient's whereabouts, to ensure adequate sharing of patient information with other providers and to inform a patient's relatives and friends of the patient's location within the hospital, whether the patient has been transferred to another facility, or what is planned in respect to such actions. Therefore, we believe that hospitals must develop a means to track patients, which would include evacuees in the hospital's care during and after an emergency event. ASPR has developed tools, programs and resources to facilitate disaster preparedness planning at the local healthcare facility-level. One of these tools, The Joint Patient Assessment and Tracking System (JPATS), was developed through an interagency association between HHS/ASPR and DoD, and is available for providers at: *https://asprwebapps.hhs.gov/jpats/protected/home.do*.

Use of the JPATS is referenced in Health Preparedness Capabilities: National Guidance for Health System Preparedness (2012). This document provides guidance for healthcare systems, healthcare coalitions and healthcare organizations emergency preparedness efforts that is intended to serve as a planning resource. Broad guidance as to the requirement for bed and patient tracking is included.

Given the lessons learned, this requirement is being proposed for providers and suppliers who provide ongoing care to inpatients or outpatients. Such providers and suppliers would include RNHCIs, hospices, PRTFs, PACE organizations, LTC facilities, ICFs/IID, HHAs, CAHs, and ESRD facilities. Despite providing services on an outpatient basis, we would require hospices, HHAs, and ESRD facilities to assume this responsibility. These providers and suppliers maintain current patient census information and would be required to provide continuing patient care during the emergency. In addition, we would require ASCs to maintain responsibility for their staff and patients if patients were in the facility. Other outpatient providers, such as CORFs, FQHCs and clinics maintain patient information but they have the flexibility of cancelling appointments during an emergency thereby not needing to assume responsibility of the patients.

This requirement is not being proposed for transplant centers; CORFs; OPOs; clinics, rehabilitation agencies as providers of outpatient physical therapy and speech-language pathology services; and RHCs/FQHCs. Transplant centers' patients and OPOs' potential donors would be in hospitals, and, thus, would be the hospital's responsibility. We believe it is likely that outpatient providers and suppliers would close their facilities prior to or immediately after an emergency, sending staff and patients home.

We are not proposing a requirement for a specific type of tracking system. A hospital would have the flexibility to determine how best to track patients and staff, whether it used an electronic

database, hard copy documentation, or some other method. However, it is important that the information be readily available, accurate, and shareable among officials within and across the emergency response system as needed in the interest of the patient. A number of states already have such tracking systems in place or under development and the systems are available for use by health care providers and suppliers. Lessons learned from the hurricanes in the Gulf States revealed that some facilities, despite having patient-related information backed up to computer databases within or outside of the state in which the disaster occurred, could not access the information in a timely manner. Therefore, we would recommend that a hospital using an electronic database consider backing up its computer system with a secondary source.

Although we believe that it is important that a hospital, and other providers of critical care, be able to track a patient's whereabouts to ensure adequate sharing of patient information with other providers and to inform a patient's relatives of the patient's location after a disaster, we are specifically soliciting comments on the feasibility of this requirement for any outpatient facilities.

We propose at § 482.15(b)(3) that hospitals have policies and procedures in place to ensure the safe evacuation from the hospital, which would include standards addressing consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

We propose at § 482.15(b)(4) that a hospital must have policies and procedures to address a means to shelter in place for patients, staff, and volunteers who remain in the facility. We expect that hospitals would include in their policies and procedures both the criteria for selecting patients and staff that would be sheltered in place and a description of the means that they would use to ensure their safety.

During the Gulf Coast hurricanes, some hospitals were able to shelter their patients and staff in place. However, the physical structures of many other hospitals were so damaged that sheltering in place was impossible. Thus, when developing policies and procedures for sheltering in place, hospitals should consider the ability of their building(s) to survive a disaster and what proactive steps they could take prior to an emergency to facilitate sheltering in place or transferring of patients to alternate settings if their facilities were affected by the emergency.

We propose at § 482.15(b)(5) that a hospital have policies and procedures that would require a system of medical documentation that would preserve patient information, protect the confidentiality of patient information, and ensure that patient records were secure and readily available during an emergency. In addition to the current hospital requirements for medical records located at § 482.24(b), we are proposing that hospitals be required to ensure that patient records are secure and readily available during an emergency.

Such policies and procedures would have to be in compliance with Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Regulations at 45 CFR parts 160 and 164, which protect the privacy and security of individual's personal health information. Information on how HIPAA requirements can be met for purposes of emergency preparedness and response can be found at: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/index.html*. The tornadoes that occurred in Joplin, Missouri in 2011, presented an example of the value of electronic health records during a disaster. There were primary care clinics and other providers that had electronic health records and because their records were not destroyed, they were able to find new locations, contact their patients and re-establish operations very quickly.

We propose at § 482.15(b)(6) that facilities would have to have policies and procedures in place to address the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency.

Facilities may find it helpful to utilize assistance from the Medical Reserve Corps (MRC), a national network of community-based volunteer units that focus on improving the health, safety and resiliency of their local communities. MRC units organize and utilize public health, medical and other volunteers to support existing local agencies with public health activities throughout the year and with preparedness and response activities for times of need. One goal of the MRC is to ensure that members are identified, screened, trained and prepared prior to their participation in any activity. While MRC units are principally focused on their local communities, they have the potential to provide assistance in a statewide or national disaster as well.

Hospitals could use the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR–VHP), found in section 107 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), to verify the credentials of volunteer health care workers. The ESAR–VHP is a federal program to establish and implement guidelines and standards for the registration, credentialing, and deployment of medical professionals in the event of a large-scale national emergency. The program is administered by ASPR within the Department. All states must participate in ESAR–VHP.

The purpose of the program is to facilitate the use of volunteers at all tiers of response (local, regional, state, interstate, and federal). The ESAR–VHP program has been working to establish a national network of state-based programs that manage the information needed to effectively use health professional volunteers in an emergency. These state-based systems will provide up-to-date information regarding the volunteer's identity and credentials to hospitals and other health care facilities in need of the volunteer's services. Each state's ESAR–VHP system is built to standards that will allow quick and easy exchange of health professionals with other states. We propose at § 482.15(b)(7) that hospitals would have to have a process for the development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations at their facilities, to ensure the continuity of services to hospital patients.

We believe this requirement should apply only to providers and suppliers that provide continuous care and services for individual patients. Thus, we are not proposing this requirement for transplant centers; CORFs; OPOs; clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services; and RHCs/FQHCs.

We also propose at § 482.15(b)(8) that hospital policies and procedures would have to address the role of the hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Act, for the provision of care and treatment at an alternate care site (ACS) identified by emergency management officials. We propose this requirement for inpatient providers only. We would expect that state or

local emergency management officials might designate such alternate sites, and would plan jointly with local providers on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages providers to collaborate with their local emergency officials in such proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted. Under section 1135 of the Act, the Secretary is authorized to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements for health care providers to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in these programs in an emergency area (or portion of such an area) during any portion of an emergency period. Under an 1135 waiver, health care providers unable to comply with one or more waiver-eligible requirements may be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). Requirements to which an 1135 waiver may apply include Medicare conditions of participation or conditions for coverage and requirements under the Emergency Medical Treatment and Labor Act (EMTALA). The 1135 waiver authority applies only to specific federal requirements and does not apply to any state requirements, including licensure.

In determining whether to invoke an 1135 waiver (once the conditions precedent to the authority's exercise have been met), the ASPR with input from relevant HHS operating divisions (OPDIVs) determines the need and scope for such modifications, considers information such as requests from Governor's offices, feedback from individual healthcare providers and associations, and requests from regional or field offices for assistance. Additional information regarding the 1135 waiver process is provided in the CMS Survey and Certification document entitled, "Requesting an 1135 Waiver", and located at: *http://www.cms.gov/About-CMS/Agency-Information/H1N1/downloads/requestingawaiver101.pdf.*

Providers must resume compliance with normal rules and regulations as soon as they are able to do so. Waivers or modifications permitted under an 1135 waiver are no longer available after the termination of the emergency period. Generally, federally certified or approved providers must operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

When a waiver has been issued under section 1135(b)(3) of the Act, EMTALA sanctions do not apply to a hospital with a dedicated emergency department, providing the conditions at § 489.24(a)(2)(i) are met. The EMTALA part of the 1135 waiver only applies for a 72-hour period, unless the emergency involves a pandemic infectious disease situation (see 42 CFR 489.24(a)(2)(ii)). Further information on the 1135 waiver process can be found at: *http://www.cms.hhs.gov/H1N1/.*

Once an 1135 waiver is authorized, health care providers and suppliers can submit requests to operate under that authority to the CMS Regional Office, with a copy to the State Survey Agency. The Regional Office or State Survey Agency may also be able to help providers and suppliers identify other relief that may be possible and which does not require an 1135 waiver.

This proposed requirement would be consistent with the ASPR's expectation that hospital grant awardees will continue to develop and improve their (ACS) plans and concept of operations for providing supplemental surge capacity within the health care system in their state. Further discussion of ASPR's expectation for ACSs can be found in the annual grant guidance on the web at: *http://www.phe.gov/Preparedness/planning/hpp/Pages/funding.aspx.*

With respect to states, ASPR stresses that effective planning and implementation would depend on close collaboration among state and local health departments (for example, state public health agencies, state Medicaid agencies, and state survey agencies), provider associations, community partners, and neighboring and regional health-care facilities. ASPR recommends that using existing buildings and infrastructure as ACSs would be the most practical solution if a surge medical care facility were needed. When identifying sites, states should consider how ACSs will interface with other state and federal assets. Federal assets may require what ASPR describes as an "environment of opportunity" for set up and operation and might not be available for as long as 72 hours. Therefore, ASPR believes it is critical that healthcare facilities, public health systems and emergency management agencies work with other emergency response partners when choosing a facility to use as an ACS. Many of the partners (for example, the American Red Cross) may have already identified sites that would be used during an event.

While our discussion is geared toward the state level response, we expect that hospitals would operationalize these efforts by working closely with the federal, state, tribal, regional, and local communities. According to AHRQ's "Providing Mass Medical Care with Scarce Resources: A Community Planning Guide," the impact of an MCE of any significant magnitude will likely overwhelm hospitals and other traditional venues for health care services. AHRQ believes an MCE may render such venues inoperable, necessitating the establishment of ACSs for the provision of care that normally would be provided in an inpatient facility. According to AHRQ, advance planning is critical to the establishment and operation of ACSs; this planning must be coordinated with existing health care facilities, as well as home care entities. Planners must delineate the specific medical functions and treatment objectives of the ACS. Finally, AHRQ asserts that the principle of managing patients under relatively austere conditions, with limited supplies, equipment, and access to pharmaceuticals and a minimal staffing arrangement, is the starting point for ACS planning.

Further discussion of the issues and challenges of establishing and operating ACSs during an MCE, as well as specific case study examples of ACSs in operation during the response to Hurricane Katrina, can be found in Chapter VI of the AHRQ publication. The chapter discusses issues surrounding non-federal, non-hospital-based ACSs. It describes different types of ACSs, including critical issues and decisions that will need to be made regarding these sites during an MCE; addresses potential barriers; and includes examples of case studies.

Subsequently, on October 1, 2009, AHRQ released two Disaster Alternate Care Facility Selection Tools, entitled the "Disaster Alternate Care Facility Selection Tool" and the "Alternate Care Facility Patient Selection Tool to help emergency planners and responders select and run alternate care facilities during disaster situations. These two tools can be found at: *http://archive.ahrq.gov/prep/acfselection/pselectmatrix/(S(fidfow2u5az1o155srb0h1nb))/default.aspx* and at: *http://archive.ahrq.gov/prep/acfselection/acftool/(S(o53i55e3v452tl550uxvm055))/default.aspx.* Under contract to AHRQ, Denver Health developed these new tools for AHRQ as an update to a previous alternate care site selection tool, entitled the Rocky Mountain

Regional Care Model for Bioterrorist Events, which it developed in 2004 and can be found at: *http://archive.ahrq.gov/research/altsites.htm#down*. AHRQ led development of the tools with funding from the ASPR National Hospital Preparedness Program (HPP), formerly the HRSA Bioterrorism Hospital Preparedness Program.

3. Communication Plan

For a hospital to operate effectively in an emergency situation, we propose at § 482.15(c) that the hospital be required to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. The hospital would be required to review and update the communication plan at least annually.

As part of its communication plan, the hospital would be required at § 482.15(c)(1) to include in its plan, names and contact information for staff; entities providing services under arrangement; patients' physicians; other hospitals; and volunteers. During an emergency, it is critical that hospitals have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the hospital and to ensure that these functions are carried out in a safe and effective manner. We propose at § 482.15(c)(2) requiring hospitals to have contact information for federal, state, tribal, regional, or local emergency preparedness staff and other sources of assistance. Patient care must be well-coordinated within the hospital, across health care providers, and with state and local public health departments and emergency systems to protect patient health and safety in the event of a disaster. Again, we support hospitals and other providers engaging in coalitions in their area for assistance in effectively meeting this requirement.

We propose to require at § 482.15(c)(3) that hospitals have primary and alternate means for communicating with the hospital's staff and federal, state, tribal, regional, or local emergency management agencies, because in an emergency, a hospital's landline telephone system may not be operable. While we do not propose specifying the type of alternate communication system that hospitals must have, we would expect that facilities would consider pagers, cellular telephones, radio transceivers (that is, walkie-talkies), and various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (HAM Radio) systems, as well as satellite telephone communications systems. In areas where available, satellite telephone communication systems may be useful as well.

We recognize that some hospitals, especially in remote areas, have difficulty using some current communication systems, such as cellular phones, even in non-emergency situations. We would expect these hospitals to address such challenges when establishing and maintaining a well-designed communication system that will function during an emergency.

The National Communication System (NCS) offers a wide range of National Security and Emergency Preparedness (NS–EP) communications services that support qualifying federal, state, local, and tribal governments, industry, and non-profit organizations in the performance of their missions during emergencies. Hospitals may seek further information on the NCS' programs for Government Emergency Telecommunications Services (GETS), Telecommunications Service Priority (TSP) Program, Wireless Priority Service (WPS), and Shared Resources (SHARES) High Frequency Radio Program at: *www.ncs.gov*. (Click on "services").

Under this proposed rule, we would also require at § 482.15(c)(4) that hospitals have a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to ensure continuity of care. Sharing of patient information and documentation was found to be a significant problem during the 2005 hurricanes and flooding in the Gulf Coast States. In some hospitals, patient care information in hard copy and electronic format was destroyed by flooding while, in others, patient information that was backed up to alternate sites was not always readily available. As a result, some patients were discharged or evacuated from facilities without adequate accompanying medical documentation of their conditions for other providers and suppliers to utilize. Other patients who sheltered in place were also left without proper medical documentation of their care while in the hospital.

We would expect hospitals to have a system of communication that would ensure that comprehensive patient care information would be disseminated across providers and suppliers in a timely manner, as needed. Such a system would ensure that information was sent with an evacuated patient to the next care provider or supplier, information would be readily available for patients being sheltered in place, and electronic information would be backed up both within and outside the geographic area where the hospital was located.

Health care providers, who were in attendance during the Emergency Preparedness Summit in New Orleans, Louisiana in March 2007, discussed the possibility of storing patient care information on flash drives, thumb devices, compact discs, or other portable devices that a patient could carry on his or her person for ready accessibility. We would expect hospitals to consider the range of options that are available to them, but we are not proposing that certain specific devices would be required because of the associated burden and the potential obsolescence of such devices.

We propose at § 482.15(c)(5) that hospitals have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 of the HIPAA Privacy Regulations. Thus, hospitals would need to have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted, to family members and others. Section 164.510 "Uses and disclosures requiring an opportunity for the individual to agree to or to object," is part of the "Standards for Privacy of Individually Identifiable Health Information," commonly known as "The Privacy Rule."

This proposed requirement would not be applied to transplant centers; CORFs; OPOs; clinics rehabilitation agencies and public health agencies as providers of outpatient physical therapy and speech-language pathology services; or RHCs/FQHCs. We believe this requirement would best be applied only to providers and suppliers who provide continuous care to patients, as well as to those providers and suppliers that have responsibilities and oversight for care of patients who are homebound or receiving services at home.

We propose at § 482.15(c)(6) requiring hospitals to have a means of providing information about the general condition and location of patients under the facility's care, as permitted under 45 CFR 164.510(b)(4) of the HIPAA Privacy Regulations. Section 164.510(b)(4), "Use and disclosures for disaster relief purposes," establishes requirements for disclosing patient information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts for purposes of notifying family members, personal representatives, or certain others of the patient's location or general condition. We are not proposing prescriptive requirements for how a hospital would comply with this requirement. Instead, we would allow hospitals the flexibility

to develop and maintain their own system.

We propose at § 482.15(c)(7) that a hospital have a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. We support hospitals and other providers engaging in coalitions in their area for assistance in effectively meeting this requirement.

4. Training and Testing

We propose at § 482.15(d) that a hospital develop and maintain an emergency preparedness training and testing program. We would require the hospital to review and update the training and testing program at least annually.

We believe a well organized, effective training program must include providing initial training in emergency preparedness policies and procedures. Therefore, we propose at § 482.15(d)(1) that hospitals provide such training to all new and existing staff, including any individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of such training. We propose that the hospital ensure that staff can demonstrate knowledge of emergency procedures, and that the hospital provides this training at least annually.

While some large hospitals may have staff that could provide such training, smaller and rural hospitals may need to find resources outside of the hospital to provide such training. Many state and local governments can provide emergency preparedness training upon request. Thus, small hospitals and rural hospitals may find it helpful to utilize the resources of their state and local governments in meeting this requirement. Again, we support hospitals and other providers participating in coalitions in their area for assistance in effectively meeting this requirement. Conducting exercises at the healthcare coalition level could help to reduce the administrative burden on individual healthcare facilities and demonstrate the value of connecting into the broader medical response community during disaster planning and response. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities. Regional planning coalitions (multistate coalitions) meet and provide exercises on a regular basis to test protocols for state-to-state mutual aid. The members of the coalitions are often able to test command and control procedures and processes for sharing of assets that promote medical surge capacity.

Regarding testing, at § 482.15(d)(2), we would require hospitals to conduct drills and exercises to test the emergency plan. We propose at § 482.15(d)(2)(i) requiring hospitals to participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, we would require the hospital to conduct an individual, facility-based mock disaster drill at least annually. However, we propose at § 482.15(d)(2)(ii) that if a hospital experienced an actual natural or man-made emergency that required activation of the emergency plan, the hospital would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the actual event.

We propose at § 482.15(d)(2)(iii) requiring a hospital to conduct a paper-based, tabletop exercise at least annually. The tabletop exercise could be based on the same or a different disaster scenario from the scenario used in the mock disaster drill or the actual emergency. In the proposed regulations text, we would define a tabletop exercise as a "group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan."

Comprehensive emergency preparedness includes anticipating and adequately addressing the various natural and man-made disasters that could impact a given facility. We expect that hospitals would conduct both mock disaster drills and tabletop exercises, using various emergency scenarios, based on their risk analyses.

Generally, in a mock disaster drill, a hospital must consider how it will move persons within and outside of the building to designated "safe zones" to ensure the safety of both ambulatory patients and those who are wheelchair users, have mobility impairments or have other special needs. Moving patients or mock patients to "safe zones" in and outside of buildings during fire drills and other mock disaster drills is common industry practice. However, if it is not feasible to evacuate patients, hospitals could meet this requirement by moving its special needs patients to "safe zones" such as a foyer or other areas as designated by the hospital. To assist hospitals, other providers, and suppliers in conducting table-top exercises, we sought additional resources to further define the actions involved in a paper-based, tabletop exercise. One hospital system representative described a tabletop exercise as one where the staff conducts, on paper, a simulated public health emergency that would impact the hospital and surrounding health care facilities. For this hospital, the tabletop exercise is a half-day event for representatives of every critical response area in the hospital. It is designed to test the effectiveness of the response plan in guiding the leadership team's efforts to coordinate the response to an emergency event.

The hospital representative further explained that the exercise consists of a group discussion led by a facilitator, using a narrated, clinically-relevant scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. Exercise facilitators introduce the scenario, keep the exercise on schedule, and inject timed challenges to stress specific disaster response systems. Following the tabletop exercise, a debriefing for hospital staff is held, and then the hospital staff provides written feedback and planning improvement suggestions to the hospital administration.

Some hospitals may be well-versed in performing mock drills and tabletop exercises. Other providers and suppliers, especially those that are small or remote, may not have any knowledge or hands-on experience in conducting such exercises. To this end, the Bureau of Communicable Disease in the New York City Department of Health and Mental Hygiene has produced a very detailed document entitled, "Bioevent Tabletop Exercise Toolkit for Hospitals and Primary Care Centers," (September 2005, found at: *http://www.nyc.gov/html/doh/downloads/pdf/bhpp/bhpp-train-hospital-toolkit-01.pdf*), which may help hospitals and other providers and suppliers that have limited or no emergency preparedness training experience. This document is designed to walk a facility through the process of performing a tabletop exercise and after-event analysis. The toolkit consists of things to consider before engaging in a tabletop exercise, the process of planning the exercise, running the exercise, evaluating the exercise and its impact, and public health emergency scenarios for tabletop exercises, including the plague, Sever Acute Respiratory Syndrome (SARS), anthrax, smallpox, and pandemic flu.

There are also other training resources that may prove useful for hospitals and other providers and suppliers to comply with as they attempt to meet this proposed emergency preparedness

requirement. In 2005, the RAND Corporation produced a technical report for ASPR entitled, "Bioterrorism Preparedness Training and Assessment Exercises for Local Public Health Agencies," by Dausey, D. J., Lurie, N., Alexis, D., Meade, B., Molander, R. C., Ricci, K. A., Stoto, M. A., and Wasserman, J. (*http://www.rand.org/pubs/technical_reports/2005/RAND_TR261.pdf*).

The report was intended as a resource to train public health workers to detect and respond to bioterrorism events and to assess local public health agencies' (LPHAs) levels of preparedness over time. The exercises were beta tested and refined in 13 LPHAs across the United States over 10 months. However, the report would be a useful resource for hospitals and other healthcare facilities to train their own healthcare workers.

RAND also developed a 2006 technical report entitled, "Tabletop Exercise for Pandemic Influenza Preparedness in Local Public Health Agencies," by Dausey, D.J., Aledort, J. E., and Lurie, N. (*http://www.rand.org/pubs/technical_reports/2006/RAND_TR319.pdf*). The report was designed to provide state and local public health agencies and their healthcare and governmental partners with exercises in training, building relationships, and evaluation. These exercises were pilot-tested at three metropolitan-area local public health agencies in three separate states from August through November 2005.

Finally, the Centers for Medicare & Medicaid Services (CMS), Survey and Certification Group has developed a document entitled, the Health Care Provider After Action Report/Improvement Plan (AAR/IP) template with the assistance of the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response, the U.S. Department of Homeland Security (DHS), and the CMS Survey and Certification Emergency Preparedness Stakeholder Communication Forum. The template can be accessed at *http://www.cms.gov/SurveyCertEmergPrep/03_HealthCareProviderGuidance.asp* and then scrolling down to click on the download entitled, the "Health Care Provider Voluntary After Action Report/Improvement Plan Template and Instructions for Completion." The AAR/IP was intended to be a voluntary, user-friendly tool for health care providers to use to document their performance during emergency planning exercises and real emergency events to make recommendations for improvements for future performance. We do not mandate use of this AAR/IP template; however thorough completion of the template complies with our requirements for provider exercise documentation.

The "Health Care Provider After Action Report/Improvement Plan" template also meets requirements for hospitals or other health care providers wishing to ensure their compliance with the Hospital Preparedness Program (HPP).

This AAR/IP template is based on the U.S. Department of Homeland and Security Exercise and Evaluation Program (HSEEP) Vol. III, issued in February 2007, which includes guidelines that are focused towards emergency management agencies and other governmental/non-governmental agencies. The HSEEP is a capabilities and performance-based exercise program that provides a standardized methodology and terminology for exercise design, development, conduct, evaluation, and improvement planning. Health care providers may also use the AAR/IP to document real life emergency events and can customize or personalize the CMS "Health Care Provider AAR/IP" template to best meet their needs.

There are seven types of exercises defined within HSEEP, each of which is either discussions-based or operations-based.

Discussions-based exercises familiarize participants with current plans, policies, agreements and procedures, or may be used to develop new plans, policies, agreements, and procedures.

Types of discussion-based exercises include the following:

- Seminar: A seminar is an informal discussion, designed to orient participants to new or updated plans, policies, or procedures (for example, a seminar to review a new Evacuation Standard Operating Procedure).
- Workshop: A workshop resembles a seminar, but is employed to build specific products, such as a draft plan or policy (for example, a Training and Exercise Plan Workshop is used to develop a Multiyear Training and Exercise Plan).
- Tabletop Exercise (TTX): A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures.
- Games: A game is a simulation of operations that often involves two or more teams, usually in a competitive environment, using rules, data, and procedure designed to depict an actual or assumed real-life situation.

Operations-based exercises validate plans, policies, agreements and procedures, clarify roles and responsibilities, and identify resource gaps in an operational environment. Types of operations-based exercises include the following:

- Drill: A drill is a coordinated, supervised activity usually employed to test a single, specific operation or function within a single entity (for example, a nursing home conducts an evacuation drill).
- Functional exercise (FE): A functional exercise examines or validates the coordination, command, and control between various multi-agency coordination centers (for example, emergency operation center, joint field office, etc.). A functional exercise does not involve any "boots on the ground" (that is, first responders or emergency officials responding to an incident in real time).
- Full-Scale Exercise (FSE): A full-scale exercise is a multi-agency, multi-jurisdictional, multi-discipline exercise involving functional (for example, joint field office, emergency operation centers, etc.) and "boots on the ground" response (for example, firefighters decontaminating mock victims). We expect hospitals to engage in such tabletop exercises to the extent possible in their communities. For example, we would expect a large hospital in a major metropolitan area to perform a comprehensive exercise with coordination, if possible, across the public health system and local geographic area.

We propose at § 482.15(d)(2)(iv) that hospitals analyze their response to and maintain documentation on all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan as needed. Resources discussed previously can be used to guide hospitals in this process.

Finally, we propose at § 482.15(e)(1)(i) that hospitals must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). We intend to require compliance with future LSC updates as may be adopted by CMS. The current LSC states that the hospital's alternate source of power (for example, generator) and all connected distribution systems and ancillary equipment, must be designed to ensure continuity of electrical power to designated areas and functions of a health care facility. Also, the LSC (NFPA 110) states that the rooms, shelters, or separate buildings housing the emergency power supply shall be located to minimize the possible damage resulting from disasters such as storms, floods, earthquakes, tornadoes,

hurricanes, vandalism, sabotage and other material and equipment failures.

In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that hospitals test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the hospital anticipates it will require during an emergency. As a result of lessons learned from hurricane Sandy, we believe that this annual 4 hour test will more closely reflect the actual conditions that would be experienced during a disaster of the magnitude of hurricane Sandy.

We have also proposed the same emergency and standby power requirements for CAHs and LTC facilities. As such, we request information on this proposal and in particular on how we might better estimate costs in light of the existing LSC and other state and federal requirements.

We have included a table of requirements based on the 5 standards in the regulation text for each of the 17 providers and suppliers. The table includes both additional requirements and exemptions. This table can be used to provide guidance to the facilities in planning their emergency preparedness program and disaster planning.

TABLE 1—EMERGENCY PREPAREDNESS REQUIREMENTS BY PROVIDER TYPE

Provider type	Emergency plan	Policies and procedures	Communication plan	Training and testing	Additional requirements
Inpatient Providers					
Hospital	*Develop a plan based on a risk assessment using an "all hazards" approach, which is an integrated approach focusing on capacities and capabilities critical to preparedness for a full spectrum of emergencies and disasters. The plan must be updated annually.	*Develop and implement policies and procedures based on the emergency plan and risk assessment, which must be reviewed and updated at least annually.	*Develop and maintain an emergency preparedness communication plan that complies with both federal and state law. Patient care must be well-coordinated within the facility, across health care providers and with state and local public health departments and emergency systems.	*Develop and maintain training and testing programs, including initial training in policies and procedures and demonstrate knowledge of emergency procedures and provide training at least annually. Conduct drills and exercises to test the emergency plan.	Generators—Develop policies and procedures that address the provision of alternate sources of energy to maintain: (1) temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; (2) emergency lighting; (3) fire detection, extinguishing, and alarm systems.
Critical Access Hospital.	*	*	*	*	Generators.
Long Term Care Facility.	Must account for missing residents (existing requirement).	*	Share with resident/family/representative appropriate information from emergency plan (additional requirement).	*	Generators.
PRTF	*	*	*	*	
ICF/IID	Must account for missing clients (existing requirement).	*	Share with client/family/representative appropriate information from emergency plan (additional requirement).	*	
RNHCI	*	*	*	No drills.	
Transplant Center	*	*	*	*	Maintain agreement with transplant center & OPO.
Outpatient Providers—Outpatient providers are not required to provide subsistence needs for staff and patients.					
Hospice	*	In home services—inform officials of patients in need of evacuation (additional requirement).	In home services—will not need to provide occupancy information.	*	
Ambulatory Surgical Center.	*	*	Will not need to provide occupancy information.	*	
PACE	*	Inform officials of patients in need of evacuation (additional requirement).	Will not need to provide occupancy information.	*	

TABLE 1—EMERGENCY PREPAREDNESS REQUIREMENTS BY PROVIDER TYPE—Continued

Provider type	Emergency plan	Policies and procedures	Communication plan	Training and testing	Additional requirements
Home Health Agency	*	Will not require shelter in place, provision of care at alternate care sites. Inform officials of patients in need of evacuation (additional requirement).	Will not need to provide occupancy information.	*	
CORF	Must develop emergency plan with assistance from fire, safety experts (existing requirement).	Will not need to provide transportation to evacuation locations, or have arrangements with other CORFs to receive patients.	Will not need to provide occupancy information.	Assign specific emergency preparedness tasks to new personnel. Provide instruction in location, use of alarm systems, signals & firefighting equip (existing requirements).	
CMHC	*	*	*	*	
OPO	Address type of hospitals OPO has agreement (additional requirement).	Needs to have system to track staff during & after emergency and maintain medical documentation (additional requirement).	Does not need to provide occupancy info, method of sharing pt. info, providing info on general condition & location of patients.	Only tabletop exercise.	Must maintain agreement with other OPOs & hospitals.
Clinics, Rehabilitation, and Therapy.	Must develop emergency plan with assistance from fire, safety experts. Address location, use of alarm systems and signals & methods of containing fire (existing requirements).	*	Does not need to provide occupancy information.	*	
RHC/FQHC	*	Appropriate placement of exit signs (existing requirement). Does not have to track patients, or have arrangements with other RHCs to receive patients or have alternate care sites.	Does not need to provide occupancy information.	*	

TABLE 1—EMERGENCY PREPAREDNESS REQUIREMENTS BY PROVIDER TYPE—Continued

Provider type	Emergency plan	Policies and procedures	Communication plan	Training and testing	Additional requirements
ESRD	Must contact local emergency preparedness agency annually to ensure dialysis facility's needs in an emergency (existing requirement).	Policies and procedures must include emergencies regarding fire equipment, power failures, care related emergencies, water supply interruption & natural disasters (existing requirement).	Does not need to provide occupancy information.	Ensure staff demonstrate knowledge of emergency procedures, informing patients what to do, where to go, whom to contact if emergency occurs while patient is not in facility (alternate emergency phone number), how to disconnect themselves from dialysis machine. Staff maintain current CPR certification, nursing staff trained in use of emergency equipment & emergency drugs, patient orientation (existing requirements).	

* Indicates that the requirements are the same as those proposed for hospitals.

B. Emergency Preparedness Regulations for Religious Nonmedical Health Care Institutions (RNHCIs) (§ 403.748)

Section 1861(ss)(1) of the Act defines the term "Religious Nonmedical Health Care Institution" (RNHCI) and lists the requirements that a RNHCI must meet to be eligible for Medicare participation.

We have implemented these provisions in 42 CFR part 403, Subpart G, "Religious Nonmedical Health Care Institutions' Benefits, Conditions of Participation, and Payment." As of March 2012, there were 16 Medicare-certified RNHCIs that were subject to the RNHCI regulations and were receiving payment for services provided to Medicare or Medicaid patients.

A RNHCI is a facility that is operated under all applicable federal, state, and local laws and regulations, which furnishes only non-medical items and services on a 24-hour basis to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs. The religious non-medical care or religious method of healing means care provided under the established religious tenets that prohibit conventional or unconventional medical care for the treatment of the patient and exclusive reliance on the religious activity to fulfill a patient's total health care needs.

Thus, Medicare would cover the nonmedical, non-religious health care items and services in a RNHCI for beneficiaries who would qualify for hospital or skilled nursing facility care but for whom medical care is inconsistent with their religious beliefs. Medicare does not cover the religious aspects of care. Nonmedical items and services are furnished to inpatients exclusively through nonmedical nursing personnel. Such Medicare coverage would include both nonmedical items that do not require a doctor's order or prescription (such as wound dressings or use of a simple walker during a stay) and non-religious health care items and services (such as room and board).

The RNHCI does not furnish medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs or biologicals) to its patients. RNHCIs must not be owned by or under common ownership or affiliated with a provider of medical treatment or services.

This proposed rule would expand the current emergency preparedness requirements for RNHCIs, which are located within § 403.742, Condition of participation: Physical Environment, by requiring RNHCIs to meet the same proposed emergency preparedness requirements as we propose for hospitals, with several exceptions.

Our "Physical environment" CoP at § 403.742(a)(1) currently requires that the RNHCI provide emergency power for emergency lights, for fire detection and alarm systems, and for fire extinguishing systems. Section 403.742(a)(4) requires that the RNHCI have a written disaster plan that addresses loss of water, sewage, power and other emergencies. Section 403.742(a)(5) requires that a RNHCI have facilities for emergency gas and water supply. We propose relocating the pertinent portions of the existing requirements at § 403.742(a)(1), (4), and (5) at proposed § 403.748(a) and § 403.748(b)(1). However, we believe these current requirements do not provide a sufficient framework for ensuring the health and safety of a RNHCI's patients in the event of a natural or man-made disaster.

Proposed § 403.748(a)(1) would require RNHCIs to consider loss of power, water, sewage and waste disposal in their risk analysis. The proposed policies and procedures at § 403.748(b)(1) would require that RNHCIs provide for subsistence needs for staff and patients, whether they evacuate or shelter in place, including, but not limited to, food, water, sewage and waste disposal, non-medical supplies, alternate sources of energy for the provision of electrical power, the maintenance of temperatures to protect patient health and safety and for the safe and sanitary storage of such provisions, gas, emergency lights, and fire detection, extinguishing, and alarm systems.

The proposed hospital requirement at § 482.15(a)(1) would be modified for RNHCIs. At proposed § 403.748(a)(1),

unlike for other providers and suppliers whom we propose to have a community risk assessment that is based upon an all-hazards approach, including the loss of power, water, sewage and waste disposal. However, at proposed § 403.748(b)(1)(i) for RNHCIs, we have removed the terms "medical and nonmedical" to reflect typical RNHCI practice. RNHCIs do not provide most medical supplies. At § 482.15(b)(3), we would require hospitals to have policies and procedures for the safe evacuation from the hospital, which would include consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. However, at § 403.748(b)(3), we propose to incorporate the hospital requirement but to remove the words "and treatment" from the hospital requirement, to more accurately reflect care provided in a RNHCI.

At proposed § 403.748(b)(5), we would remove the term "health" from the proposed hospital requirement for "health care documentation" to reflect the non-medical care provided by RNHCIs.

The proposed hospital requirements at § 482.15(b)(6) would require hospitals to have policies and procedures to address the use of volunteers in an emergency or other staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency. For RNHCIs, at proposed § 403.748(b)(6), we propose to use the hospital provision, but remove the language, "including the process and role for integration of state or federally designated health care professionals" since it is not within the religious framework of a RNHCI to integrate care issues for their patients with health care professionals outside of the RNHCI industry.

The proposed hospital requirements at § 482.15(b)(7) would require that hospitals develop arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients. For RNHCIs, at § 403.748(b)(7) we added the term "non-medical" to accommodate the uniqueness of the RNHCI non-medical care.

The proposed hospital requirement at § 482.15(c)(1) would require hospitals to include in their communication plan: names and contact information for: staff; entities providing services under agreement; patients' physicians; other hospitals; and volunteers. For RNHCIs, we propose substituting "next of kin, guardian or custodian" for "patients' physicians" because RNHCI patients do not have physicians.

Finally, unlike proposed regulations for hospitals at § 482.15(c)(4), at proposed § 403.748(c)(4), we propose to require RNHCIs to have a method for sharing information and care documentation for patients under the RNHCIs' care, as necessary, with health care providers to ensure continuity of care, based on the written election statement made by the patient or his or her legal representative. Also, at proposed § 403.748(c)(4), we have removed the term "other" from the requirement for sharing information with "other health care providers" to more accurately reflect the care provided by RNHCIs.

At § 482.15(d)(2), "Testing," we propose that hospitals would conduct drills and exercises to test the emergency plan. Because RNHCIs have such a specific role and provide such a specific service in the community, we believe RNHCIs would not participate in performing such drills. We propose the RNHCI would be required to only conduct a tabletop exercise annually. Likewise, unlike that which we have proposed for hospitals at § 482.15(d)(2)(i), we do not propose that the RNHCI conduct a community mock disaster drill at least annually or to conduct an individual, facility-based mock disaster drill. Although we proposed for hospitals at § 482.15(d)(2)(ii) that if the hospital experienced an actual natural or man-made emergency, the hospital would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event, we are not proposing this requirement for RNHCIs.

At § 482.15(d)(2)(iv), we propose to require hospitals to maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed. Again, at § 403.748(d)(2)(d)(ii), for RNHCIs, we propose to remove reference to drills.

Currently, at existing § 403.724(a), we require that an election form be made by the Medicare beneficiary or his or her legal representative and further requires that the election must be a written statement that the beneficiary: (1) is conscientiously opposed to accepting non-excepted medical treatment; (2) believes that non-excepted medical treatment is inconsistent with his or her sincere religious beliefs; (3) understands that acceptance of non-excepted medical treatment constitutes revocation of the election and possible limitation of receipt of further services in a RNHCI; (4) knows that he/she may revoke the election by submitting a written statement to CMS, and (5) knows that the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs. Thus, at § 403.748(c)(4), we are proposing that election documentation be shared with other care providers to preserve continuity of care.

C. Emergency Preparedness Requirements for Ambulatory Surgical Centers (ASCs) (§ 416.54)

Section 416.2 defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, and in which the expected duration of services would not exceed 24 hours following an admission.

Section 1833(i)(1)(A) of the Act authorizes the Secretary to specify those surgical procedures that can be performed safely in an ASC. The surgical services performed in ASCs generally are scheduled, elective, non-life-threatening procedures that can be safely performed in either a hospital setting (inpatient or outpatient) or in a Medicare-certified ASC.

Patients are examined immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Patients also are evaluated just prior to discharge from the ASC to ensure proper anesthesia recovery.

Currently, there are 5,354 Medicare certified ASCs in the U.S. The ASC Conditions for Coverage (CfCs) at 42 CFR part 416, Subpart C are the minimum health and safety standards a facility must meet to obtain Medicare certification. The existing ASC CfCs do not contain requirements that address emergency situations. However, existing § 416.41(c), which was adopted in November 2008, requires ASCs to have a disaster preparedness plan. This existing requirement states the ASC must—(1) have a written disaster plan that provides for the emergency care of its patients, staff and others in the facility; (2) coordinate the plan with state and local authorities; and (3) conduct drills, annually and complete a written evaluation of each drill, promptly implementing any correction to the plan. Since these proposed requirements are similar to and would be redundant with existing rules, we propose to remove existing § 416.41(c). Existing § 416.41(c)(1) would be incorporated into proposed § 416.54(a),

(a)(1), (a)(2), and (a)(4). Existing § 416.41(c)(2) would be incorporated into proposed § 416.54(a)(4) and (c)(2). Existing § 416.41(c)(3) would be incorporated into proposed § 416.54(d)(2)(i) and § 416.54(d)(2)(iv).

This proposed regulation would require the ASC to meet most of the same proposed emergency preparedness requirements as those we propose for hospitals, with two exceptions. At § 416.54(c)(7), we propose that ASCs would be required to have policies and procedures that include a means of providing information about the ASCs' needs and its ability to provide assistance (such as physical space and medical supplies) to the authority having jurisdiction (local, state agencies) or the Incident Command Center, or designee. However, we are not proposing that these facilities provide information regarding their occupancy, as we have proposed for hospitals, since the term "occupancy" usually refers to bed occupancy in an inpatient facility. We are not proposing that these facilities provide for subsistence needs for their patients and staff.

While a large ASC in a metropolitan area may find it relatively easy to perform a risk analysis and develop an emergency plan, policies and procedures, a communications plan, and train staff, we understand a small or rural ASC may find it more challenging to meet our proposed requirements. However, we believe these requirements are important and small or rural ASCs would be able to develop an appropriate emergency preparedness plan and meet our proposed requirements with the assistance of resources in their state and local community guidance.

D. Emergency Preparedness Regulations for Hospices (§ 418.113)

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Public Law 97–248, added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the CoPs that a hospice must meet in order to participate in Medicare and Medicaid. Under section 1861(dd) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of patients under hospice care. To implement this requirement, state survey agencies conduct surveys of hospices to assess their compliance with the CoPs. The CoPs found at part 418, Subparts C and D apply to a hospice, as well as to the services furnished to each patient under hospice care.

Hospice care provides palliative care rather than traditional medical care and curative treatment to terminally ill patients. Palliative care improves the quality of life of patients and their families facing the problems associated with terminal illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues. Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family and by keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life. Hospices use an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of caregivers.

Hospices are unique health care providers because they serve patients and their families in a wide variety of settings. Hospice patients may be served in their place of residence, whether that residence is a private home, a nursing home, an assisted living facility, or even a recreational vehicle, as long as such locations are determined to be the patient's place of residence. Hospice patients may also be served in inpatient facilities operated by the hospice.

As of March 2013, there were 3,773 hospice facilities nationally. Under the existing hospice regulations, hospice inpatient facilities are required to have a written disaster preparedness plan that is periodically rehearsed with hospice employees, with procedures to be followed in the event of an internal or external disaster, and procedures for the care of casualties (patients and staff) arising from such disasters. This requirement, which is limited in scope, is found at § 418.110(c)(1)(ii) under "Standard: Physical environment."

We believe that all hospices, even those without inpatient facilities, should have an emergency plan. Also, we believe that, given the diverse nature of hospice patients and the variety of locations where they receive hospice services, simply having a written plan that is "periodically" rehearsed with staff does not provide sufficient protection for hospice patients and hospice employees.

For hospices, we propose to retain existing regulations at § 418.110(c)(1)(i), which states that a hospice must address real or potential threats to the health and safety of the patients, others, and property. However, we propose incorporating the existing requirements at § 418.110(c)(1)(ii) into proposed § 418.113(a)(2) and proposed § 418.113(d)(1). We would require at § 418.113(a)(2) that the hospice have in effect an emergency preparedness plan for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. In addition, we would require at § 418.113(d)(1) that the hospice must periodically review and rehearse its emergency preparedness plan with hospice employees with special emphasis placed on carrying out the procedures necessary to protect patients and others. Section 418.110(c)(1)(ii) and the designation for clause § 418.110(c)(1)(i) would be removed.

Otherwise, the proposed emergency preparedness requirements for hospice providers are very similar to those for hospitals. However, the average hospice (freestanding, not-for-profit, with far fewer annual admissions, and employees) is very different from an average hospital. Typically, hospice inpatient facilities are small buildings or a single unit in a larger medical complex, such as a hospital or long term care facility. Furthermore, hospice patients, given their terminally ill status, may be equally or more vulnerable in an emergency situation than their hospital counterparts. This may be due to the inherent severity of the hospice patient's illness or to the probability that the hospice patient's caregiver may not have the level of professional expertise, supplies, or equipment as that of the hospital-based clinician surrounding a natural or man-made emergency.

Despite these core differences, we believe the hospital emergency preparedness requirement, with some reorganization and revision, is appropriate for hospice providers. Thus, our discussion will focus on the requirements as they differ from the requirements for hospitals within the context of the hospice setting. Since hospices serve patients in both the community and within various types of facilities, we propose to re-organize the requirements for the hospice provider's policies and procedures differently from the proposed policies and procedures for hospitals. Specifically, we propose to group requirements that apply to all hospice providers at § 418.113(b)(1) through § 418.113(b)(5) followed by requirements at § 418.113(b)(6) that apply only to hospice inpatient care facilities.

Unlike our proposed hospital policies and procedures, we would require all hospices, regardless of whether or not they operate their own inpatient facilities, to have policies and

procedures to inform state and local officials about hospice patients in need of evacuation from their respective residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Rule, as appropriate. This proposed requirement recognizes that many of the frail hospice patients may be unable to evacuate from their homes without assistance during an emergency. This additional proposed requirement recognizes the responsibility of the hospice to support the safety of its patients that reside in the community.

We expect that hospices would be able to identify patients most in need of evacuation assistance (for example, patients residing alone and patients using certain types of durable medical equipment), safe and appropriate evacuation methods, and the appropriate state or local authorities to assist in such evacuations. We believe this requirement is necessary to ensure the safety of vulnerable hospice patients, who are likely not capable of evacuating without assistance.

We note that the proposed requirements for communication at § 418.113(c) are the same as for hospitals, with the exception of proposed § 418.113(c)(7). At § 418.113(c)(7), for hospice facilities, we are proposing to limit to inpatients the proposed requirement that the hospice have policies and procedures that would include a means of providing information about the hospice's occupancy and needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. Since hospice facilities provide care to patients in the home or in an inpatient setting, we are proposing that only inpatient hospice facilities, including those under arrangement, be required to report the hospice facilities' inpatient occupancy. The proposed requirements for patients receiving care in their home would require only that hospices report their needs and ability to provide assistance. The proposed requirements for training and testing at § 418.113(d) are similar to those proposed for hospitals.

E. Emergency Preparedness Regulation for Inpatient Psychiatric Residential Treatment Facilities (PRTFs) (§ 441.184)

Sections 1905(a)(16) and (h) of the Act define the term "Psychiatric Residential Treatment Facility" (PRTF) and list the requirements that a PRTF must meet to be eligible for Medicaid participation. To qualify for Medicaid participation, a PRTF must be certified and comply with conditions of payment and conditions of participation (CoPs), at § 441.150 through § 441.182 and § 483.350 through § 483.376 respectively. As of March 2013, there were 387 PRTFs.

A PRTF provides inpatient psychiatric services for patients under age 21; services must be provided under the direction of a physician. Inpatient psychiatric services must involve active treatment which means implementation of a professionally developed and supervised individual plan of care. The patient's plan of care includes an integrated program of therapies, activities, and experiences designed to meet individual treatment objectives that have been developed by a team of professionals along with the patient, his or her parents, legal guardians, or others into whose care the patient will be released after discharge. The plan must also include post-discharge plans and coordination with community resources to ensure continued services for the patient, his or her family, school, and community.

The current PRTF requirements do not include any requirements for emergency preparedness. We propose requiring that PRTF facilities meet the same requirements we are proposing for hospitals. Because these facilities vary widely in size, we expect their risk analyses, emergency plans, emergency policies and procedures, emergency communication plans, and emergency preparedness training will vary widely as well. Nevertheless, we believe each of these providers/suppliers has the capability to comply fully with the requirements so that the health and safety of its patients are protected in the event of an emergency situation or disaster.

F. Emergency Preparedness Regulations for Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.84)

The Balanced Budget Act (BBA) of 1997 established the Program of All-Inclusive Care for the Elderly (PACE) as a permanent Medicare and Medicaid provider type. Under sections 1894 and 1934 of the Act, a state participating in PACE must have a program agreement with CMS and a PACE organization. Regulations at § 460.2 describe the statutory authority that permits entities to establish and operate PACE programs under section 1894 and 1934 of the Act and § 460.6 defines a PACE organization as an entity that has in effect a PACE program agreement. Sections 1894(a)(3) and 1934(a)(3) of the Act define a "PACE provider." The PACE model of care was adopted from On Lok Senior Health Services, an organization that continues to serve seniors in San Francisco and surrounding areas of California. It is a unique model of managed care service delivery for the frail community-dwelling elderly. The PACE model of care includes the provision of adult day health care and interdisciplinary team care management as core services. Medical, therapeutic, ancillary, and social support services are furnished in the patient's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract.

Generally, a PACE organization provides medical and other support services to patients predominately in a PACE adult day care center. Day center attendance is based on individual needs. The majority of PACE patients go to a PACE adult day health center on a regular basis. On average, a PACE patient attends the day center 3 times a week. As of March 2013, there are 91 PACE programs nationally.

Regulations for PACE organizations at part 460, subparts E through H, set out the minimum health and safety standards a facility must meet in order to obtain Medicare certification. The current CoPs for PACE organizations include some requirements for emergency preparedness. We propose to remove the current PACE organization requirements at § 460.72(c)(1) through (5) and incorporate these existing requirements into proposed § 460.84, Emergency preparedness requirements for Programs of All-Inclusive Care for the Elderly (PACE).

Existing § 460.72(c)(1), Emergency and disaster preparedness procedures, states that the PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the patients, staff, or the public. Existing § 460.72(c)(2) defines emergencies to include, but not be limited to: fire; equipment, water, or power failure; care-related emergencies; and natural disasters likely to occur in the organization's geographic area.

We propose incorporating the language from § 460.72(c)(1) into § 460.84(b). Existing § 460.72(c)(2), which defines the various emergencies, would be incorporated into § 460.84(b) as well. The statement in current § 460.72(c)(2), that "an organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location", would not be added to the proposed rule because we are proposing that PACE organizations utilize an "all

hazards" approach as proposed in § 460.84(a)(1).

Existing § 460.72(c)(3), which states that "a PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and patients to ensure that staff demonstrate a knowledge of emergency procedures, including informing patients what to do, where to go, and whom to contact in case of an emergency," would be incorporated into proposed § 460.84(d)(1). The existing requirements for having available emergency medical equipment, for having staff who know how to use the equipment, and having a documented plan to obtain emergency medical assistance from outside sources in current § 460.72(c)(4) would be relocated to proposed § 460.84(b)(9). Finally, current § 460.72(c)(5), which states that the PACE organization must test the emergency and disaster plan at least annually and evaluate and document its effectiveness would be addressed by proposed § 460.84(d)(2). The current version of § 460.72(c)(1) through (c)(5) would be removed.

We are proposing that PACE organizations would adhere to the same requirements for emergency preparedness as hospitals, with three exceptions.

The first difference between the proposed hospital emergency preparedness requirements and the proposed PACE emergency preparedness requirements is that we are not proposing that PACE organizations provide basic subsistence needs for staff and patients, whether they evacuate or shelter in place, including food, water, and medical supplies; alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; emergency lighting; and fire detection, extinguishing, and alarm systems; and sewage and waste disposal as we are proposing for hospitals at § 482.15(b)(1).

The second difference between the proposed hospital emergency preparedness requirements and the proposed PACE emergency preparedness requirements is that we propose adding at § 460.84(b)(3), a requirement for a PACE organization to have policies and procedures to inform state and local officials about PACE patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric conditions and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Rule, as appropriate. This proposed requirement recognizes that many of the frail PACE patients may be unable to evacuate from their homes without assistance during an emergency.

Finally, the third difference between the proposed requirements for hospitals and the proposed requirements for PACE organizations is that, at § 460.84(c)(7), we propose to require these organizations to have a communication plan that includes a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose requiring these organizations to provide information regarding their occupancy, as we propose for hospitals (§ 482.15(c)(7)), since the term occupancy usually refers to bed occupancy in an inpatient facility.

G. Emergency Preparedness Regulations for Transplant Centers (§ 482.78)

Transplant centers are located within hospitals that meet the requirements for Conditions of Participation (CoPs) in Medicare. Therefore, transplant centers must meet all hospital CoPs at § 482.1 through § 482.57. In addition, unless otherwise specified, heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers must meet all requirements for transplant centers at § 482.72 through § 482.104.

Transplant centers are responsible for providing organ transplantation services from the time of the potential transplant candidate's initial evaluation through the recipient's post-transplant follow-up care. In addition, if a center performs living donor transplants, the center is responsible for the care of the living donor from the time of the initial evaluation through post-surgical follow-up care.

Organs are viable for transplantation for a limited time after organ recovery. Although kidneys may remain viable for transplantation for more than 24 hours, other organs remain viable for only a few hours. Thus, according to the Organ Procurement and Transplantation Network (OPTN) longstanding policy, if a transplant center must turn down an organ for one of its patients, the organ may go to the next patient on the waiting list at another transplant center (Organ Distribution: Organ Procurement, Distribution and Allocation, *http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_6.pdf*) . In such a situation, the patient on the waiting list of the transplant center experiencing an emergency may die before an organ becomes available again. In fact, according to the OPTN, about 18 patients die every day waiting for an organ transplant. (*http://optn.transplant.hrsa.gov/*)

There are 770 Medicare-approved transplant centers. These centers provide specialized services that are not available at all hospitals. Thus, we believe that it is crucial for every transplant center to make arrangements with one or more other Medicare-approved transplant centers to provide transplantation services and other care to its patients during an emergency. Making such arrangements would increase the likelihood that if an organ became available for one of the transplant center's waiting list patients during an emergency, the patient would receive the transplant. Further, having such arrangements with other transplant centers would increase the odds that during an emergency, a transplant center's patients would receive critically important post-transplant care to prevent graft failure.

Our regulations at § 482.68 currently require that a transplant center that has a Medicare provider agreement meet the hospital CoPs specified in § 482.1 through § 482.57. Our proposed hospital CoP, "Emergency preparedness," at § 482.15, would apply to transplant centers. We also propose to add a new transplant center CoP at § 482.78, "Emergency preparedness". A transplant center would be required to comply with the proposed emergency preparedness hospital requirements at § 482.15, as well as the proposed CoP for emergency preparedness for transplant centers at § 482.78. We propose at § 482.78(a) that a transplant center have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and other care for its patients during an emergency. Ideally, the Medicare-approved transplant center that agrees to provide care for a center's patients during an emergency would perform the same type of organ transplant as the center seeking the agreement. However, we recognize that this may not always be feasible. Under some circumstances, a transplant center may wish to establish an agreement for the provision of post-transplant care and follow-up for its patients with a center that is Medicare-approved for a different organ type.

We believe a transplant center entering into an agreement for the provision of services during an emergency would be in the best position to judge whether post-transplant care could be competently provided during an emergency by a Medicare-approved transplant center that transplanted a

different organ type. We expect that transplant centers establishing such agreements would consider the types of services the other center had the ability to provide during an emergency.

We also propose at § 482.78(a) that the agreement between the transplant center and another Medicare-approved transplant center that agreed to provide care during an emergency would have to address, at a minimum: (1) the circumstances under which the agreement would be activated; and (2) the types of services that would be provided during an emergency.

Currently, under the transplant center CoP at § 482.100, Organ procurement, a transplant center is required to ensure that the hospital in which it operates has a written agreement for the receipt of organs with the hospital's designated Organ Procurement Organization (OPO) that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation. We propose at § 482.78(b) to require transplant centers to ensure that the written agreement required under § 482.100 also addresses the duties and responsibilities of the hospital and the OPO during an emergency. We have included a similar requirement for OPOs at § 486.360(c) in this proposed rule. We would expect the transplant center, the hospital in which it is located, and the designated OPO to collaborate in identifying their specific duties and responsibilities during emergency situations and include them in the agreement.

We are not proposing to require transplant centers to provide basic subsistence needs for staff and patients, as we are proposing for hospitals at § 482.15(b)(1). Also, we are not proposing to require transplant centers to separately comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites identified by emergency management officials. This requirement would be applicable to inpatient providers since the overnight provision of care could be challenged in an emergency. Transplant centers would have to meet this requirement since the transplant patient would be under the care and responsibility of the hospital.

H. Emergency Preparedness Requirements for Long Term Care (LTC) Facilities (§ 483.73)

Section 1819(a) of the Act defines a skilled nursing facility (SNF) for Medicare purposes as an institution or a distinct part of an institution that is primarily engaged in providing skilled nursing care and related services to patients that require medical or nursing care or rehabilitation services due to an injury, disability, or illness. Section 1919(a) of the Act defines a nursing facility (NF) for Medicaid purposes as an institution or a distinct part of an institution that is primarily engaged in providing to patients: skilled nursing care and related services for patients who require medical or nursing care; rehabilitation services due to an injury, disability, or illness; or, on a regular basis, health-related care and services to individuals who due to their mental or physical condition require care and services (above the level of room and board) that are available only through an institution.

To participate in the Medicare and Medicaid programs, long-term care (LTC) facilities must meet certain requirements located at part 483, Subpart B, Requirements for Long Term Care Facilities. SNFs must be certified as meeting the requirements of section 1819(a) through (d) of the Act. NFs must be certified as meeting section 1919(a) through (d) of the Act. A LTC facility may be both Medicare and Medicaid approved.

LTC facilities provide a substantial amount of care to Medicare and Medicaid beneficiaries, as well as "dual eligible individuals" who qualify for both Medicare and Medicaid. As of March 1, 2013, there were 15,157 LTC facilities and these facilities provided care for about 1.7 million patients.

The current requirements for LTC facilities contain specific requirements for emergency preparedness set out at 42 CFR 483.75(m)(1) and (2). Section 483.75(m)(1) states that a "facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents." We are proposing that this language be incorporated into proposed § 483.73(a)(1). Existing § 483.75(m)(2) states that a "facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures." These requirements would be incorporated into proposed § 483.73(d)(1)and (d)(2). Sections § 483.75(m)(1) and (2) would be removed.

These requirements are not sufficient to ensure that facilities are prepared for more widespread disasters that may affect most or all of the other health care facilities in their area and that may tax the ability of local, state, and federal emergency management officials to provide assistance. For example, current LTC facility requirements do not require facilities to conduct a risk assessment or to have a plan, policies, or procedures to ensure continuity of facility operations during emergencies. We believe the additional requirements in this proposed rule would ensure facilities would be prepared for the emergencies they may face now and in the future. Thus, our proposed emergency preparedness requirements for LTC facilities are identical to those we are proposing for hospitals at § 482.15, with two exceptions. Specifically, at § 483.73(a)(1), we propose that LTC facilities would establish emergency plans utilizing an "all-hazards" approach, which in an emergency situation, would include a directive to account for missing residents.

In addition, long term care facilities are unlike many of the inpatient care providers. Many of the residents can be expected to have long term or extended stays in these facilities. Due to the long term nature of their stays, these facilities essentially become the residents' residences or homes. We believe this changes the nature of the relationship and duty to the residents and their families or representatives. Section § 483.73(c) requires these facilities to develop an emergency preparedness communication plan, which includes, among other things, a means of providing information about the general condition and location of residents under the facility's care. We also believe that the residents and their families or representatives require more information about the facility's emergency plan. Specifically, long term care facilities should be required to determine what information in their emergency plan is appropriate to share with its residents and their families or representatives and that the facility have a means by which that information is disseminated to those individuals. The facility should also determine the appropriate time for that information to be disseminated. We are not indicating what information from the emergency plan should be shared or the timing or manner in which it should be disseminated. We believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its residents and their families or representatives and the most efficient manner in which to share that information. Therefore, we propose to add an additional requirement at § 483.73(c)(8) that reads, "A method for sharing information from the emergency plan that the facility has determined is

appropriate with residents and their families or representatives."

Also, as discussed in section II.A.4 of the preamble we are proposing at § 483.73(e)(1)(i) that LTC facilities must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that LTC facilities test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the LTC facility anticipates it will require during an emergency.

In addition to the emergency energy requirements discussed earlier, we also believe that LTC facilities should consider their individual residents' power needs. For example, some residents could have motorized wheelchairs that they need for mobility or require a continuous positive airway pressure or CPAP machine due to sleep apnea. In § 483.73(a)(1) and (3), we propose that the LTC facility address, among other things, its resident population and continuity of operations in its emergency plan. The LTC facility must also base its emergency plan on a risk assessment, utilizing an all-hazards approach. We believe that the currently proposed requirements encompass consideration of individual residents' power needs and should be included in LTC facilities' risk assessments and emergency plans. However, we are also soliciting comments on whether there should be a specific requirement for "residents' power needs" in the LTC requirements.

I. Emergency Preparedness Regulations for Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs/IID) (§ 483.475)

Section 1905(d) of the Act created the ICF/IID benefit to fund "institutions" with four or more beds to serve people with [intellectual disability] or other related conditions. To qualify for Medicaid reimbursement, ICFs/IID must be certified and comply with CoPs at 42 CFR part 483, Subpart I, § 483.400 through § 483.480. As of March 2013, there were 6,442 ICFs/IID, serving approximately 129,000 patients, and all patients receiving ICF/IID services must qualify financially for Medicaid assistance. Patients with intellectual disabilities who receive care provided by ICFs/IID may have additional emergency planning and preparedness requirements. For example, some care recipients are non-ambulatory, or may experience additional mobility or sensory disabilities or impairments, seizure disorders, behavioral challenges, or mental health challenges.

Some ICFs/IID are small and serve only a few patients. However, we do not believe small ICFs/IID or ICFs/IID in general would have difficulty meeting the proposed requirements. In fact, small facilities might find it easier than large facilities to develop an emergency preparedness plan and emergency preparedness policies and procedures. As an example, an ICF/IID with only four patients is likely to have a sufficient number of its own vehicles available during an emergency to evacuate patients and staff, eliminating the need to contract with an outside entity to provide transportation during an emergency situation or disaster.

Because ICFs/IID vary widely in size and the services they provide, we expect that the risk analyses, emergency plans, emergency policies and procedures, emergency communication plans, and emergency preparedness training will vary widely as well. Nevertheless, we believe each of them has the capability to comply fully with the requirements so that the health and safety of its patients are protected in the event of an emergency situation or disaster.

Thus, we propose requiring that ICFs/IID meet the same requirements we are proposing for hospitals, with two exceptions. At § 483.475(a)(1), we propose that ICFs/IID utilize an all hazards approach, including consideration for missing clients. We believe that in the event of a natural or man-made disaster, ICFs/IID would maintain responsibility for care of their own patient population but would not receive patients from the community. Also, because we recognize that all ICFs/IID patients have special needs, we propose requiring ICFs/IID to "address the special needs of its client population . . ." at § 483.475(a)(3).

In addressing the special needs of its client population, we believe that ICFs/IID should consider their individual residents' power needs. For example, some residents could have motorized wheelchairs that they need for mobility or require a continuous positive airway pressure or CPAP machine due to sleep apnea. We believe that the currently proposed requirements at § 483.475(a) (a risk assessment utilizing an all-hazards approach and that the facility address the special needs of its client population) encompass consideration of individual residents' power needs and should be included in ICFs/IID's risk assessments and emergency plans. However, we are also soliciting comments on whether there should be a specific requirement for "residents' power needs" in the ICFs/IID CoPs.

As we stated earlier, the purpose of this proposed rule is to establish requirements to ensure that Medicare/Medicaid providers and suppliers are prepared to protect the health and safety of patients in their care during more widespread local, state, and national emergencies. We do not believe the existing requirements for ICFs/IID are sufficiently comprehensive to protect patients during an emergency that impacts the larger community. For example, they do not require facilities to plan for sheltering in place. However, in developing this proposed rule, we have been careful not to remove emergency preparedness requirements that are more rigorous than those we are proposing.

The current regulations for ICFs/IID include requirements for emergency preparedness. Specifically, § 483.430(c)(2) and (c)(3) contain specific requirements to ensure that direct care givers are available at all times to respond to illness, injury, fire, and other emergencies. However, we do not propose to relocate these existing facility staffing requirements at § 483.430(c)(2) and § 483.430(c)(3) because they address staffing issues based on the number of patients per building and patient behaviors, such as aggression. Such requirements, while related to emergency preparedness tangentially, are not within the scope of our proposed emergency preparedness requirements for ICFs/IID.

Current § 483.470, Physical environment, includes a standard for emergency plan and procedures at § 483.470(h) and a standard for evacuation drills at § 483.470(i). The standard for emergency plan and procedures at current § 483.470(h)(1) requires facilities to develop and implement detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing clients. This requirement would be relocated to proposed § 483.475(a)(1). Existing § 483.470(h)(1) would be removed.

Currently § 483.470(h)(2) states, with regard to a facility's emergency plan, that the facility must communicate, periodically review the plan, make the plan available, and provide training to the staff. These requirements are covered in proposed § 483.475(d). Current § 483.470(h)(2) would be removed.

ICFs/IID are unlike many of the inpatient care providers. Many of the clients can be expected to have long term or extended stays in these facilities. Due to the long term nature of

their stays, these facilities essentially become the clients' residences or homes. We believe this changes the nature of the relationship and duty to the clients and their families or representatives. Section 483.475(c) requires these facilities to develop an emergency preparedness communication plan, which includes, among other things, a means of providing information about the general condition and location of clients under the facility's care. We also believe that the clients and their families or representatives require more information about the facility's emergency plan. Specifically, ICFs/IID should be required to determine what information in their emergency plan is appropriate to share with its clients and their families or representatives and that facilities have a means by which that information is disseminated to those individuals. The facility should also determine the appropriate time for that information to be disseminated. We are not indicating what information from the emergency plan should be shared or the timing or manner in which it should be disseminated. We believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its clients and their families or representatives and the most efficient manner in which to share that information. Therefore, we propose to add an additional requirement at § 483.475(c)(8) that reads, "A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives."

The standard for disaster drills set forth at existing § 483.470(i)(1) specifies that facilities must hold evacuation drills at least quarterly for each shift of personnel under varied conditions to ensure that all personnel on all shifts are trained to perform assigned tasks; ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and evaluate the effectiveness of their emergency and disaster plans and procedures. Currently § 483.470(i)(2) further specifies that facilities must evacuate patients during at least one drill each year on each shift; make special provisions for the evacuation of patients with physical disabilities; file a report and evaluation on each evacuation drill; and investigate all problems with evacuation drills, including accidents, and take corrective action. Further, during fire drills, facilities may evacuate patients to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code. Finally, at existing § 483.470(i)(3), facilities must meet the requirements of paragraphs § 483.470(i)(1) and (2) for any live-in and relief staff they utilize. Because these existing requirements are so extensive, we propose cross referencing § 483.470(i) (redesignated as § 483.470(h)) at proposed § 483.475(d).

J. Emergency Preparedness Regulations for Home Health Agencies (HHAs) (§ 484.22)

Under the authority of sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a home health agency (HHA) must meet to participate in the Medicare program. Home health services are covered for qualifying elderly and people with disabilities who are beneficiaries under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services include skilled nursing care, physical, occupational, and speech therapy, medical social work and home health aide services which must be furnished by, or under arrangement with, an HHA that participates in the Medicare program and must be provided in the beneficiary's home.

As of March 1, 2013, there were 12,349 HHAs participating in the Medicare program. The majority of HHAs are for-profit, privately owned agencies. The effective delivery of quality home health services is essential to the care of illnesses and prevention of hospitalizations.

With so many patients depending on the services of HHAs nationwide, it is imperative that HHAs have processes in place to address the safety of patients and staff and the continued provision of services in the event of a disaster or emergency. However, there are no existing emergency preparedness requirements contained under the HHA Medicare regulations at part 484, Subparts B and C.

Thus, we propose to add emergency preparedness requirements at § 484.22, pursuant to which HHAs would be required to comply with some of the requirements that we propose to require for hospitals. We are proposing additional requirements under the HHA policies and procedures that would apply to HHAs but not to hospitals to address the unique circumstances under which HHAs provide services.

First, because HHAs provide health care in patients' homes, we propose at § 484.22(b)(1) that an HHA have policies and procedures that include plans for its patients during a natural or man-made disaster. We propose that the HHA include individual emergency preparedness plans for each patient as part of the comprehensive patient assessment at § 484.55.

Second, because we learned from the experience of Hurricane Katrina that many medically compromised people were unable to escape their homes to seek safe shelter, at § 484.22(b)(2), we propose requiring an HHA to have policies and procedures to inform state and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Regulations, as appropriate. Although we do not propose how such notification would take place. we expect that maintaining an accurate list of HHA patients would be necessary. However, we believe the potential need for assistance with such factors as transportation or evacuation, for example, could be addressed as an ongoing process of evaluating the patient's medical and psychiatric condition and home environment.

We are not proposing to require that HHAs meet all of the same requirements that we are proposing for hospitals. Since HHAs provide health care services only in patients' homes, we are not including proposed requirements for policies and procedures for the provision of subsistence needs (§ 482.15(b)(1)); safe evacuation (§ 482.15(b)(3)); and a means to shelter in place (§ 482.15(b)(4)). We would not expect an HHA to be responsible for sheltering HHA patients in their homes or sheltering staff at an HHA main or branch offices. We do not propose to require that HHAs comply with the proposed hospital requirement at § 482.15(b)(8) regarding the provision of care and treatment at alternate care sites identified by emergency management officials. This proposed requirement would be applicable only to inpatient providers. With respect to communication, we have not included proposed requirements for HHAs to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 as we are proposing for hospitals at § 482.15(c)(5). We have also modified the proposed requirement for hospitals at § 482.15(c)(7) by eliminating the reference to providing information regarding the facility's occupancy. The term occupancy usually refers to bed occupancy in an inpatient facility. Instead, at § 484.22(c)(6), we would require HHAs to provide information

about the HHA's needs and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee.

In developing its policies and procedures, we would expect an HHA to consider whether it would accept new referrals during a disaster or emergency situation, and how it would care for new patients. We also would urge HHAs to include a method for providing information to all new patients and their families about the role the HHA would play in the event of an emergency.

Overall, our expectation for HHAs is that they would work closely with other HHAs and with the hospitals in their referral areas to plan for disasters and emergency situations.

K. Emergency Preparedness Regulations for Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§ 485.68)

Section 1861(cc) of the Act defines the term "comprehensive outpatient rehabilitation facility" (CORF) and lists the requirements that a CORF must meet to be eligible for Medicare participation. By definition, a CORF is a non-residential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, sick, and persons with disabilities, at a single fixed location, by or under the supervision of a physician. As of March 2013, there were 272 Medicare-certified CORFs in the U.S.

Section 1861(cc)(2)(J) of the Act also states that the CORF must meet other requirements that the Secretary finds necessary in the interest of the health and safety of a CORF's patients. Under this authority, the Secretary has established in regulations, at part 485, Subpart B, requirements that a CORF must meet to participate in the Medicare program.

Currently § 485.64 "Conditions of Participation: Disaster procedures" includes emergency preparedness requirements CORFs must meet. The regulations state that the CORF must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. The regulation requires that all personnel be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

Currently § 485.64(a) requires a CORF to have a written disaster plan that is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts. The other elements under § 485.64(a) require that CORFs have: (1) procedures for prompt transfer of casualties and records; (2) procedures for notifying community emergency personnel; (3) instructions regarding the location and use of alarm systems and signals and firefighting equipment; and (4) specification of evacuation routes and procedures for leaving the facility.

Currently § 485.64(b) requires each CORF to: (1) provide ongoing training and drills for all personnel associated with the CORF in all aspects of disaster preparedness; and (2) orient and assign specific responsibilities regarding the facility's disaster plan to all new personnel within 2 weeks of their first workday.

Although these requirements are important, they do not address the coordination across providers and suppliers and across the various federal, state, and local emergency response systems necessary to ensure the health and safety of CORF patients during an emergency.

Despite CORFs being non-residential treatment facilities, we believe they should comply with the same requirements that would be required for hospitals, with appropriate exceptions.

At § 485.68(a)(5), we propose that CORFs develop and maintain the emergency preparedness plan with assistance from fire, safety, and other appropriate experts. We do not propose to require CORFs to provide basic subsistence needs for staff and patients as we are proposing for hospitals at § 482.15(b)(1). Because CORFs are outpatient facilities, we are not proposing that CORFs have a system to track the location of staff and patients under the CORF's care both during and after the emergency as we propose to require for hospitals at § 482.15(b)(2).

At § 482.15(b)(3), we propose that hospitals have policies and procedures for safe evacuation from the hospital, which would include consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We do not believe all of these requirements are appropriate for CORFs, which serve only outpatients. Therefore, at § 485.68(b)(1), we are proposing to require that CORFs have policies and procedures for evacuation from the CORF, including staff responsibilities and needs of the patients.

Because CORFs are outpatient facilities that provide specific, limited services to patients, we are not proposing that CORFS have arrangements with other CORFs or other providers to receive patients in the event of limitations or cessation of operations. Finally, we do not propose to require CORFs to comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites identified by emergency management officials.

With respect to communication, we would not require CORFs to comply with the proposed requirement for hospitals at § 482.15(c)(5) that would require a hospital to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510. In addition, CORFs would not be required to comply with the proposed requirement at § 482.15(c)(6), which would state that a hospital must have a means of providing information about the general condition and location of patients as permitted under 45 CFR 164.510(b)(4).

We propose including in the CORF emergency preparedness provisions a requirement for CORFs to have a method for sharing information and medical documentation for patients under the CORF's care with other health care providers, as necessary, to ensure continuity of care (see proposed § 485.68(c)(4)). However, we would expect CORFs to implement this requirement only for patients receiving care at the facility at the time of the disaster or emergency situation. Given that CORFs are primarily providers of a limited range of outpatient services, we do not expect a CORF to know the whereabouts of its patients who are living in the community, as we would expect of hospices, HHAs, and PACE facilities. An additional modification from what has been proposed for hospitals at § 482.15(c)(7), at § 485.68(c)(5), we propose to require CORFs to have a communication plan that include a means of providing information about the CORF's needs and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose requiring CORFs to provide information regarding their occupancy, as we propose for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

Our goal is to ensure that we incorporate existing CORF disaster preparedness requirements into our proposed emergency preparedness rule. Although we believe the current CORF disaster preparedness requirements are largely reflected in the language we propose for other providers and suppliers, there are specific instances in which the existing CORF requirements

are more stringent, such as the requirement to assign specific disaster preparedness tasks to new personnel within two weeks of their first work day. This existing requirement at § 485.64(b)(2) would be relocated to proposed § 485.68(d)(1).

Currently § 485.64 requires a CORF to develop and maintain its disaster plan with assistance from fire, safety, and other appropriate experts. We have incorporated this requirement at proposed § 485.68(a)(5). Currently § 485.64(a)(3) would require that the training program include instruction in the location and use of alarm systems and signals and firefighting equipment. We have incorporated these requirements at proposed § 485.68(d)(1). We propose to remove current § 485.64.

L. Emergency Preparedness Regulations for Critical Access Hospitals (CAHs) (§ 485.625)

Sections 1820 and 1861(mm) of the Act provide that critical access hospitals participating in Medicare and Medicaid meet certain specified requirements. We have implemented these provisions in 42 CFR part 485, Subpart F, Conditions of Participation for Critical Access Hospitals (CAHs). As of March 1, 2013, there are 1,332 CAHs that must meet the CAH CoPs and 95 CAHs with psychiatric or rehabilitation distinct part units (DPUs) that must meet the hospital CoPs in order to receive payment for services provided to Medicare or Medicaid patients in the DPU.

CAHs are small, generally rural, limited-service facilities with low patient volume. The intent of designating facilities as "critical access hospitals" is to preserve access to primary care and emergency services that meet community needs.

A CAH is not required to be staffed if there are no inpatients in the facility. However, in the event of an emergency, existing requirements state there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact and available onsite within 30 minutes on a 24-hour basis or, under certain circumstances, within 60 minutes. CAHs currently are required to coordinate with emergency response systems in the area to provide 24-hour emergency coverage. We believe the existing requirements provide only a limited framework for protecting the health and safety of CAH patients in the event of a major disaster. They do not include the requirements we propose that we believe will ensure a well-coordinated emergency preparedness system of care.

CAHs are required at existing § 485.623(c), "Standard: Emergency procedures," to assure the safety of patients in non-medical emergencies by training staff in handling emergencies, including prompt reporting of fires; extinguishing of fires; protection and, where necessary, evacuation of patients, personnel, and guests; and cooperation with firefighting and disaster authorities. CAHs must provide for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas; provide for fuel and water supply; and take other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located. Since CAHs are required to provide emergency services on a 24-hour a day basis, they must keep equipment, supplies, and medication used to treat emergency cases readily available.

We propose to remove the current standard at § 485.623(c) and relocate these requirements into the appropriate sections of a new CoP entitled, "Condition of Participation: Emergency Preparedness" at § 485.625, which would include the same requirements that we propose for hospitals. Since CAHs function as acute care providers in rural and remote communities, we believe that they should be prepared in the event of a disaster to provide critical care to individuals in their communities. Although CAHs are much smaller than most Medicare- and Medicaid-participating hospitals, we do not expect them to have difficulty meeting the same requirements we propose for hospitals. CAHs can draw upon a large number of resources at the federal, state, and local level for assistance in meeting the requirements.

We propose to relocate current § 485.623(c)(1) to proposed § 485.625(d)(1). We propose to incorporate current § 485.623(c)(2) into § 485.625(b)(1). Current § 485.623(c)(3) would be included in proposed § 485.625(b)(1). Current § 485.623(c)(4) would be reflected by the use of the term "all-hazards" in proposed § 485.625(a)(1). Section 485.623(d) would be redesignated as § 485.623 (c).

Also, as discussed in section II.A.4 of the preamble we are proposing at § 485.625(e)(1)(i) that CAHs must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that CAHs test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the CAH anticipates it will require during an emergency.

M. Emergency Preparedness Regulation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (§ 485.727)

Under the authority of section 1861(p) of the Act, the Secretary has established CoPs that clinics, rehabilitation agencies, and public health agencies must meet when they provide outpatient physical therapy (OPT) and speech-language pathology (SLP) services. Under section 1861(p) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of individuals receiving OPT and SLP services from these entities. The CoPs are set forth at part 485, Subpart H.

Section 1861(p) of the Act describes "outpatient physical therapy services" to mean physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient. The patient must be under the care of a physician.

The term "outpatient physical therapy services" also includes physical therapy services furnished to an individual by a physical therapist (in the physical therapist's office or the patient's home) who meets licensing and other standards prescribed by the Secretary in regulations, other than under arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. The term also includes SLP services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement.

As of March 1, 2013, there are 2,256 clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language pathology services. In the remainder of this proposed rule and throughout the requirements, we use the

term "organizations" instead of "clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services" for consistency with current regulatory language. Most of these providers are small facilities operated by a group of three or more physicians, as required at § 485.703 under the definition of "clinic", practicing medicine together, as well as various other rehabilitation professionals.

At § 485.727(b)(1), we are proposing to require that organizations have policies and procedures for evacuation from the organization, including staff responsibilities and needs of the patients.

We believe these organizations comply with a provision similar to our proposed requirement for hospitals at § 482.15(c)(7) which states that a communication plan must include a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee. At § 485.727(c)(5), we propose to require that these organizations to have a communication plan that include a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction (local and state agencies) or the Incident Command Center, or designee. We do not propose to require these organizations to provide information regarding their occupancy, as we proposed for hospitals, since the term "occupancy" usually refers to bed occupancy in an inpatient facility.

The current regulations at § 485.727, "Disaster preparedness," require these organization to have a disaster plan. The plan must be periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster. Additionally, current § 485.727(a) requires that the facility have a plan in operation with procedures to be followed in the event of fire, explosion, or other disaster. We believe these requirements are addressed throughout the proposed CoP, and we do not propose including the specific language in our proposed rule.

However, existing § 485.727(a) also requires that the plan be developed and maintained with the assistance of qualified fire, safety, and other appropriate experts. Because this existing requirement is specific to existing disaster preparedness requirements for these organizations, we have relocated the language to proposed § 485.727(a)(6).

Existing requirements at § 485.727(a) also state that the disaster plan must include: (1) transfer of casualties and records; (2) the location and use of alarm systems and signals; (3) methods of containing fire; (4) notification of appropriate persons, and (5) evacuation routes and procedures. Because transfer of casualties and records, notification of appropriate persons, and evacuation routes are addressed under policies and procedures in our proposed language, we do not propose to relocate these requirements. However, because the requirements for location and use of alarm systems and signals and methods of containing fire are specific for these organizations, we propose relocating these requirements to § 485.727(a)(4).

Currently § 485.727(b) specifies requirements for staff training and drills. This requirement states that all employees must be trained, as part of their employment orientation, in all aspects of preparedness for any disaster. This disaster program must include orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his or her assigned role in case of a disaster. Because these requirements are addressed in proposed § 485.727(d), we do not propose to relocate them but merely to address them in that paragraph. Current § 485.727, "Disaster preparedness," would be removed.

N. Emergency Preparedness Regulations for Community Mental Health Centers (CMHCs) (§ 485.920)

A Community Mental Health Center (CMHC) as defined in section 1861(ff)(3)(B) of the Act, is an entity that meets applicable licensing or certification requirements in the state in which it is located and provides the set of services specified in section 1913(c)(1) of the Public Health Service Act. Section 4162 of Public Law 101–508 (OBRA 1990), which amended section 1861(ff)(3)(A) and 1832(a)(2)(J) of the Act, includes CMHCs as entities that are authorized to provide partial hospitalization services under Part B of the Medicare program, effective for services provided on or after October 1, 1991. Section 1866(e)(2) of the Act and 42 CFR part 489.2(c)(2) recognize CMHCs as providers of services for purposes of provider agreement requirements but only with respect to providing partial hospitalization services. In 2010 there were 207 Medicare-certified CMHCs serving approximately 27,738 Medicare beneficiaries.

Pursuant to 42 CFR 410.2 and 410.110, a CMHC may receive Medicare payment for partial hospitalization services only if it demonstrates that it provides the following core services:

- Outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of the CMHC's service area who have been discharged from inpatient treatment at a mental health facility.
- 24 hour-a-day emergency care services.
- Day treatment, or other partial hospitalization services, or psychosocial rehabilitation services.
- Screening for clients being considered for admission to state mental health facilities to determine the appropriateness of such admission. However, effective March 1, 2001, the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000 allows CMHCs to provide these services by contract if state law precludes the entity from providing the screening services.
- Meets applicable licensing or certification requirements for CMHCs in the state in which it is located.
- Provides at least 40 percent of its services to individuals who are not eligible for benefits under Title XVIII of the Act.

To qualify for Medicare reimbursement, CMHCs must comply with requirements for coverage of partial hospitalization services at § 410.110 and conditions for Medicare payment of partial hospitalization services at § 424.24(e). We will soon finalize the first health and safety CoPs for CMHCs, and while CMS is cognizant of the overall burden, we believe it is appropriate to also require CMHCs to meet the same emergency preparedness requirements as other outpatient facilities. Consistent with our proposed requirements for other Medicare and Medicaid participating providers and suppliers, we would require that CMHCs comply with emergency preparedness requirements to ensure a well-coordinated emergency response in the event of a disaster or emergency situation. We are proposing that CMHCs meet the same emergency preparedness requirements we propose for hospitals, with a few exceptions.

Since CMHCs are outpatient facilities, we would expect that in an emergency, the CMHC would instruct clients and staff not to report to the facility. In the event that clients and staff were in the facility when a disaster or emergency situation occurred, we would expect the

CMHC to encourage clients and staff to leave the facility to seek safe shelter in the community. We would expect most clients and staff to return to their homes.

Additionally, at § 485.920(c)(7), we propose to require these CMHCs to have a communication plan that include a means of providing information about the CMHCs needs and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee.

Some CMHCs are small facilities with just a few clients and may be located in rural areas. These CMHCs could find it challenging to develop a well-coordinated emergency preparedness plan. However, we believe even small CMHCs would be able to develop an appropriate emergency preparedness plan with the assistance of federal, state, and local community resources.

O. Emergency Preparedness Regulations for Organ Procurement Organizations (OPOs) (§ 486.360)

Section 1138(b) of the Act and 42 CFR part 486, subpart G establish that OPOs must be certified by the Secretary as meeting the requirements to be an OPO and designated by the Secretary for a specific Donation Service Area (DSA). The current OPO CfCs do not contain any emergency preparedness requirements.

There are currently 58 Medicare certified OPOs that are responsible for identifying potential organ donors in hospitals, assessing their suitability for donation, obtaining consent from next-of-kin, managing potential donors to maintain organ viability, coordinating recovery of organs, and arranging for transport of organs to transplant centers. If an emergency affects an OPO's ability to provide its services, organ procurement services to its entire DSA may be affected.

Our proposed requirements for OPOs to develop and maintain an emergency preparedness plan, are similar to those proposed for hospitals, with some exceptions.

Since potential donors generally are located within hospitals, at proposed § 486.360(a)(3), instead of addressing the patient population as proposed for hospitals at § 482.15(a)(3), we propose that the OPO address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans. That is, we would expect an OPO to consider the type of hospitals it serves when it develops its emergency plan, for example, a large hospital with a trauma center located in a major metropolitan area or a small rural hospital lacking an operating room.

Because the services provided by OPOs are so different from the services provided by a hospital and because potential donors generally are located within hospitals, we propose only two requirements for OPOs at § 486.360(b): (1) a system to track the location of staff during and after an emergency; and (2) a system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and ensures records are secure and readily available.

Since OPOs' potential donors generally are located within hospitals and since OPOs do not have physical structures in which to house patients, OPOs would not be expected to have policies and procedures to address the provision of subsistence needs for staff and patients. Instead, we believe these responsibilities would rest upon the hospital.

In addition, at § 486.360(c), we are proposing only three requirements for an OPO's communication plan. An OPO's communication plan would include: (1) names and contact information for staff; entities providing services under arrangement; volunteers; other OPOs; and transplant and donor hospitals in the OPO's DSA; (2) contact information for federal, state, tribal, regional, or local emergency preparedness staff and other sources of assistance; and (3) primary and alternate means for communicating with the OPO's staff, federal, state, tribal, regional, or local emergency management agencies. We believe the additional proposed requirements regarding communication would specifically be a hospital's responsibility in caring for its patient population.

Unlike the requirement we have proposed for hospitals at § 482.15(d)(2)(i) and (iii), which would be required to conduct both a mock disaster drill and a tabletop exercise, we propose at § 486.360(d)(2)(i) that an OPO would be required only to conduct a tabletop exercise. Since the OPO's patients reside in the hospital, we expect the OPO to show due consideration for its emergency response efforts by engaging in such a tabletop exercise. However, the OPO typically does not have physical possession of patients to fully engage in a mock disaster drill as proposed for hospitals. Since an OPO does not deal directly with patients, a mock disaster drill would be unnecessary.

Finally, at § 486.360(e), we propose that each OPO have agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's DSA in the event that the OPO cannot provide such services due to an emergency. We also propose that the OPO include within its agreements with hospitals required under § 486.322(a) and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

P. Emergency Preparedness Regulations for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (§ 491.12)

Section 1861(aa) sets forth the Rural Health Clinic and Federally Qualified Health Center services covered by the Medicare and Medicaid program. "RHCs" must be located in an area that is both rural and underserved.

Conditions for Certification for RHCs and Conditions of Coverage for FQHCs are found at 42 CFR part 491, Subpart A. Current emergency preparedness requirements are found at § 491.6.

Currently, an RHC is staffed with personnel that are required to provide medical emergency procedures as a first response to common life threatening injuries and acute illnesses and to have available the drugs and biologicals commonly used in life-saving procedures. The definition of a "first response" is a service that is commonly provided in a physician's office. FQHCs are required to provide emergency care either on site or through clearly defined arrangements for access to health care for medical emergencies during and after the FQHC's regularly scheduled hours. Therefore, FQHCs must provide for access to emergency care at all times. Clinics and centers have varying hours and days of operation based on staff and anticipated patient load.

We are aware of the difficulties that rural communities have attracting and retaining a variety of professionals, including health care professionals. However, there is a present and growing need for all providers and suppliers to develop plans to care for their staff and patients during a disaster. We propose that the RHCs' and FQHCs' emergency preparedness plans must address the type of services the facility has the capacity to provide in an emergency. We expect that they would evaluate their ability to provide services based on, but not limited to, the facility's size, available human and material resources, geographic location, and ability to coordinate with community resources.

Thus, while Medicare providers or suppliers in a large metropolitan community may be better able to provide the majority of its services during an emergency event, rural, providers and suppliers, especially those in frontier areas, may find it far more challenging to provide similar services during an emergency.

We believe many RHCs and FQHCs would be able to develop a comprehensive emergency plan that addresses "all-hazards" policies and procedures, a communication plan, and training and testing by drawing upon a variety of resources that can provide technical assistance. For example, HRSA's Office of Rural Health Policy (ORHP), guide entitled, "Rural Health Communities and Emergency Preparedness," that is available on HRSA's Web site at: *ftp://ftp.hrsa.gov/ruralhealth/RuralPreparedness.pdf* is a good source.

Although RHCs and FQHCs currently do not have specific requirements for emergency preparedness, they have requirements for "Emergency Procedures" found at § 491.6, under "Physical plant and environment." At § 491.6(c)(1), the RHC or FQHC must train staff in handling non-medical emergencies. This requirement would be addressed at proposed § 491.12(d)(1). At § 491.6(c)(2), the RHC or FQHC must place exit signs in appropriate locations. This requirement would be incorporated into our proposed requirement at § 491.12(b)(1), which would require RHCs and FQHCs to have policies and procedures for safe evacuation from the facility which includes appropriate placement of exit signs. Finally, at § 491.6(c)(3), the RHC or FQHC must take other appropriate measures that are consistent with the particular conditions of the area in which the facility is located. This requirement would be addressed throughout the proposed CoP for RHCs and FQHCs, particularly proposed § 491.12(a)(1), which requires the RHCs and FQHCs to perform a risk assessment based on an "all-hazards" approach. Current § 491.6(c) would be removed.

We are proposing emergency preparedness requirements based on the requirements that we are proposing for hospitals, modified to address the specific characteristics of RHCs and FQHCs. We do not propose to require RHC/FQHCs to provide basic subsistence needs for staff and patients. Also, unlike that proposed for hospitals at § 482.15(b)(2), we are not proposing that RHCs/FQHCs have a system to track the location of staff and patients in the facility's care both during and after the emergency.

At § 482.15(b)(3), we propose that hospitals have policies and procedures for safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We do not believe all of these requirements are appropriate for RHCs/FQHCs, which serve only outpatients. Therefore, at § 491.12(b)(1), we are proposing to require that RHCs/FQHCs have policies and procedures for evacuation from the RHC/FQHC, including appropriate placement of exit signs, staff responsibilities, and needs of the patients.

Unlike the requirement that is being proposed for hospitals at § 482.15(b)(7), we are not proposing that RHCs/FQHCs have arrangements with other RHCs/FQHCs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to RHC/FQHC patients. We do not propose to require RHC/FQHCs to comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites.

In addition, we would not require RHCs/FQHCs to comply with the proposed requirement for hospitals found at § 482.15(c)(5), which would require that a hospital have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510. Modified from what has been proposed for hospitals at § 482.15(c)(7), at § 491.12(c)(5), we propose to require RHCs/FCHCs to have a communication plan that would include a means of providing information about the RHCs/FQHCs needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose requiring RHCs/FQHCs to provide information regarding their occupancy, as we propose for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

Q. Emergency Preparedness Regulation for End-Stage Renal Disease (ESRD) Facilities (§ 494.62)

Sections 1881(b), 1881(c), and 1881(f)(7) of the Act establish requirements for End-Stage Renal Disease (ESRD) facilities. ESRD is a kidney impairment that is irreversible and permanent and requires either a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. There are 5,923 Medicare-participating ESRD facilities in the U.S.

We addressed emergency preparedness requirements for ESRD facilities in the April 15, 2008 final rule (73 FR 20370) entitled, "Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule". Emergency preparedness requirements are located at § 494.60(d), Condition: Physical environment, Standard: Emergency preparedness. We propose to relocate these existing requirements to proposed § 494.62, Emergency preparedness.

Current regulations include the requirement that dialysis facilities be organized into ESRD Network areas. Our regulations describe these networks at § 405.2110 as "CMS-designated ESRD Networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients." The ESRD Networks have an important role in an ESRD facility's response to emergencies, as they often arrange for alternate dialysis locations for patients and provide information and resources during emergency situations. As noted earlier, we do not propose incorporating the ESRD Network requirements into this proposed rule. We do not propose to require ESRD facilities to provide basic subsistence needs for staff and patients, whether they evacuate or shelter in place, including food, water, and medical supplies; alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; emergency lighting; and fire detection, extinguishing, and alarm systems; and sewage and waste disposal as we are proposing for hospitals at § 482.15(b)(1).

At § 494.62(b), we propose to require facilities to address in their policies and procedures, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters in the facility's geographic area.

At § 482.15(b)(3), we propose that hospitals have policies and procedures for the safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We do not believe all of these requirements are appropriate for ESRD facilities, which serve only outpatients. Therefore, at § 494.62(b)(2), we are proposing to require that ESRD facilities have policies and procedures for evacuation from the facility,

including staff responsibilities and needs of the patients.

At § 494.62(b)(6), we are proposing to require ESRD facilities to develop arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to dialysis facility patients. Experience has shown that ESRD facilities tend to use hospitals as back-up when hospital space and personnel need to be used to care for the sickest patients in the community during such emergencies. Thus, we want to emphasize that an organized system of patient care among ESRD facilities during and surrounding emergency events encompasses having a robust system for back-up care available at the various dialysis centers.

At § 494.62(c)(7), dialysis facilities would be required to comply with the proposed requirement for hospitals at § 482.15(c)(7), with one exception. At § 494.62(c)(7), we propose to require dialysis facilities to have a communication plan that include a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose to require dialysis facilities to provide information regarding their occupancy, as we proposed for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

At § 494.62(d)(1)(i), we propose to require ESRD facilities to ensure that staff can demonstrate knowledge of various emergency procedures, including: informing patients of what to do; where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and how to disconnect themselves from the dialysis machine if an emergency occurs.

We would relocate existing requirements for patient training from § 494.60(d)(2) to proposed § 494.62(d)(3), patient orientation. In addition, the facility would have to ensure that, at a minimum, patient care staff maintained current CPR certification and ensure that nursing staff were properly trained in the use of emergency equipment and emergency drugs. With respect to emergency preparedness, the relevance of these requirements has already been established, and since they are existing regulations, they are standard business practice in ESRD facilities.

Current § 494.60(d) would be redesignated. Current requirements for emergency plans at § 494.60 are captured within proposed § 494.62(a). Current language that defines an emergency for dialysis facilities found at § 494.60(d) would be incorporated into proposed § 494.62(b). We would relocate existing requirements for emergency equipment and emergency drugs found at existing § 494.60(d)(3) to § 494.62(b)(9). We would relocate the existing requirement at § 494.60(d)(4)(i) that requires the facility to have a plan to obtain emergency medical system assistance when needed to proposed § 494.62(b)(8). We would relocate the current requirements at § 494.60(d)(4)(iii) for contacting the local emergency preparedness agency at least annually to ensure that the agency is aware of dialysis facility's needs in the event of an emergency to proposed § 494.62(a)(4). We would also redesignate the current § 494.60(e) as § 494.60(d).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Factors Influencing ICR Burden Estimates

Please note that under this proposed rule, a hospital's ICRs would differ from the ICRs of other Medicare or Medicaid provider and supplier types. A significant factor in the burden for each provider or supplier type would be whether the type of facility provides inpatient services, outpatient services, or both. Moreover, even where the proposed regulatory requirements are the same, certain factors would greatly affect the burden for different providers and suppliers. Current Medicare or Medicaid regulations for some providers and suppliers include requirements similar to those in this proposed regulation. For example, existing regulations for RNHCIs and dialysis facilities require both types of facilities to have written disaster plans that address emergencies (42 CFR 403.742(a)(4) and 42 CFR 494.60(d)(4), respectively).

Further, some accrediting organizations (AOs) that have deeming authority for Medicare providers and suppliers have emergency preparedness standards. Those organizations are: The Joint Commission (TJC), the American Osteopathic Association (AOA), the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), the American Association for Accreditation for Ambulatory Surgery Facilities, Inc. (AAAASF), and Det Norske Veritas Healthcare, Inc. (DNVHC). Each of these AOs has deeming authority for different types of facilities; for example, TJC has comprehensive emergency preparedness requirements for hospitals. Thus, as noted in the hospital discussion later in this section, we anticipate that TJC-accredited hospitals would have a smaller burden associated with this proposed rule than many other providers or suppliers.

In addition, many facilities already have begun preparing for emergencies. According to a study by Niska and Burt, virtually all hospitals already have plans to respond to natural disasters (Niska, R.W. and Burt, C.W. "Bioterrorism and Mass Casualty Preparedness in Hospitals: United States, 2003," CDC, Advance Data, September 27, 2005 found at *http://www.cdc.gov/nchs/data/ad/ad364.pdf*).

Hospitals, as well as other health care providers, also receive grant funding for disaster or emergency preparedness from the federal and state governments, as well as other private and non-profit entities. However, we were unable to determine the amount of funding that has been granted to hospitals, the number of hospitals that received funding, or whether that funding would continue in a predictable manner. We also do not know how the hospitals spent this funding. Therefore, in

determining the burden for this proposed rule, we did not take into account any funding a hospital or other health care provider might have received from sources other than Medicare or Medicaid.

B. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

We obtained the data used in this discussion on the number of the various Medicare and Medicaid providers and suppliers from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of March 1, 2013. We have not included data for health care facilities that are not Medicare or Medicaid certified.

Unless otherwise indicated, we obtained all salary information for the different positions identified in the following assessments from the May 2011 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics at *http://www.bls.gov/oes/current/oes_nat.htm*. We calculated the estimated hourly rates based upon the national median salary for that particular position, including benefits. Where we were able to identify positions linked to specific providers or suppliers, we used that compensation information. However, in some instances, we used a general position description, such as director of nursing, or we used information for comparable positions. For example, we were not able to locate specific information for physicians who practice in hospices. However, since hospices provide palliative care, we used the compensation information for physicians who work in specialty hospitals.

Based on our experience, certain providers and suppliers typically pay less than the median salary, in which case, we used a salary from a lower percentile. Salary may also be affected by the rural versus urban locations. For example, based on our experience with CAHs, they usually pay their administrators less than the mean hourly wage for Health Service Managers in general medical and surgical hospitals. Thus, we considered the impact of the rural nature of CAHs to estimate the hourly wage for CAH administrators and calculated total compensation by adding in an amount for fringe benefits. According to the Bureau of Labor Statistics, wages and salaries accounted for about 70 percent of total employee compensation. (Bureau of Labor Statistics News Release, "Employer Cost Index—December 2011", retrieved from *www.bls.gov/news.release/pdf/eci.pdf*). Thus, we calculated total compensation using the assumption that salary accounts for 70 percent of total compensation. We would welcome any comments on the accuracy of our compensation estimates. Many health care providers and suppliers could reduce their burden by partnering or collaborating with other facilities to develop their emergency management plans or programs. In estimating the burden associated with this proposed rule, we also took into consideration the many free or low cost emergency management resources health care facilities have available to them. Following is a list of some of the available resources:

Department of Health and Human Services (HHS)

- *http://www.phe.gov*

Office of the Assistant Secretary for Preparedness and Response (ASPR)

- *http://www.phe.gov/about*

Health Resources and Services Administration—Emergency Preparedness and Continuity of Operations

- *http://www.hrsa.gov/emergency/*

Centers for Medicare and Medicaid Services (CMS)

- *www.cms.hhs.gov/Emergency/*

Centers for Disease Control and Prevention—Emergency Preparedness & Response

- *www.emergency.cdc.gov*

Food and Drug Administration (FDA)—Emergency Preparedness and Response

- *http://www.fda.gov/EmergencyPreparedness/default.htm*

Substance Abuse and Mental Health Services Administration (SAMHSA)—Disaster Readiness and Response

- *http://www.samhsa.gov/Disaster/*

National Institute for Occupational Safety and Health (NIOSH)—Business Emergency Management Planning

- *www.cdc.gov/niosh/topics/emres/business.html*

Department of Labor (DOL), Occupational Safety and Health Administration (OSHA)—Emergency Preparedness and Response

- *www.osha.gov/SLTC/emergencypreparedness*

Federal Emergency Management Agency (FEMA)—State Offices and Agencies of Emergency Management—Contact Information

- *http://www.fema.gov/about/contact/statedr.shtm*
- *http://www.fema.gov/plan-prepare-mitigate*

Department of Homeland Security (DHS)

- *http://www.dhs.gov/training-technical-assistance*

We will discuss the burden for each provider and supplier type included in this proposed rule in the order in which they appear in the CFR.

C. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 403.748)

Proposed § 403.748(a) would require Religious Nonmedical Health Care Institutions (RNHCIs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We propose that the plan must meet the requirements specified at § 403.748(a)(1) through (4). We will discuss the burden for these activities individually beginning with the risk assessment requirement in § 403.748(a)(1).

The current RNHCI CoPs already require RNHCIs to have a written disaster plan that addresses "loss of power, water, sewage, and other emergencies" (42 CFR 403.742(a)(4)). In addition, the CoPs also require RNHCIs' to include measures to evaluate facility safety issues, including physical environment, in their quality assessment and performance improvement (QAPI) program (42 CFR 403.732(a)(1)(vi)). We expect that all RNHCIs have considered some of the risks likely to happen in their facility. However, we expect that all RNHCIs would need to review any existing risk assessment and perform the tasks necessary to ensure their assessment is documented and utilize a facility-based and community based all-hazards approach.

We have not designated any specific process or format for RNHCIs to use in conducting their risk assessment because we believe they need the flexibility to determine how best to accomplish this task. However, we expect that they would obtain input from all of their major departments in the process of developing their risk assessments.

Based on our experience with RNHCIs, we expect that complying with this requirement would require the involvement of an administrator, the

director of nursing, and the head of maintenance. It is important to note that RNHCIs do not provide medical care to their patients. Depending upon the state in which they are located, RNHCIs may not be licensed and may not have licensed or certified staff. RNHCIs generally do not compensate their staff at the same level we have used to determine the burden for other health care providers and suppliers. Therefore, for the purpose of estimating the burden, we have used lower hourly wages for the RNHCI staff than for other providers and suppliers whose staff must comply with licensing and certification standards.

We expect that to perform a risk assessment, the RNHCI's administrator, the director of nursing, and the head of maintenance would attend an initial meeting; review relevant sections of the current risk assessment; prepare comments; attend a follow-up meeting; perform a final review, and approve the risk assessment. We expect that the director of nursing would coordinate the meetings, review and critique the current risk assessment, coordinate comments, develop the new risk assessment, and ensure that it is approved.

We estimate that it would require 9 burden hours for each RNHCI to complete the risk assessment at a cost of $265. There are 16 RNHCIs. Therefore, it would require an estimated 144 annual burden hours (9 burden hours for each RNHCI × 16 RNHCIs = 144 burden hours) for all 16 RNHCIs to comply with this requirement at a cost of $4,240 ($265 estimated cost for each RNHCI × 16 RNHCIs = $4,240 estimated cost).

After conducting a risk assessment, RNHCIs would need to review, revise, and, if necessary, develop new sections for their emergency plans. The current RNHCI CoPs require RNHCIs to have a written disaster plan for emergencies (42 CFR § 403.742(a)(4)). However, based on our experience with RNHCIs, their plans likely would address only evacuation from their facilities. We expect that all RNHCIs would need to review, revise, and develop new sections for their plans.

We expect that the same individuals who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect that it would require substantially more time to complete the plan than to complete the risk assessment. We estimate that complying with this requirement would require 12 burden hours for each RNHCI at a cost of $348. Therefore, for all 16 RNHCIs to comply with these requirements would require an estimated 192 burden hours (12 burden hours for each RNHCI × 16 RNHCIs = 192 burden hours) at a cost of $5,568 ($348 estimated cost for each RNHCI × 16 RNHCIs = $5,568 estimated cost).

Under this proposed rule, RNHCIs would be required to review and update their emergency preparedness plans at least annually. For the purpose of determining the burden associated with this requirement, we would expect that RNHCIs already review their plans annually. Based on our experience with Medicare providers and suppliers, health care facilities generally have a compliance officer or other staff member who periodically reviews the facility's program to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. While this requirement is subject to the PRA, we expect that complying with the requirement for an annual review of the emergency preparedness plan would constitute a usual and customary business practice as defined at 5 CFR 1320.3(b)(2). Therefore, we have not assigned a burden.

Proposed § 403.748(b) would require RNHCIs to develop and implement emergency preparedness policies and procedures in accordance with their emergency plan based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. These policies and procedures would have to be reviewed and updated at least annually. At a minimum, we propose that the policies and procedures be required to address the requirements specified in § 403.748(b)(1) through (8). The RNHCIs would need to review their policies and procedures and compare them to their emergency plan, risk assessment, and communication plan. Most RNHCIs would need to revise their existing policies and procedures or develop new policies and procedures.

The current RNHCI CoPs require them to have written policies concerning their services (42 CFR § 403.738). Thus, some RNHCIs may have some emergency preparedness policies and procedures. However, based on our experience with RNHCIs, most of their emergency preparedness policies address only evacuation from the facility.

We expect that these tasks would involve the administrator, the director of nursing, and the head of maintenance. All three would need to review and comment on the RNHCI's current policies and procedures. The director of nursing would revise or develop new policies and procedures, as needed, ensure that they are approved, and compile and disseminate them to the appropriate parties. We estimate that it would require 6 burden hours for each RNHCI to comply with this requirement at a cost of $164. Thus, it would require 96 burden hours (6 burden hours for each RNHCI × 16 RNHCIs = 96 burden hours) for all 16 RNHCIs to comply with the requirements in § 403.748(b)(1) through (8) at a cost of $2,624 ($164 estimated cost for each RNHCI × 16 RNHCIs = $2,624 estimated cost).

Proposed § 403.748(c) would require RNHCIs to develop and maintain an emergency preparedness communication plan that complies with both federal and state law and must be reviewed and updated at least annually. We propose that the communication plan include the information specified at § 403.748(c)(1) through (7). The burden associated with complying with this requirement would be the resources required to review and, if necessary, revise an existing communication plan or develop a new plan. Based on our experience with RNHCIs, we expect that these activities would require the involvement of the RNHCI's administrator, the director of nursing, and the head of maintenance. We estimate that complying with this requirement would require 4 burden hours for each RNCHI at a cost of $116. Thus, it would require an estimated 64 burden hours (4 burden hours for each RNHCI × 16 RNHCIs = 64 burden hours) at a cost of $1,856 ($116 estimated cost for each RNHCI × 16 RNHCIs = $1,856 estimated cost).

We propose that RNHCIs would also have to review and update their emergency preparedness communication plan at least annually. We believe that RNHCIs already review their emergency preparedness communication plans periodically. Thus, complying with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2). Therefore, we have not assigned a burden.

Proposed § 403.748(d) would require RNHCIs to develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. We are proposing that a RNHCI meet the requirements specified at § 403.748(d)(1) and (2). Section 403.748(d)(1) would require RNHCIs to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain

documentation of the training. Thereafter, the RNHCI would have to provide training at least annually. Based on our experience, all RNHCIs have some type of emergency preparedness training program. However, all RNHCIs would need to compare their current emergency preparedness training programs to their risk assessments and updated emergency preparedness plans, policies and procedures, and communication plans and revise or, if necessary, develop new sections for their training programs.

We expect that complying with these requirements would require the involvement of the RNHCI administrator and the director of nursing. We estimate that it would require 7 burden hours for each RNHCI to develop an emergency training program at a cost of $218. Thus, it would require an estimated 112 burden hours (7 burden hours for each RNHCI × 16 RNHCIs = 112 burden hours) at a cost of $3,488 ($218 estimated cost for each RNHCI × 16 RNHCI = $3,488 estimated cost).

We are proposing that RNHCIs also review and update their emergency preparedness training and testing programs at least annually. Based on our experience with Medicare providers and suppliers, health care facilities generally have a compliance officer or other staff member who periodically reviews the facility's program to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. While this requirement is subject to the PRA, we expect that complying with this requirement would constitute a usual and customary business practice as defined at 5 CFR 1320.3(b)(2). Therefore, we have not calculated an estimate of the burden.

Proposed § 403.748(d)(2) would require RNHCIs to conduct a paper-based, tabletop exercise at least annually. The RNHCI must also analyze its response to and maintain documentation of all tabletop exercises and emergency events, and revise its emergency plan, as needed.

The burden associated with complying with this requirement would be the resources RNHCIs would need to develop the scenarios for the exercises and the necessary documentation. Based on our experience with RNHCIs, RNHCIs already conduct some type of exercise periodically to test their emergency preparedness plans. However, we expect that RNHCIs would not be fully compliant with our proposed requirements. We expect that the director of nursing would develop the scenarios and required documentation. We estimate that these tasks would require 3 burden hours at a cost of $72 for each RNCHI. Based on this estimate, for all 16 RNHCIs to comply with these requirements would require 48 burden hours (3 burden hours for each RNHCI × 16 RNHCIs = 48 burden hours) at a cost of $1,152 ($72 estimated cost for each RNHCI × 16 RNHCI = $1,152 estimated cost).

TABLE 2—BURDEN HOURS AND COST ESTIMATES FOR ALL 16 RNHCIS TO COMPLY WITH THE ICRS CONTAINED IN § 403.748 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 403.748(a)(1)	0938—New	16	16	9	144	**	4,240	0	4,240
§ 403.748(a)(1)—(4)	0938—New	16	16	12	192	**	5,568	0	5,568
§ 403.748(b)	0938—New	16	16	6	96	**	2,624	0	2,624
§ 403.748(c)	0938—New	16	16	4	64	**	1,856	0	1,856
§ 403.748(d)(1)	0938—New	16	16	7	112	**	3,488	0	3,488
§ 403.748(d)(2)	0938—New	16	16	3	48	**	1,152	0	1,152
Totals		16	108	41	656				18,928

** The hourly labor cost is blended between the wages for multiple staffing levels.

D. ICRs Regarding Condition for Coverage: Emergency Preparedness (§ 416.54)

Proposed § 416.54(a) would require Ambulatory Surgical Centers (ASCs) to develop and maintain an emergency preparedness plan and review and update that plan at least annually. We propose that the plan must meet the requirements contained in § 416.54(a)(1) through (4).

We will discuss the burden for these activities individually below beginning with the risk assessment requirement in § 416.54(a)(1). We expect that each ASC would conduct a thorough risk assessment. This would require the ASC to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. We expect that an ASC would consider its location and geographical area; patient population, including those with special needs; and the type of services the ASC has the ability to provide in an emergency. The ASC also would need to identify the measures it must take to ensure continuity of its operation, including delegations and succession plans.

The burden associated with this requirement would be the time and effort necessary to perform a thorough risk assessment. There are 5,354 ASCs. The current regulations covering ASCs include some emergency preparedness requirements; however, those requirements primarily are related to internal emergencies, such as a fire.

A significant factor in determining the burden is the accreditation status of an ASC. Of the 5,354 ASCs, 3,786 are non-accredited and 1,568 are accredited. Of the 1,568 accredited ASCs, we estimate that 350 are accredited by The Joint Commission (TJC), 876 by the AAAHC, and additional facilities are accredited by the AOA or the AAAASF. The accreditation standards for these organizations vary in their requirements related to emergency preparedness. The AOA's standards are very similar to the current ASC regulations. AAAASF does have some emergency preparedness requirements, such as requirements for responses or written protocols for security emergencies, for example, intruders and other threats to staff or patients; power failures; transferring patients; and emergency evacuation of the facility. However, the accreditation standards for both the AOA and AAAASF would not significantly satisfy the ICRs contained in this proposed rule. Therefore, for the purpose of determining the burden imposed on ASCs by this proposed rule, we will include the ASCs that are accredited by both the AOA and AAAASF with the non-accredited ASCs.

TJC and AAAHC's accreditation standards contain more extensive emergency preparedness requirements than the accreditation standards of either AOA or AAAASF. For example, TJC standards contain requirements for risk assessments and an emergency management plan. AAAHC's standards include requirements for both internal and external emergencies and drills for the facility's internal emergency plan.

Therefore, in discussing the individual burden requirements in this proposed rule, we will discuss the burden for the estimated 1,226 accredited ASCs by either the AAHC or TJC (876 AAAHC-accredited ASCs + 350 TJC-accredited ASCs = 1,226 ASCs accredited by TJC or AAAHC) separately from the remaining 4,128 (ASCs that are not accredited by an accrediting organization or accredited by the AOA and AAAASF). For some requirements, only the TJC accreditation standards are significantly like those in the proposed rule. For those requirements, we will analyze the 350 TJC-accredited ASCs separately from the 5,004 non TJC-accredited ASCs (5,354 ASCs—350 TJC-accredited ASCs = 5,004 non TJC-accredited ASCs).

For the purpose of determining the burden for the TJC-accredited ASCs, we used TJC's Comprehensive Accreditation Manual for Ambulatory Care: The Official Handbook 2008 (CAMAC). Concerning the requirement for a risk assessment in proposed § 416.54(a)(1), in the chapter entitled "Management of the Environment of Care" (EC), ASCs are required to conduct comprehensive, proactive risk assessments (CAMAC, CAMAC Refreshed Core, January 2007, (CAMAC), TJC Standard EC.1.10, EP 4, p. EC–9). In addition, ASCs must conduct a hazard vulnerability analysis (HVA) (CAMAC, Standard EC.4.10, EP 1, p. EC–12). The HVA requires the identification of potential emergencies and the effects those emergencies could have on the ASC's operations and the demand for its services (CAMAC, p. EC–12). We expect that TJC-accredited ASCs already conduct a risk assessment that complies with these requirements. If there are any tasks these ASCs need to complete to satisfy the requirement for a risk assessment, we expect that the burden imposed by this proposed requirement would be negligible. For the 350 TJC-accredited ASCs, the risk assessment requirement would constitute a usual and customary business practice. While this requirement is subject to the PRA, we expect that complying with this requirement would constitute a usual and customary business practice as defined at 5 CFR 1320.3(b)(2). Therefore, we have not estimated the amount of regulatory burden.

For the purpose of determining the burden for the 876 AAAHC-accredited ASCs, we used the Accreditation Handbook for Ambulatory Health Care 2008 (AHAHC). The AAAHC standards do not contain a specific requirement for the ASC to perform a risk assessment. However, in discussing the requirement for drills, the AAAHC notes that such drills should be appropriate to the facility's activities and environment (AHAHC, Accreditation Association for Ambulatory Health Care, Inc., Core Standards, Chapter 8. Facilities and Environment, Element E, p. 37). Therefore, we expect that in fulfilling this core standard that the 876 AAAHC-accredited ASCs have performed some type of risk assessment. However, we do not expect that this would satisfy the requirement for a documented, facility-based and community-based risk assessment that addressed the elements required for the emergency plan. Therefore, the 876 AAAHC-accredited ASCs would be included in the burden analysis with the ASCs that are non-accredited or are accredited by AOA and AAAASF for the risk assessment requirement for 5,004 non TJC-accredited ASCs (5,354 total ASCs–350 TJC-accredited ASCs = 5,004 non TJC-accredited ASCs).

We expect that all ASCs have already performed at least some of the work needed for a risk assessment. However, many probably have not performed a thorough risk assessment. Therefore, we expect that all non TJC-accredited ASCs would perform thorough reviews of their current risk assessments, if they have them, and revise them to ensure they have updated the assessments and that they have included all of the requirements in proposed § 416.54(a).

We have not designated any specific process or format for ASCs to use in conducting their risk assessments because we believe that ASCs, as well as other health care providers and suppliers, need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect health care facilities to, at a minimum, include input from all of their major departments in the process of developing their risk assessments. Based on our experience working with ASCs, we expect that conducting the risk assessment would require the involvement of an administrator and a quality improvement nurse. We expect that to comply with the requirements of this subsection, both of these individuals would need to attend an initial meeting, review the current assessment, prepare their comments, attend a follow-up meeting, perform a final review, and approve the risk assessment. In addition, we expect that the quality improvement nurse would coordinate the meetings; perform an initial review of the current risk assessment; provide suggestions or a critique of the risk assessment; coordinate comments; revise the original risk assessment; develop any necessary sections for the risk assessment; and ensure that the appropriate parties approve the new risk assessment. We estimate that complying with this risk assessment requirement would require 8 burden hours for each ASC at a cost of $477. Based on that estimate, it would require 40,032 burden hours (8 burden hours for each ASC × 5,004 non TJC-accredited ASCs = 40,032 burden hours) for all non TJC-accredited ASCs to comply with this risk assessment requirement at a cost of $2,386,908 ($477 estimated cost for each ASC × 5,004 ASCs = $2,386,908 estimated cost).

After conducting the risk assessment, ASCs would be required to develop and maintain emergency preparedness plans in accordance with § 416.54(a)(1) through (4). All TJC-accredited ASCs must already comply with many of the requirements in proposed § 416.54(a). All TJC-accredited ASCs are already required to develop and maintain a "written emergency management plan describing the process for disaster readiness and emergency management" (CAMAC, Standard EC.4.10, EP 3, EC–13). We expect that the TJC-accredited ASCs already have emergency preparedness plans that comply with these requirements. If there are any activities required to comply with these requirements, we expect that the burden would be negligible. Thus, for 350 TJC-accredited ASCs, this requirement would constitute a usual and customary business practice for these ASCs in accordance with 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis for those ASCs.

AAAHC-accredited ASCs are required to have a "comprehensive emergency plan to address internal and external emergencies" (AHAC, Chapter 8. Facilities and Environment, Element D, p. 37). However, we do not believe that this requirement ensures compliance with all of the requirements for an emergency plan. We will include the 876 AAAAHC-accredited ASCs in the burden analysis for this requirement.

We expect that the 5,004 non TJC-accredited ASCs have developed some type of emergency preparedness plan. However, under this proposed rule, all of these ASCs would have to review their current plans and compare them to the risk assessments they performed in accordance with proposed § 416.54(a)(1). The ASCs would then need to update, revise, and in some cases, develop new sections to ensure that their plans incorporate their risk assessments and address all of the proposed requirements. The ASC would also need to review, revise, and, in some

cases, develop the delegations of authority and succession plans that ASCs determine are necessary for the appropriate initiation and management of their emergency preparedness plans.

The burden associated with this requirement would be the time and effort necessary to develop an emergency preparedness plan that complies with all of the requirements in proposed § 416.54(a)(1) through (4). Based upon our experience with ASCs, we expect that the administrator and the quality improvement nurse who would be involved in the risk assessment would also be involved in developing the emergency preparedness plan. We estimate that complying with this requirement would require 11 burden hours for each ASC at a cost of $653. Therefore, based on that estimate, for the 5,004 non TJC-accredited ASCs to comply with the requirements in this section would require burden hours (11 burden hours for each non TJC-accredited ASC × 5,004 non TJC-accredited ASCs = 55,044 burden hours) at a cost of $3,267,612 ($653 estimated cost for each non TJC-accredited ASC × 5,004 non TJC-accredited ASCs = $3,267,612).

All of the ASCs would also be required to review and update their emergency preparedness plans at least annually. For the purpose of determining the burden for this requirement, we would expect that ASCs would review their plans annually. All ASCs have a professional staff person, generally a quality improvement nurse, whose responsibility entails ensuring that the ASC is delivering quality patient care and that the ASC is complying with regulations concerning patient care. We expect that the quality improvement nurse would be primarily responsible for the annual review of the ASC's emergency preparedness plan. We expect that complying with this requirement would constitute a usual and customary business practice for ASCs in accordance with 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis.

Section 416.54(b) proposes that each ASC be required to develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan set forth in paragraphs (c) of this section. We would require ASCs to review and update these policies and procedures at least annually. These policies and procedures would be required to include, at a minimum, the requirements listed at § 416.54(b)(1) through (7). We expect that ASCs would develop emergency preparedness policies and procedures based upon their risk assessments, emergency preparedness plans, and communication plans. Therefore, ASCs would need to thoroughly review their emergency preparedness policies and procedures and compare them to all of the information previously noted. The ASCs would then need to revise, or in some cases, develop new policies and procedures that would ensure that the ASCs' emergency preparedness plans address the specific proposed elements.

The TJC accreditation standards already require many of the specific elements that are required in this subsection. For example, in the chapter entitled "Leadership" (LD), TJC-accredited ASCs are required to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMAC, Standard LD.3.90, EP 1, p. LD–12a). In addition, TJC-accredited ASCs must already address or perform a HVA; processes for communicating with and assigning staff under emergency conditions; provision of subsistence or critical needs; evacuation of the facility; and alternate sources for fuel, water, electricity, etc. (CAMAC, Standard EC.4.10, EPs 1, 7–10, 12, and 20, pp. EC–12–13). They must also critique their drills and modify their emergency management plans in response to the critiques (CAMAC, Standard EC.4.20, EPs 12–16, pp. EC–14–14a). In the chapter entitled, "Management of Information" (IM), they are required to protect and preserve the privacy and confidentiality of sensitive data (CAMAC, Standard IM.2.10, EPs 1 and 9, p. IM–6). If TJC-accredited ASCs have any tasks required to satisfy these requirements, we expect they would constitute only a negligible burden. For the 350 TJC-accredited ASCs, the requirement for emergency preparedness policies and procedures would constitute a usual and customary business practice in accordance with 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis for these 350 TJC-accredited ASCs.

AAAHC standards require ASCs to have "the necessary personnel, equipment and procedures to handle medical and other emergencies that may arise in connection with services sought or provided" (AHAHC, Chapter 8. Facilities and Environment, Element B, p. 37). Although, we expect that AAAHC-accredited ASCs probably already have policies and procedures that address at least some of the requirements, we expect that they will sustain a considerable burden in satisfying all of the requirements. We will include the AAAHC-accredited ASCs with the non-accredited ASCs in determining the burden for the requirements in proposed § 416.54(b).

We expect that all of the 5,004 non TJC-accredited ASCs have some emergency preparedness policies and procedures. However, we expect that all of these ASCs would need to review their policies and procedures and revise their policies and procedures to ensure that they address all of the proposed requirements. We expect that the quality improvement nurse would initially review the ASC's emergency preparedness policies and procedures. The quality improvement nurse would send any recommendations for changes or additional policies or procedures to the ASC's administrator. The administrator and quality improvement nurse would need to make the necessary revisions and draft any necessary policies and procedures. We estimate that for each non TJC-accredited ASC to comply with this proposed requirement would require 9 burden hours at a cost of $505. For all 5,004 ASCs to comply with this requirement would require an estimated 45,036 burden hours (9 burden hours for each non TJC-accredited ASC × 5,004 non TJC-accredited ASCs = 45,036) at a cost of $2,527,020. ($505 estimated cost for each non TJC-accredited ASC × 5,004 ASCs = $2,527,020 estimated cost).

Proposed § 416.54(c) would require each ASC to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. We also propose that ASCs would have to review and update these plans at least annually. These communication plans would have to include the information listed in § 416.54(c)(1) through (7). The burden associated with developing and maintaining an emergency preparedness communication plan would be the time and effort necessary to review, revise, and, if necessary, develop new sections for the ASC's emergency preparedness communications plan to ensure that it satisfied these requirements.

The TJC-accredited ASCs are required to have a plan that "identifies backup internal and external communication systems in the event of failure during emergencies" (CAMAC, Standard EC.4.10, EP 18, p. EC–13). There are also requirements for identifying, notifying, and assigning staff, as well as notifying external authorities (CAMAC, Standard EC.4.10, EPs 7–9, p. EC–13). In addition, the facility's plan must provide for controlling information about patients

(CAMAC, Standard EC.4.10, EP 10, p. EC–13). If any revisions or additions are necessary to satisfy the proposed requirements, we expect the revisions or additions would be those incurred during the course of normal business and thereby impose no additional burden. Thus, for the TJC-accredited ASCs, the proposed requirements for the emergency preparedness communication plan would constitute a usual and customary business practice for ASCs as stated in 5 CFR 1320.3(b)(2). Thus, we will not include this activity by these TJC-accredited ASCs in the burden analysis.

The AAAHC standards do not have a specific requirement for a communication plan for emergencies. However, AAAHC-accredited ASCs are required to have the "necessary personnel, equipment and procedures to handle medical and other emergencies that may arise in connection with services sought or provided (AAAHC, 8. Facilities and Environment, Element B, p. 37) and "a comprehensive emergency plan to address internal and external emergencies" (AAAHC, 8. Facilities and Environment, Element D, p. 37). Since communication is vital to any ASC's operations, we expect that communications would be included in the AAAHC-accredited ASC's plans and procedures. However, we do not believe that these requirements ensure that the AAAHC-accredited ASCs are already fully satisfying all of the requirements. Therefore, we will include the AAAHC-accredited ASCs in with the non-accredited ASCs in determining the burden for these requirements for a total of 5,004 non TJC-accredited ASCs (5,354 total ASCs—350 TJC-accredited ASCs).

We expect that all non TJC-accredited ASCs currently have some type of emergency preparedness communication plan. It is standard practice in the health care industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. We expect that all ASCs already satisfy the requirements in proposed § 416.54(c)(1) through (4). However, for the requirements in proposed § 416.54(c)(5) through (7), all ASCs would need to review, revise, and, if necessary, develop new sections for their plans to ensure that they include all of the proposed requirements. We expect that this would require the involvement of the ASC's administrator and a quality improvement nurse. We estimate that complying with this proposed requirement would require 4 burden hours at a cost of $227. Therefore, for all non TJC-accredited ASCs to comply with the requirements in this section would require an estimated 20,016 burden hours (4 hours for each non TJC-accredited ASC × 5,004 non TJC-accredited ASCs = 20,016 burden hours) at a cost of $1,135,908 ($227 estimated cost for each non TJC-accredited ASC × 5,004 non TJC-accredited ASCs = $1,135,908 estimated cost).

We also propose that ASCs must review and update their emergency preparedness communication plans at least annually. We believe that ASCs already review their emergency preparedness communication plans periodically. Therefore, complying with this requirement would constitute a usual and customary business practice for ASCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 416.54(d) would require ASCs to develop and maintain emergency preparedness training and testing programs that ASCs must review and update at least annually. Specifically, ASCs must meet the requirements listed at proposed § 416.54(d)(1) and (2).

The burden associated with complying with these requirements would be the time and effort necessary for an ASC to review, update, and, in some cases, develop new sections for its emergency preparedness training program. We expect that all ASCs already provide training on their emergency preparedness policies and procedures. However, all ASCs would need to review their current training and testing programs and compare their contents to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans.

Proposed § 416.54(d)(1) would require ASCs to provide initial training in their emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. ASCs would have to ensure that their staff can demonstrate knowledge of emergency procedures. Thereafter, ASCs would have to provide the training at least annually. TJC-accredited ASCs must provide an initial orientation to their staff and independent practitioners (CAMAC, Standard 2.10, HR–8). They must also provide "on-going education, including in-services, training, and other activities" to maintain and improve staff competence (CAMAC, Standard 2.30, HR–9). We expect that these TJC-accredited ASCs include some training on their facilities' emergency preparedness policies and procedures in their current training programs. However, these requirements do not contain any requirements for training volunteers. Thus, TJC accreditation standards do not ensure that TJC-accredited ASCs are already fulfilling all of the proposed requirements, and we expect that the TJC-accredited ASCs will incur a burden complying with these requirements. Therefore, we will include these TJC-accredited ASCs in determining the burden for these requirements.

The AAAHC-accredited ASCs are already required to ensure that "all health care professionals have the necessary and appropriate training and skills to deliver the services provided by the organization" (AAAHC, Chapter 4. Quality of Care Provided, Element A, p. 28). Since these ASCs are required to have an emergency plan that addresses internal and external emergencies, we expect that all of the AAAHC-accredited ASCs already are providing some training on their emergency preparedness policies and procedures. However, this requirement does not include any requirement for annual training or for any training for staff that are not health care professionals. This AAAHC-accredited requirement does not ensure that these ASCs are already complying with the proposed requirements. Therefore, we will include these AAAHC-accredited ASCs in determining the information collection burden for these requirements.

Based upon our experience with ASCs, we expect that all 5,354 ASCs have some type of emergency preparedness training program. We also expect that these ASCs would need to review their training programs and compare them to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. The ASCs would then need to make any necessary revisions to their training programs to ensure they comply with these requirements. We expect that complying with this requirement would require the involvement of an administrator and a quality improvement nurse. We estimate that for each ASC to develop a comprehensive emergency training program would require 6 burden hours at a cost of $329. Therefore, the estimated annual burden for all 5,354 ASCs to comply with these requirements is 32,124 burden hours (6

burden hours × 5,354 ASCs =32,124 burden hours) at a cost of $1,761,466 ($329 estimated cost for each ASC × 5,354 ASCs = $1,761,466 estimated cost).

We propose that ASCs would also have to review and update their emergency preparedness training programs at least annually. For the purpose of determining the burden for this requirement, we would expect that ASCs would review their emergency preparedness training program annually. We expect that all ASCs have a quality improvement nurse responsible for ensuring that the ASC is delivering quality patient care and that the ASC is complying with patient care regulations. We expect that the quality improvement nurse would be primarily responsible for the annual review of the ASC's emergency preparedness training program. Thus, complying with this requirement would constitute a usual and customary business practice for ASCs in accordance with 5 CFR 1320.3(b)(2). Thus, we will not include this activity in this burden analysis.

Proposed § 416.54(d)(2) would require ASCs to participate in a community mock disaster drill and, if one was not available, conduct an individual, facility-based mock disaster drill, at least annually. ASCs would also have to conduct a paper-based, tabletop exercise at least annually. If the ASC experiences an actual natural or man-made emergency that requires activation of their emergency plan, the ASC would be exempt from the requirement for a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. ASCs would also be required to analyze their response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, ASCs would need to develop a scenario for each drill and exercise. ASCs would also need to develop the documentation necessary for recording what happened during drills, exercises, and emergency events and analyze their responses to these events.

TJC-accredited ASCs are required to regularly test their emergency management plans at least twice a year, critique each exercise, and modify their emergency management plans in response to those critiques (CAMAC, Standard EC.4.20, EP 1 and 12–16, p. EC–14–14a). In addition, the scenarios for these drills should be realistic and related to the priority emergencies the ASC identified in its HVA (CAMAC, Standard EC.4.20, EP 5, p. EC–14). However, the EPs for this standard do not contain any requirements for the drills to be community-based; for there to be a paper-based, tabletop exercise; or for the ASCs to maintain documentation of these drills, exercises, or emergency events. These TJC accreditation requirements do not ensure that TJC-accredited ASCs are already complying with these requirements. Therefore, the TJC-accredited ASCs will be included in the burden estimate.

The AAAHC-accredited ASCs already are required to perform at least four drills annually of their internal emergency plans (AAAHC, Chapter 8. Facilities and Environment, Element E, p. 37). However, there is no requirement for a paper-based, tabletop exercise; for a community-based drill; or for the ASCs to maintain documentation of their drills, exercises, or emergency events. This AAAHC accreditation requirement does not ensure that AAAHC-accredited ASCs are already complying with these requirements. Therefore, the AAAHC-accredited ASCs will be included in the burden estimate.

Based on our experience with ASCs, we expect that all of the 5,354 ASCs would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the documentation necessary to record and analyze these events, as well as any emergency events. Although we believe many ASCs may have developed scenarios and documentation for whatever type of drills or exercises they had previously performed, we expect all ASCs would need to ensure that the testing of their emergency preparedness plans comply with these requirements. Based upon our experience with ASCs, we expect that complying with this requirement would require the involvement of an administrator and a quality improvement nurse. We estimate that for each ASC to comply would require 5 burden hours at a cost of $278. Therefore, for all 5,354 ASCs to comply with this requirement would require an estimated 26,770 burden hours (5 burden hours for each ASC × 5,354 ASCs = 26,770 burden hours) at a cost of $1,488,412 ($278 estimated cost for each ASC × 5,354 ASCs = $1,488,412 estimated cost).

TABLE 3—BURDEN HOURS AND COST ESTIMATES FOR ALL 5,354 ASCS TO COMPLY WITH THE ICRS CONTAINED IN § 416.54 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 416.54(a)(1)	0938—New	5,004	5,004	8	40,032	**	2,386,908	0	2,386,908
§ 416.54(a)(1)–(4)	0938—New	5,004	5,004	11	55,044	**	3,267,612	0	3,267,612
§ 416.54(b)	0938—New	5,004	5,004	9	45,036	**	2,527,020	0	2,527,020
§ 416.54(c)	0938—New	5,004	5,004	4	20,016	**	1,135,908	0	1,135,908
§ 416.54(d)(1)	0938—New	5,354	5,354	6	32,124	**	1,758,176	0	1,758,176
§ 416.54(d)(2)	0938—New	5,354	5,354	5	26,770	**	1,488,412	0	1,488,412
Totals		5,354	30,724		219,022				12,564,036

** The hourly labor cost is blended between the wages for multiple staffing levels.

E. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 418.113)

Proposed § 418.113(a) would require hospices to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We propose that the plan meet the criteria listed in proposed § 418.113(a)(1) through (4).

Although proposed § 418.113(a) is entitled "Emergency Plan" and the requirement for the plan is stated first, the emergency plan must include and be based upon a risk assessment. Therefore, since hospices must perform their risk assessments before beginning, or at least before they complete, their plans, we will discuss the burden related to performing the risk assessment first.

Proposed § 113(a)(1) would require all hospices to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. We expect that in performing a risk assessment, a hospice would need to consider its physical location, the geographic area in which it is located, and its patient population.

The burden associated with this requirement would be the time and effort necessary to perform a thorough

risk assessment. There are 3,773 hospices. There are 2,584 hospices that provide care only to patients in their homes and 1,189 hospices that offer inpatient care directly (inpatient hospices). When we use the term "inpatient hospice," we are referring to a hospice that operates its own inpatient care facility; that is, the hospice provides the inpatient care itself. By "outpatient hospices", we are referring to hospices that only provide in-home care, and contract with other facilities to provide inpatient care. The current requirements for hospices contain emergency preparedness requirements for inpatient hospices only (42 CFR 418.110). Inpatient hospices must have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care," as stated in 42 CFR 418.110(c)(1)(ii). Thus, we expect inpatient hospices already have performed some type of risk assessment during the process of developing their disaster preparedness plan. However, these risk assessments may not be documented or may not address all of the requirements under proposed § 418.113(a). Therefore, we believe that all inpatient hospices would have to conduct a thorough review of their current risk assessments and then perform the necessary tasks to ensure that their facilities' risk assessments comply with these requirements.

We have not designated any specific process or format for hospices to use in conducting their risk assessments because we believe hospices need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we believe that in the process of developing a risk assessment, health care institutions should include representatives from or obtain input from all of their major departments. Based on our experience with hospices, we expect that conducting the risk assessment would require the involvement of the hospice's administrator and an interdisciplinary group (IDG). The current Hospice CoPs require every hospice to have an IDG that includes a physician, registered nurse, social worker, and pastoral or other counselor. The responsibilities of one of a hospice's IDGs, if they have more than one, include the establishment of "policies governing the day-to-day provision of hospice care and services" (42 CFR 418.56(a)(2)). Thus, we believe the IDG would be involved in performing the risk assessment.

We expect that members of the IDG would attend an initial meeting; review any existing risk assessment; develop comments and recommendations for changes to the assessment; attend a follow-up meeting; perform a final review; and approve the risk assessment. We expect that the administrator would coordinate the meetings, perform an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary staff approves the new risk assessment. We believe it is likely that the administrator would spend more time reviewing and working on the risk assessment than the other individuals in the IDG. We estimate it would require 10 burden hours to review and update the risk assessment at a cost of $496. There are 1,189 inpatient hospices. Therefore, based on that estimates, it would require 11,890 burden hours (10 burden hours for each inpatient hospice × 1,189 inpatient hospices 11,890 burden hours) for all inpatient hospices to comply with this requirement at a cost of $589,744 ($496 estimated cost for each inpatient hospice × 1,189 inpatient hospices = $589,744 estimated cost).

There are no emergency preparedness requirements in the current hospice CoPs for hospices that provide care to patients in their homes. However, it is standard practice for health care facilities to plan and prepare for common emergencies, such as fires, power outages, and storms. Although we expect that these hospices have considered at least some of the risks they might experience, we anticipate that these facilities would require more time than an inpatient hospice to perform a risk assessment. We estimate that each hospice that provides care to patients in their homes would require 12 burden hours to develop its risk assessment at a cost of $593. Therefore, based on that estimate, for all 2,584 hospices that provide care to patients in their homes, it would require 31,008 burden hours (12 burden hours for each hospice × 2,584 hospices = 31,008 burden hours) to comply with this requirement at a cost of $1,532,312 ($593 estimated cost for each hospice × 2,584 hospices = $1,532,312 estimated cost). Based on the previous calculations, we estimate that for all 3,773 hospices to develop a risk assessment would require 42,898 burden hours at a cost of $2,122,056.

After conducting the risk assessments, hospices would have to develop and maintain emergency preparedness plans that they would have to review and update at least annually. We expect all hospices to compare their current emergency plans, if they have them, to the risk assessments they performed in accordance with proposed § 418.113(a)(1). In addition, hospices would have to comply with the requirements in § 418.113(a)(1) through (4). They would then need to review, revise, and, if necessary, develop new sections of their plans to ensure they comply with these requirements.

The current hospice CoPs require inpatient hospices to have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care" (42 CFR 418.110(c)(1)(ii)). We believe that all inpatient hospices already have some type of emergency preparedness or disaster plan. However, their plans may not address all likely medical and non-medical emergency events identified by the risk assessment. Further, their plans may not include strategies for addressing likely emergency events or address their patient population; the type of services they have the ability to provide in an emergency; or continuity of operations, including delegations of authority and succession plans. We expect that an inpatient hospice would have to review its current plan and compare it to its risk assessment, as well as to the other requirements we propose. We expect that most inpatient hospices would need to update and revise their existing emergency plans, and, in some cases, develop new sections to comply with our proposed requirements.

The burden associated with this proposed requirement would be the time and effort necessary to develop an emergency preparedness plan or to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with inpatient hospices, we expect that these activities would require the involvement of the hospice's administrator and an IDG, that is, a physician, registered nurse, social worker, and counselor. We believe that developing the plan would require more time to complete than the risk assessment.

We expect that these individuals would have to attend an initial meeting, review relevant sections of the facility's current emergency preparedness or disaster plan(s), develop comments and recommendations for changes to the facility's plan, attend a follow-up meeting, perform a final review, and approve the emergency plan. We expect

that the administrator would probably coordinate the meetings, perform an initial review of the current emergency plan, provide a critique of the emergency plan, offer suggested revisions, coordinate comments, develop the new emergency plan, and ensure that the necessary parties approve the new emergency plan. We expect the administrator would probably spend more time reviewing and working on the emergency plan than the other individuals. We estimate that it would require 14 burden hours for each inpatient hospice to develop its emergency preparedness plan at a cost of $742. Based on this estimate, it would require 16,646 burden hours (14 burden hours for each inpatient hospice × 1,189 inpatient hospices = 16,646 burden hours) for all inpatient hospices to complete their plans at a cost of $882,238 ($742 estimated cost for each inpatient hospice × 1,189 inpatient hospices = $882,238 estimated cost).

As discussed earlier, we have no current regulatory requirement for hospices that provide care to patients in their homes to have emergency preparedness plans. However, it is standard practice for health care providers to plan for common emergencies, such as fires, power outages, and storms. Although we expect that these hospices already have some type of emergency or disaster plan, each hospice would need to review its emergency plan to ensure that it addressed the risks identified in its risk assessment and complied with the proposed requirements. We expect that an administrator and the individuals from the hospice's IDG would be involved in reviewing, revising, and developing a facility's emergency plan. However, since there are no current requirements for hospices that provide care to patients in their homes have emergency plans, we believe it would require more time for each of these hospices than for inpatient hospices to complete an emergency plan. We estimate that for each hospice that provides care to patients in their homes to comply with this proposed requirement would require 20 burden hours at an estimated cost of $1,046. Based on that estimate, for all 2,584 of these hospices to comply with this requirement would require 51,680 burden hours (20 burden hours for each hospice × 2,584 hospices = 51,680 burden hours) at a cost of $2,702,864 ($1,046 estimated cost for each hospice × 2,584 hospices = $2,702,864 estimated cost). We estimate that for all 3,773 hospices to develop an emergency preparedness plan would require 68,326 burden hours at a cost of $3,585,102.

Hospices would also be required to review and update their emergency preparedness plans at least annually. The current hospice CoPs require inpatient hospices to periodically review and rehearse their disaster preparedness plan with their staff, including non-employee staff (42 CFR 418.110(c)(1)(ii)). For purposes of this burden estimate, we would expect that under this proposed rule, inpatient hospices would review their emergency plans prior to reviewing them with all of their employees and that this review would occur annually.

We expect that all hospices, both inpatient and those that provide care to patients in their homes, have an administrator who is responsible for the day-to-day operation of the hospice. Day-to-day operations would include ensuring that all of the hospice's plans are up-to-date and in compliance with relevant federal, state, and local laws, regulations, and ordinances. In addition, it is standard practice in health care organizations to have a professional employee, generally an administrator, who periodically reviews their plans and procedures. We expect that complying with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2). Thus, we will not include this activity in the burden analysis.

Proposed § 418.113(b) would require each hospice to develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. It would also require hospices to review and update these policies and procedures at least annually. At a minimum, the hospice's policies and procedures would be required to address the requirements listed at § 418.113((b)(1) through (6).

We expect that all hospices have some emergency preparedness policies and procedures because the current hospice CoPs for inpatient hospices already require them to have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care" (42 CFR 418.110(c)(1)(ii)). In addition, the responsibilities for at least one of a hospice's IDGs, if they have more than one, include the establishment of "policies governing the day-to-day provision of hospice care and services" (42 CFR 418.56(a)(2)). However, we also expect that all inpatient hospices would need to review their current policies and procedures, assess whether they contain everything required by their facilities' emergency preparedness plans, and revise and update them as necessary.

The burden associated with reviewing, revising, and updating a hospice's emergency policies and procedures would be the resources needed to ensure they comply with these requirements. Since at least one of a hospice's IDGs would be responsible for developing policies that govern the daily care and services for hospice patients (42 CFR 418.56(a)(2)), we expect that an IDG would be involved with reviewing and revising a hospice's existing policies and procedures and developing any necessary new policies and procedures. We estimate that an inpatient hospice's compliance with this requirement would require 8 burden hours at a cost of $399. Therefore, based on that estimate, all 1,189 inpatient hospices' compliance with this requirement would require 9,512 burden hours (8 burden hours for each inpatient hospice × 1,189 inpatient hospices = 9,512 burden hours) at a cost of $474,411 ($399 estimated cost for each inpatient hospice × 1,189 inpatient hospices = $474,411 estimated cost).

Although there are no existing regulatory requirements for hospices that provide care to patients in their homes to have emergency preparedness policies and procedures, it is standard practice for health care organizations to prepare for common emergencies, such as fires, power outages, and storms. We expect that these hospices already have some emergency preparedness policies and procedures. However, under this proposed rule, the IDG for these hospices would need to accomplish the same tasks as described earlier for inpatient hospices to ensure that these policies and procedures comply with the proposed requirements.

We estimate that each hospice's compliance with this requirement would require 9 burden hours at a cost of $454. Therefore, based on that estimate, all 2,584 hospices' that provide care to patients in their homes to comply with this requirement would require 23,256 burden hours (9 burden hours for each hospice × 2,584 hospices = 23,256 burden hours) at a cost of $1,173,136 ($454 estimated cost for each hospice × 2,584 hospices = $1,173,136 estimated cost).

Thus, we estimate that development of emergency preparedness policies and procedures for all 3,773 hospices would

require 32,768 burden hours at a cost of $1,647,547.

Proposed § 418.113(c) would require a hospice to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. Hospices would also have to review and update their plans at least annually. The communication plan would have to include the requirements listed at § 418.113(c)(1) through (7).

We believe that all hospices already have some type of emergency preparedness communication plan. Although only inpatient hospices have a current requirement for disaster preparedness (42 CFR 418.110(c)), it is standard practice for health care organizations to maintain contact information for their staff and for outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the organization (for example, cell phones); and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many hospices, both inpatient hospices and hospices that provide care to patients in their homes, may not have formal, written emergency preparedness communication plans. We expect that all hospices would need to review, update, and in some cases, develop new sections for their plans to ensure that those plans include all of the elements we propose requiring for hospice communication plans.

The burden associated with complying with this requirement would be the resources required to ensure that the hospice's emergency communication plan complied with these requirements. Based upon our experience with hospices, we anticipate that satisfying these requirements would require only the involvement of the hospice's administrator. Thus, for each hospice, we estimate that complying with this requirement would require 3 burden hours at a cost of $165. Therefore, based on that estimate, compliance with this requirement for all 3,773 hospices would require 11,319 burden hours (3 burden hours for each hospice × 3,773 hospices = 11,319 burden hours) at a cost of $622,545 ($165 estimated cost for each hospice × 3,773 hospices = $622,545 estimated cost).

We are proposing that a hospice review and update its emergency preparedness communication plan at least annually. We believe that all hospices already review their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for hospices and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 418.113(d) would require each hospice to develop and maintain an emergency preparedness training and testing program that would be reviewed and updated at least annually. Proposed § 418.113(d)(1) would require hospices to provide initial training in emergency preparedness policies and procedures to all hospice employees, consistent with their expected roles, and maintain documentation of the training. The hospice would also have to ensure that their employees could demonstrate knowledge of their emergency procedures. Thereafter, the hospice would have to provide emergency preparedness training at least annually. Hospices would also be required to periodically review and rehearse their emergency preparedness plans with their employees, with special emphasis placed on carrying out the procedures necessary to protect patients and others.

Under current regulations, all hospices are required to provide an initial orientation and in-service training and educational programs, as necessary, to each employee (§ 418.100(g)(2) and (3)). They must also provide employee orientation and training consistent with hospice industry standards (42 CFR 418.78(a)). In addition, inpatient hospices must periodically review and rehearse their disaster preparedness plans with their staff, including non-employee staff (42 CFR 418.110(c)(1)(ii)). We expect that all hospices already provide training to their employees on the facility's existing disaster plans, policies, and procedures. However, under this proposed rule, all hospices would need to review their current training programs and compare their contents to their updated emergency preparedness plans, policies and procedures, and communications plans. Hospices would then need to review, revise, and in some cases, develop new material for their training programs so that they complied with these requirements.

The burden associated with the aforementioned requirements would be the time and effort necessary for a hospice to bring itself into compliance with the requirements in this section. We expect that compliance with this requirement would require the involvement of a registered nurse. We expect that the registered nurse would compare the hospice's current training program with the facility's emergency preparedness plan, policies and procedures, and communication plan, and then make any necessary revisions, including the development of new training material, as needed. We estimate that these tasks would require 6 burden hours at a cost of $252. Based on this estimate, compliance by all 3,773 hospices would require 22,638 burden hours (6 burden hours for each hospice × 3,773 hospices = 22,638 burden hours) at a cost of $950,796 ($252 estimated cost for each hospice × 3,773 hospices = $950,796 estimated cost).

We are proposing that hospices also be required to review and update their emergency preparedness training programs at least annually. We believe that hospices already review their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for hospices and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 418.113(d)(2) would require hospices to participate in a community mock disaster drill, and if one were not available, conduct an individual, facility-based mock disaster drill, and a paper-based, tabletop exercise at least annually. Hospices would also be required to analyze their responses to and maintain documentation of all their drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, a hospice would need to develop scenarios for their drills and exercises. A hospice also would have to develop the required documentation.

Hospices would also have to periodically review and rehearse their emergency preparedness plans with their staff (including nonemployee staff), with special emphasis on carrying out the procedures necessary to protect patients and others (§ 418.110(c)(1)(ii)). However, this periodic rehearsal requirement does not ensure that hospices are performing any type of drill or exercise annually or that they are documenting their responses. In addition, there is no requirement in the current CoPs for outpatient hospices to have an emergency plan or for these hospices to test any emergency procedures they may currently have. We believe that developing the scenarios for these drills and exercises and the documentation necessary to record the events during drills, exercises, and emergency events would be new requirements for all hospices.

The associated burden would be the time and effort necessary for a hospice to comply with these requirements. We expect that complying with these

requirements would require the involvement of a registered nurse. We expect that the registered nurse would develop the necessary documentation and the scenarios for the drills and exercises. We estimate that these tasks would require 4 burden hours at an estimated cost of $168. Based on this estimate, in order for all 3,773 hospices to comply with these requirements, it would require 15,092 burden hours (4 burden hours for each hospice × 3,773 hospices = 15,092 burden hours) at a cost of $633,864 ($168 estimated cost for each hospice × 3,773 hospices = $633,864 estimated cost).

Thus, for all 3,773 hospices to comply with all of the requirements in § 418.113, it would require an estimated 193,041 burden hours at a cost of $10,444,148.

TABLE 4—BURDEN HOURS AND COST ESTIMATES FOR ALL 3,773 HOSPICES TO COMPLY WITH THE ICRS IN § 418.113 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 418.113(a)(1) (inpatient)	0938—New	1,189	1,189	10	11,890		589,744		589,744
§ 418.113(a)(1) (outpatient)	0938—New	2,584	2,584	12	31,008		1,532,312		1,532,312
§ 418.113(a)(1)–(4) (inpatient)	0938—New	1,189	1,189	14	16,646		882,238		882,238
§ 418.113(a)(1)–(4) (outpatient)	0938—New	2,584	2,584	20	51,680		2,702,864		2,702,864
§ 418.113(b) (inpatient)	0938—New	1,189	1,189	8	9,512		474,411		474,411
§ 418.113(b) (outpatient)	0938—New	2,584	2,584	9	23,256		1,173,136		1,173,136
§ 418.113(c)	0938—New	3,773	3,773	3	11,319		622,545		622,545
§ 418.113(d)(1)	0938—New	3,773	3,773	6	22,638		950,796		950,796
§ 418.113(d)(2)	0938—New	3,773	3,773	4	15,092		633,864		633,864
Totals		3,773	22,638		193,041				10,444,148

**The hourly labor cost is blended between the wages for multiple staffing levels.

F. ICRs Regarding Emergency Preparedness (§ 441.184)

Proposed § 441.184(a) would require Psychiatric Residential Treatment Facilities (PRTFs) to develop and maintain emergency preparedness plans and review and update those plans at least annually. We propose that these plans meet the requirements listed at § 441.184(a)(1) through (4).

Section § 441.184(a)(1) would require each PRTF to develop a documented, facility-based and community-based risk assessment that would utilize an all-hazards approach. We expect that all PRTFs have already performed some of the work needed for a risk assessment because it is standard practice for health care facilities to prepare for common hazards, such as fires and power outages, and disasters or emergencies common in their geographic area, such as snowstorms or hurricanes. However, many PRTFs may not have documented their risk assessments or performed one that would comply with all of our proposed requirements. Therefore, we expect that all PRTFs would have to review and revise their current risk assessments.

We have not designated any specific process or format for PRTFs to use in conducting their risk assessments because we believe that PRTFs need maximum flexibility to determine the best way to accomplish this task. However, we expect that PRTFs would include representation from or seek input from all of their major departments. Based on our experience with PRTFs, we expect that conducting the risk assessment would require the involvement of the PRTF's administrator, a psychiatric registered nurse, and a clinical social worker. We expect that all of these individuals would attend an initial meeting, review their current assessment, develop comments and recommendations for changes, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the psychiatric registered nurse would coordinate the meetings, perform an initial review, offer suggested revisions, coordinate comments, develop a new risk assessment, and ensure that the necessary parties approve the new risk assessment. We also expect that the psychiatric registered nurse would spend more time reviewing and working on the risk assessment than the other individuals. We estimate that in order for each PRTF to comply, it would require 8 burden hours at a cost of $394. There are currently 387 PRTFs. Therefore, based on that estimate, compliance by all PRTFs would require 3,096 burden hours (8 burden hours for each PRTF × 387 PRTFs = 3,096 burden hours) at a cost of $152,478 ($394 estimated cost for each PRTF × 387 PRTFs = $152,478 estimated cost).

After conducting the risk assessment, § 441.184(a)(1) through (4) would require PRTFs to develop and maintain an emergency preparedness plan. Although it is standard practice for health care facilities to have some type of emergency preparedness plan, all PRTFs would need to review their current plans and compare them to their risk assessments. Each PRTF would need to update, revise, and, in some cases, develop new sections to complete its emergency preparedness plan.

Based upon our experience with PRTFs, we expect that the administrator and psychiatric registered nurse who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect it would require substantially more time to complete the plan than the risk assessment. We expect that the psychiatric nurse would be the most heavily involved in reviewing and developing the PRTF's emergency preparedness plan. We also expect that a clinical social worker would review the drafts of the plan and provide comments on it to the psychiatric registered nurse. We estimate that for each PRTF to comply with this requirement would require 12 burden hours at a cost of $634. Thus, we estimate that it would require 4,644 burden hours (12 burden hours for each PRTF × 387 PRTFs = 4,644 burden hours) for all PRTFs to comply with this requirement at a cost of $245,358 ($634 estimated cost per PRTF × 387 PRTFs = $245,358 estimated cost).

PRTFs also would be required to review and update their emergency preparedness plans at least annually. We believe that PRTFs are already reviewing their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(b) would require each PRTF to develop and implement emergency preparedness policies and procedures, based on their emergency plan set forth in paragraph (a) of this

section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. We also propose requiring PRTFs to review and update these policies and procedures at least annually. At a minimum, we would require that the PRTF's policies and procedures address the requirements listed at § 441.184(b)(1) through (8).

Since we expect that all PRTFs already have some type of emergency plan, we also expect that all PRTFs have some emergency preparedness policies and procedures. However, we expect that all PRTFs would need to review their policies and procedures; compare them to their risk assessments, emergency preparedness plans, and communication plans they developed in accordance with § 441.183(a)(1), (a) and (c), respectively; and then revise their policies and procedures accordingly.

We expect that the administrator and a psychiatric registered nurse would be involved in reviewing and revising the policies and procedures and, if needed, developing new policies and procedures. We estimate that it would require 9 burden hours at a cost of $498 for each PRTF to comply with this requirement. Based on this estimate, it would require 3,483 burden hours (9 burden hours for each PRTF × 387 PRTFs = 3,483 burden hours) for all PRTFs to comply with this requirement at a cost of $192,726 ($498 estimated cost per PRTF × 387 PRTFs = $192,726 estimated cost).

We are also proposing that PRTFs review and update their emergency preparedness policies and procedures at least annually. We believe that PRTFs are already reviewing their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(c) would require each PRTF to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. PRTFs also would have to review and update these plans at least annually. The communication plan would have to include the information set out in § 441.184(c)(1) through (7).

We expect that all PRTFs have some type of emergency preparedness communication plan. It is standard practice for health care facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their residents. However, most PRTFs may not have formal, written emergency preparedness communication plans. Therefore, we expect that all PRTFs would need to review and, if needed, revise their plans.

Based on our experience with PRTFs, we anticipate that satisfying these requirements would require the involvement of the PRTF's administrator and a psychiatric registered nurse to review, revise, and if needed, develop new sections for the PRTF's emergency preparedness communication plan. We estimate that for each PRTF to comply would require 5 burden hours at a cost of $286. Based on that estimate, for all PRTFs to comply would require 1,935 burden hours (5 burden hours for each PRTF × 387 PRTFs = 1,935 burden hours) at a cost of $110,682 ($286 estimated cost for each PRTF × 387 PRTFs = $110,682 estimated cost).

PRTFs must also review and update their emergency preparedness communication plans at least annually. We believe that PRTFs are already reviewing their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(d) would require PRTFs to develop and maintain emergency preparedness training programs and review and update those programs at least annually. Proposed § 441.184(d)(1) would require PRTFs to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The PRTF would also have to ensure that their staff could demonstrate knowledge of the emergency procedures. Thereafter, the PRTF would have to provide emergency preparedness training at least annually.

Based on our experience with PRTFs, we expect that all PRTFs have some type of emergency preparedness training program. However, PRTFs would need to review their current training programs and compare them to their risk assessments and emergency preparedness plans, policies and procedures, and communication plans and update and, in some cases, develop new sections for their training programs.

We expect that complying with this requirement would require the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse would review the PRTF's current training program; determine what tasks would need to be performed and what materials would need to be developed; and develop the necessary materials. We estimate that for each PRTF to comply with the requirements in this section would require 10 burden hours at a cost of $460. Based on this estimate, for all PRTFs to comply with this requirement would require 3,870 burden hours (10 burden hours for each PRTF × 387 PRTFs = 3,870 burden hours) at a cost of $178,020 ($460 estimated cost for each PRTF × 387 PRTFs = $178,020 estimated cost).

PRTFs would also be required to review and update their emergency preparedness training program at least annually. We believe that PRTFs are already reviewing their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(d)(2) would require PRTFs to participate in a community mock disaster drill, and if one were not available, conduct an individual, facility-based mock disaster drill, and a paper-based, tabletop exercise at least annually. PRTFs would also have to analyze their responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. However, if a PRTF experienced an actual natural or man-made emergency that required activation of its emergency plan, that PRTF would be exempt from engaging in a community or an individual, facility-based mock disaster drill for 1 year following the onset of the actual emergency event. To comply with this requirement, PRTFs would need to develop scenarios for each drill and exercise and the documentation necessary to record and analyze drills, exercises, and actual emergency events.

Based on our experience with PRTFs, we expect that all PRTFs have some type of emergency preparedness testing program and most, if not all, PRTFs already conduct some type of drill or exercise to test their emergency preparedness plans. We also expect that they have already developed some type of documentation for drills, exercises,

and emergency events. However, we do not expect that all PRTFs are conducting both a drill and a paper-based, tabletop exercise annually or have developed the appropriate documentation. Thus, we will analyze the burden of these requirements for all PRTFs.

Based on our experience with PRTFs, we expect that the same individual who developed the emergency preparedness training program would develop the scenarios for the drill and the exercise and the accompanying documentation. We estimate that for each PRTF to comply with the requirements in this section would require 3 burden hours at a cost of $138. We estimate that for all PRTFs to comply would require 1,161 burden hours (3 burden hours for each PRTF × 387 PRTFs = 1,161 burden hours) at a cost of $53,406 ($138 estimated cost for each PRTF × 387 PRTFs = $53,406 estimated cost).

Based on the previous analysis, for all 387 PRTFs to comply with the ICRs in this proposed rule would require 18,189 burden hours at a cost of $932,670.

TABLE 5—BURDEN HOURS AND COST ESTIMATES FOR ALL 387 PRTFS TO COMPLY WITH THE ICRS CONTAINED IN § 441.184 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 441.184(a)(1)	0938—New	387	387	8	3,096	**	152,478	0	152,478
§ 441.184(a)(1)–(4)	0938—New	387	387	12	4,644	**	245,358	0	245,358
§ 441.184(b)	0938—New	387	387	9	3,483	**	192,726	0	192,726
§ 441.184(c)	0938—New	387	387	5	1,935	**	110,682	0	110,682
§ 441.184(d)(1)	0938—New	387	387	10	3,870	**	178,020	0	178,020
§ 441.184(d)(2)	0938—New	387	387	3	1,161	**	53,406	0	53,406
Totals		387	2,322		18,189				932,670

G. ICRs Regarding Emergency Preparedness (§ 460.84)

Proposed § 460.84(a) would require the Program for the All-Inclusive Care for the Elderly (PACE) organizations to develop and maintain emergency preparedness plans and review and update those plans at least annually. We propose that each plan must meet the requirements listed at § 460.84(a)(1) through (4).

Section § 460.84(a)(1) would require PACE organizations to develop documented, facility-based and community-based risk assessments utilizing an all-hazards approach. We believe that the performance of a risk assessment is a standard practice, and that all of the PACE organizations have already conducted some sort of risk assessment based on common emergencies the organization might encounter, such as fires, loss of power, loss of communications, etc. Therefore, we believe that each PACE organization should have already performed some sort of risk assessment.

Under the current regulations, PACE organizations are required to establish, implement, and maintain procedures for managing medical and non-medical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public (§ 460.72(c)(1)). The definition of "emergencies" includes natural disasters that are likely to occur in the PACE organization's area (§ 460.72(c)(2)). PACE organizations are required to plan for emergencies involving participants who are in their center(s) at the time of an emergency, as well as participants receiving services in their homes.

For the purpose of determining the burden, we will assume that a PACE organization's risk assessment, emergency plan, policies and procedures, communication plan, and training and testing program would apply to all of a PACE organization's centers. Based on the existing PACE regulations, we expect that they already assess their physical structure(s), the areas in which they are located, and the location(s) of their participants. However, these risk assessments may not be documented or address all of our proposed requirements. Therefore, we expect that all 91 PACE organizations would have to review, revise, and update their current risk assessments.

We have not designated any specific process or format for PACE organizations to use in conducting their risk assessments because we believe that they would be able to determine the best way for their facilities to accomplish this task. However, we expect that they would include representation or input from all of their major departments. Based on our experience with PACE organizations, we expect that conducting the risk assessment would require the involvement of the PACE organization's program director, medical director, home care coordinator, quality improvement nurse, social worker, and a driver. We expect that these individuals would either attend an initial meeting or be asked to individually review relevant sections of the current risk assessment and prepare and forward their comments to the quality assurance nurse. After initial comments are received, some would attend a follow-up meeting, perform a final review, and ensure the new risk assessment was approved by the appropriate individuals. We expect that the quality improvement nurse would coordinate the meetings, review the current risk assessment, suggest revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the quality improvement nurse and the home care coordinator would spend more time reviewing and developing the risk assessment than the other individuals.

We estimate that complying with the requirement to conduct a risk assessment would require 14 burden hours at a cost of $761. For all 91 PACE organizations to comply with this requirement would require an estimated 1,274 burden hours (14 burden hours for each PACE organization × 91 PACE organizations = 1,274 burden hours) at a cost of $69,251 ($761 estimated cost for each PACE organization × 91 PACE organizations = $69,251 estimated cost).

After conducting a risk assessment, PACE organizations would have to develop and maintain emergency preparedness plans that satisfied all of the requirements in § 460.84(a)(1) through (4). In addition to the requirement to establish, implement, and maintain procedures for managing emergencies and disasters, current regulations require PACE organizations to have a governing body or designated person responsible for developing policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of the PACE organization's participants (§ 460.62(a)(6)). We expect that an emergency preparedness plan would be

an essential component of such a comprehensive, systemic operational plan. However, this regulatory requirement does not guarantee that all PACE organizations have developed a plan that complies with our proposed requirements.

Thus, we expect that all PACE organizations would need to review their current plans and compare them to their risk assessments. PACE organizations would need to update, revise, and, in some cases, develop new sections to complete their emergency preparedness plans.

Based upon our experience with PACE organizations, we expect that the same individuals who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect that it would require more time to complete the plan. We expect that the quality improvement nurse would have primary responsibility for reviewing and developing the PACE organization's emergency preparedness plan. We expect that the program director, home care coordinator, and social worker would review the current plan, provide comments, and assist the quality improvement nurse in developing the final plan. Other staff members would work only on the sections of the plan that would be relevant to their areas of responsibility.

We estimate that for each PACE organization to comply with the requirement for an emergency preparedness plan would require 23 burden hours at a cost of $1,239. We estimate that for all PACE organizations to comply would require 2,093 burden hours (23 burden hours for each PACE Organization × 91 PACE organizations = 2,093 burden hours) at a cost of $112,749 ($1,239 estimated cost for each PACE organization × 91 PACE organizations = $112,749 estimated cost).

PACE organizations would also be required to review and update their emergency preparedness plans at least annually. We believe that PACE organizations are already reviewing their emergency preparedness plans periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for PACE organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(b) would require each PACE organization to develop and implement emergency preparedness policies and procedures based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at (c) of this section. It would also require PACE organizations to review and update these policies and procedures at least annually. At a minimum, we would require that a PACE organization's policies and procedures address the requirements listed at § 460.84(b)(1) through (9).

Current regulations already require that PACE organizations establish, implement, and maintain procedures for managing emergencies and disasters (§ 460.72(c)). The definition of "emergencies" includes medical and nonmedical emergencies, such as natural disasters likely to occur in a PACE organization's area (42 CFR 460.72(c)(2)). In addition, all PACE organizations must have a governing body or a designated person who functions as the governing body responsible for developing policies on participant health and safety (§ 460.62(a)(6)). Thus, we expect that all PACE organizations have some emergency preparedness policies and procedures. However, these requirements do not ensure that all PACE organizations have policies and procedures that would comply with our proposed requirements.

The burden associated with the proposed requirements would be the resources needed to review, revise, and, if needed, develop new emergency preparedness policies and procedures. We expect that the program director, home care coordinator, and quality improvement nurse would be primarily responsible for reviewing, revising, and if needed, developing any new policies and procedures needed to comply with our proposed requirements. We estimate that for each PACE organization to comply with our proposed requirements would require 12 burden hours at a cost of $598. Therefore, based on this estimate, for all PACE organizations to comply would require 1,092 burden hours (12 burden hours for each PACE organization × 91 PACE organizations = 1,092 burden hours) at a cost of $54,418 ($598 estimated cost for each PACE organization × 91 PACE organizations = $54,418 estimated cost).

We propose that each PACE organization must also review and update its emergency preparedness policies and procedures at least annually. We believe that PACE organizations are already reviewing their emergency preparedness policies and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(c) would require each PACE organization to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. Each PACE organization would also have to review and update this plan at least annually. The communication plan must include the information set out at § 460.84(c)(1) through (7).

All PACE organizations must have a governing body (or a designated person who functions as the governing body) that is responsible for developing policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of the PACE organization's participants (§ 460.62(a)(6)). We expect that the PACE organizations' comprehensive, systemic operational plans would include at least some of our proposed requirements. In addition, it is standard practice in the health care industry to maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for patients. Thus, we expect that all PACE organizations have some type of emergency preparedness communication plan. However, each PACE organization would need to review its current plan and revise or, in some cases, develop new sections to comply with our proposed requirements.

Based on our experience with PACE organizations, we expect that the home care coordinator and the quality assurance nurse would be primarily responsible for reviewing, and if needed, revising, and developing new sections for the communication plan. We estimate that for each PACE organization to comply with the proposed requirements would require 7 burden hours at a cost of $315. Therefore, based on this estimate, for all PACE organizations to comply with this requirement would require 637 burden hours (7 burden hours for each PACE organization × 91 PACE organizations = 637 burden hours) at a cost of $28,665 ($315 estimated cost for each PACE organization × 91 PACE organizations = $28,665 estimated cost).

Each PACE organization must also review and update its emergency preparedness communication plan at least annually. We believe that PACE organizations are already reviewing and updating their emergency preparedness communication plans periodically.

Thus, compliance with this requirement would constitute a usual and customary business practice for PACE organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(d) would require PACE organizations to develop and maintain emergency preparedness training and testing programs and review and update those programs at least annually. We propose that each PACE organization would have to meet the requirements listed at § 460.84(d)(1) and (2).

Proposed § 460.84(d)(1) would require PACE organizations to provide initial training on their emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles and maintain documentation of this training. PACE organizations would also have to ensure that their staff could demonstrate knowledge of the emergency procedures. Thereafter, PACE organizations would be required to provide this training annually.

Current regulations require PACE organizations to provide periodic orientation and appropriate training to their staffs and participants in emergency procedures (§ 460.72(c)(3)). However, these requirements do not ensure that all PACE organizations would be in compliance with our proposed requirements. Thus, each PACE organization would need to review its current training program and compare the training program to its risk assessment, emergency preparedness plan, policies and procedures, and communication plan. The PACE organization would also need to revise and, in some cases, develop new sections to ensure that its emergency preparedness training program complied with our proposed requirements. We expect that the quality assurance nurse would review all elements of the PACE organization's training program and determine what tasks would need to be performed and what materials would need to be developed to comply with our proposed requirements. We expect that the home care coordinator would work with the quality assurance nurse to develop the revised and updated training program. We estimate that for each PACE organization to comply with the proposed requirements would require 12 burden hours at a cost of $540. Therefore, it would require an estimated 1,092 burden hours (12 burden hours for each PACE organization × 91 PACE organizations = 1,092 burden hours) to comply with this requirement at a cost of $49,140 ($540 estimated cost for each PACE organization × 91 PACE organizations = $49,140 estimated cost).

PACE organizations would also be required to review and update their emergency preparedness training program at least annually. We believe that PACE organizations are already reviewing and updating their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for PACE organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(d)(2) would require PACE organizations to participate in a community mock disaster drill at least annually. If a community mock disaster drill was not available, the PACE organization would have to conduct an individual, facility-based mock disaster drill. They would also be required to conduct a paper-based, tabletop exercise at least annually. PACE organizations would also be required to analyze their responses to, and maintain documentation of, all drills, exercises, and any emergency events they experienced. If a PACE organization experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. To comply with these requirements, PACE organizations would need to develop a specific scenario for each drill and exercise. The PACE organizations would also have to develop the documentation necessary for recording and analyzing their response to all drills, exercises, and emergency events.

Current regulations require each PACE organization to conduct a test of its emergency and disaster plan at least annually (42 CFR 460.72(c)(5)). They also must evaluate and document the effectiveness of their emergency and disaster plans. Thus, PACE organizations already conduct at least one test annually of their plans. We expect that as part of testing their emergency plans annually, PACE organizations would develop a scenario for and document the testing. However, this does not ensure that all PACE organizations would be in compliance with all of our proposed requirements, especially the proposed requirement for conducting a paper-based, tabletop exercise; performing a community-based mock disaster drill; and using different scenarios for the drill and the exercise.

The 91 PACE organizations would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the documentation necessary to record and analyze their response to all drills, exercises, and any emergency events. Based on our experience with PACE organizations, we expect that the same individuals who developed their emergency preparedness training programs would develop the required documentation. We expect the quality improvement nurse would spend more time on these activities than the health care coordinator. We estimate that this activity would require 5 burden hours for each PACE organization at a cost of $225. We estimate that for all PACE organizations to comply with these requirements would require 455 burden hours (5 burden hours for each PACE organization × 91 PACE organizations = 455 burden hours) at a cost of $20,475 ($225 estimated cost for each PACE organization × 91 PACE organizations = $20,475 estimated cost).

TABLE 6—BURDEN HOURS AND COST ESTIMATES FOR ALL 91 PACE ORGANIZATIONS TO COMPLY WITH THE ICRS CONTAINED IN § 460.84 EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of eporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 460.84(a)(1)	0938—New	91	91	14	1,274	**	69,251	0	69,251
§ 460.84(a)(1)–(4)	0938—New	91	91	23	2,093	**	112,749	0	112,749
§ 460.84(b)	0938—New	91	91	12	1,092	**	54,418	0	54,418
§ 460.84(c)	0938—New	91	91	7	637	**	28,665	0	28,665
§ 460.84(d)(1)	0938—New	91	91	12	1,092	**	49,140	0	49,140
§ 460.84(d)(2)	0938—New	91	91	5	455	**	20,475	0	20,475
Totals		91	546		6,643				334,698

** The hourly labor cost is blended between the wages for multiple staffing levels.

H. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 482.15)

Proposed § 482.15(a) would require hospitals to develop and maintain emergency preparedness plans. We propose that hospitals be required to review and update their emergency preparedness plans at least annually and meet the requirements set out at § 482.15(a)(1) through (4).

Note that we obtain data on the number of hospitals, both accredited and non-accredited, from the CMS CASPER data system, which are updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited hospitals shown may not equal the number of hospitals at the time of this proposed rule's publication. In addition, some hospitals may have chosen to be accredited by more than one accrediting organization.

There are approximately 4,928 Medicare-certified hospitals. This includes 107 critical access hospitals (CAHs) that have rehabilitation or psychiatric distinct part units (DPUs) as of March 27, 2013. The services provided by CAH psychiatric or rehabilitation DPUs must comply with the hospital Conditions of Participation (CoPs) (42 CFR 485.647(a)). RNHCIs and CAHs that do not have DPUs have been excluded from this number and are addressed separately in this analysis. Of the 4,928 hospitals reported in CMS' CASPER data system, approximately 4,587 are accredited hospitals and the remainder is non-accredited hospitals. Three organizations have accrediting authority for these hospitals: TJC, formerly known as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the AOA, and DNVHC.

Accreditation can substantially affect the burden a hospital would sustain under this proposed rule. The Joint Commission accredits 3,410 hospitals. Many of our proposed requirements are similar or virtually identical to the standards, rationales, and elements of performance (EPs) required for TJC accreditation. The TJC standards, rationales, and elements of performance (EPs) are on the TJC Web site at *http://www.jointcommission.org/*.

The other two accrediting organizations, AOA and DNVHC, accredit 185 and 176 hospitals, respectively. The AOA hospital accreditation requirements do not emphasize emergency preparedness. In addition, these hospitals account for less than 5 percent of all of the hospitals. Thus, for purposes of determining the burden, we have included the 185 AOA-accredited hospitals and the 176 DNVHC-accredited hospitals in with the hospitals that are not accredited. Therefore, unless indicated otherwise, we have analyzed the burden for the 3,410 TJC-accredited hospitals separately from the remaining 1,518 non TJC-accredited hospitals (4,928 hospitals—3,410 TJC-accredited hospitals = 1,518 non TJC-accredited hospitals).

We have used TJC's "Comprehensive Accreditation Manual for Hospitals: The Official Handbook 2008 (CAMH)" to determine the burden for TJC-accredited hospitals. In the chapter entitled, "Management of the Environment of Care" (EC), hospitals are required to plan for managing the consequences of emergencies (CAMH, Standard EC.4.11, CAMH Refreshed Core, January 2008, p. EC–13a). Individual standards have EPs, which provide the detailed and specific performance expectations, structures, and processes for each standard (CAMH, CAMH Refreshed Core, January 2008, p. HM–6). The EPs for Standard EC.4.11 require, among other things, that hospitals conduct a hazard vulnerability analysis (HVA) (CAMH, Standard EC.4.11, EP 2, CAMH Refreshed Core, January 2008, p. EC–13a). Performing an HVA would require a hospital to identify the events that could possibly affect demand for the hospital's services or the hospital's ability to provide services. A TJC-accredited hospital also must determine the likeliness of the identified risks occurring, as well as their consequences. Thus, we expect that TJC-accredited hospitals already conduct an HVA that complies with our proposed requirements and that any additional tasks necessary to comply would be minimal. Therefore, for TJC-accredited hospitals, the risk assessment requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(a)(1) would require that hospitals perform a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. We expect that most non TJC-accredited hospitals have already performed at least some of the work needed for a risk assessment. The Niska and Burt article indicated that most hospitals already have plans for natural disasters. However, many may not have thoroughly documented this activity or performed as thorough a risk assessment as needed to comply with our proposed requirements.

We have not designated any specific process or format for hospitals to use in conducting a risk assessment because we believe that hospitals need the flexibility to determine how best to accomplish this task. However, we expect that hospitals would obtain input from all of their major departments when performing a risk assessment. Based on our experience, we expect that conducting a risk assessment would require the involvement of at least a hospital administrator, the risk management director, the chief medical officer, the chief of surgery, the director of nursing, the pharmacy director, the facilities director, the health information services director, the safety director, the security manager, the community relations manager, the food services director, and administrative support staff. We expect that most of these individuals would attend an initial meeting, review relevant sections of their current risk assessment, prepare and send their comments to the risk management director, attend a follow-up meeting, perform a final review, and approve the new risk assessment.

We expect that the risk management director would coordinate the meetings, review and comment on the current risk assessment, suggest revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the hospital administrator would spend more time reviewing the risk assessment than most of the other individuals.

We estimate that the risk assessment would require 36 burden hours to complete at a cost of $2,923 for each non-TJC accredited hospital. There are approximately 1,518 non TJC-accredited hospitals. Therefore, it would require an estimated 54,648 burden hours (36 burden hours for each non TJC-accredited hospitals × 1,518 non TJC-accredited hospitals = 54,648 burden hours) for all non TJC-accredited hospitals to comply at a cost of $4,437,114 ($2,923 estimated cost for each non TJC-hospital × 1,518 non TJC-accredited hospitals = $4,437,114 estimated cost).

Proposed § 482.15(a)(1) through (4) would require hospitals to develop and maintain emergency preparedness plans. We expect that all hospitals would compare their risk assessments to their emergency plans and revise and, if necessary, develop new sections for their plans. TJC-accredited hospitals must develop and maintain written Emergency Operations Plans (EOPs) (CAMH, Standard EC.4.12, EP 1, CAMH Refreshed Care, January 2008, p. EC–13b). The EOP should describe an "all-

hazards" approach to coordinating six critical areas: communications, resources and assets, safety and security, staff roles and responsibilities, utilities, and patient clinical and support activities during emergencies (CAMH, Standard EC.4.13—EC.4.18, CAMH Refreshed Core, January 2008, pp. EC–13b—EC–13g). Hospitals also must include in their EOP "[r]esponse strategies and actions to be activated during the emergency" and "[r]ecovery strategies and actions designed to help restore the systems that are critical to resuming normal care, treatment and services" (CAMH, Standard EC.4.11, EPs 7 and 8, p. EC–13a). In addition, hospitals are required to have plans to manage "clinical services for vulnerable populations served by the hospital, including patients who are pediatric, geriatric, disabled or have serious chronic conditions or addictions" (CAMH, Standard EC.4.18, EP 2, p. EC–13g). Hospitals also must plan how to manage the mental health needs of their patients (CAMH, Standard EC.4.18, EP 4, EC–13g). Thus, we expect that TJC-accredited hospitals have already developed and are maintaining EOPs that comply with the requirement for an emergency plan in this proposed rule. If a TJC-accredited hospital needed to complete additional tasks to comply with the proposed requirement, we believe that the burden would be negligible. Therefore, for TJC-accredited hospitals, this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

We expect that most, if not all, non TJC-accredited hospitals already have some type of emergency preparedness plan. The Niska and Burt article noted that the majority of hospitals have plans for natural disasters; incendiary incidents; and biological, chemical, and radiological terrorism. In addition, all hospitals must already meet the requirements set out at 42 CFR 482.41, including emergency power, lighting, gas and water supply requirements as well as specified Life Safety Code provisions. However, those existing plans may not be fully compliant with our proposed requirements. Thus, it would be necessary for non TJC-accredited hospitals to review their current plans and compare them to their risk assessments and revise, update, or, in some cases, develop new sections for their emergency plans.

Based on our experience with hospitals, we expect that the same individuals who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we estimate that it would require substantially more time to complete an emergency preparedness plan. We estimate that complying with this requirement would require 62 burden hours at a cost of $5,085 for each non TJC-accredited hospital. There are approximately 1,518 non TJC-accredited hospitals. Therefore, based on this estimate, it would require 94,116 burden hours for all non TJC-accredited hospitals (62 burden hours for each non TJC-accredited hospitals × 1,518 non TJC-accredited hospitals = 94,116 burden hours) to complete an emergency preparedness plan at a cost of $7,719,030 ($5,085 estimated cost for each non TJC-accredited hospital × 1,518 non TJC-accredited hospitals = $7,719,030 estimated cost).

Under this proposed rule, a hospital also would be required to review and update its emergency preparedness plan at least annually. We believe that hospitals already review their emergency preparedness plans periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for hospitals and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Under proposed § 482.15(b), we would require each hospital to develop and implement emergency preparedness policies and procedures based on its emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. We would also require hospitals to review and update these policies and procedures at least annually. At a minimum, we would require that the policies and procedures address the requirements at § 482.15(b)(1) through (8).

We would expect all hospitals to review their emergency preparedness policies and procedures and compare them to their emergency plans, risk assessments, and communication plans. We expect that hospitals would then review, revise, and, if necessary, develop new policies and procedures that comply with our proposed requirements.

The CAMH's chapter entitled, "Leadership" (LD), requires TJC-accredited hospital leaders to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMH, Standard LC.3.90, EP 1, CAMH Refreshed Core, January 2008, p. LD–15). Thus, we expect that TJC-accredited hospitals already have some policies and procedures related to our proposed requirements. As discussed later, many of the requirements in proposed § 482.15(b) has a corresponding requirement in the TJC hospital accreditation standards. Hence, we will discuss each proposed section individually.

Proposed § 482.15(b)(1) would require hospitals to have policies and procedures for the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place. TJC-accredited hospitals are required to make plans for obtaining and replenishing medical and non-medical supplies, including food, water, and fuel for generators and transportation vehicles (CAMH, Standard EC.4.14, EPs 1–8 and 10–11, p. EC–13d). In addition, hospitals must identify alternative means of providing electricity, water, fuel, and other essential utility needs in cases when their usual supply is disrupted or compromised (CAMH, Standard EC.4.17, EPs 1–5, p. EC–13f). Thus, we expect that TJC-accredited hospitals would be in compliance with our proposed provision of subsistence requirements in proposed § 482.15(b)(1).

Proposed § 482.15(b)(2) would require hospitals to have policies and procedures to track the location of staff and patients in the hospital's care both during and after an emergency. TJC-accredited hospitals must plan for communicating with patients and their families at the beginning of and during an emergency (CAMH, Standard EC.4.13, EPs 1, 2, and 5, p. EC–13c). We expect that TJC-accredited hospitals would be in compliance with proposed § 482.15(b)(2).

Proposed § 482.15(b)(3) would require hospitals to have policies and procedures for a plan for the safe evacuation from the hospital. TJC-accredited hospitals are required to make plans to evacuate patients as part of managing their clinical activities (CAMH, Standard EC.4.18, EP 1, p. EC–13g). They also must plan for the evacuation and transport of patients, as well as their information, medications, supplies, and equipment, to alternative care sites (ACSs) when the hospital cannot provide care, treatment, and services in their facility (CAMH, Standard EC.4.14, EPs 9–11, p. EC–13d). Proposed § 482.15(b)(3) also would require hospitals to have "primary and alternate means of communication with external sources of assistance." TJC-accredited hospitals must plan for communicating with external authorities once the hospital initiates its emergency response measures (CAMH, Standard EC.4.13, EP 4, p. EC–13c). Thus, TJC-accredited hospitals would be in compliance with most of the

requirements in proposed § 482.15(b)(3). However, we do not believe these requirements would ensure compliance with the proposed requirement that the hospital establish policies and procedures for staff responsibilities.

Proposed § 482.15(b)(4) would require hospitals to have policies and procedures that address a means to shelter in place for patients, staff, and volunteers who remain at the facility. The rationale for CAMH Standard EC.4.18 states, "a catastrophic emergency may result in the decision to keep all patients on the premises in the interest of safety" (CAMH, Standard EC.4.18, p. EC–13f). We expect that TJC-accredited hospitals would be in compliance with our proposed shelter in place requirement in § 482.15(b)(4).

Proposed § 482.15(b)(5) would require hospitals to have policies and procedures that address a system of medical documentation that preserves patient information, protects the confidentiality of patient information, and ensures that records are secure and readily available. The CAMH chapter entitled "Management of Information" requires TJC-accredited hospitals to have storage and retrieval systems for their clinical/service and hospital-specific information (CAMH, Standard IM.3.10, EP 5, CAMH Refreshed Core, January 2008, p. IM–10) and to ensure the continuity of their critical information "needs for patient care, treatment, and services (CAMH, Standard IM.2.30, Rationale for IM.2.30, CAMH Refreshed Core, January 2008, p. IM–8). They also must ensure the privacy and confidentiality of patient information (CAMH, Standard IM.2.10, CAMH Refreshed Core, January 2008, p. IM–7) and have plans for transporting and tracking patients' clinical information, including transferring information to ACSs (CAMH Standard EC.4.14, EP 11, p. EC–13d and Standard EC.4.18, EP 6, pp. EC–13d and EC–13g, respectively). Therefore, we expect that TJC-accredited hospitals would be in compliance with the requirements we propose in § 482.15(b)(5).

Proposed § 482.15(b)(6) would require hospitals to have policies and procedures that address the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state and federally-designated health care professionals to address surge needs during an emergency. TJC-accredited hospitals must already define staff roles and responsibilities in their EOPs and ensure that they train their staffs for their assigned roles (CAMH, Standard EC.4.16, EPs 1 and 2, p. EC–13e). The rationale for Standard EC.4.15 indicates that the "hospital determines the type of access and movement to be allowed by . . . emergency volunteers . . . when emergency measures are initiated." In addition, in the chapter entitled "Medical Staff" (MS), hospitals "may grant disaster privileges to volunteers that are eligible to be licensed independent practitioners" (CAMH, Standard MS.4.110, CAMH Refreshed Care, January 2008, p. MS–27). Finally, in the chapter entitled "Management of Human Resources" (HR), hospitals "may assign disaster responsibilities to volunteer practitioners" (CAMH, Standard HR.1.25, CAMH Refreshed Core, January 2008, p. HR–5). Although TJC accreditation requirements partially address our proposed requirements, we do not believe these requirements would ensure compliance with all requirements in proposed in § 482.15(b)(6).

Proposed § 482.15(b)(7) would require hospitals to have policies and procedures that would address the development of arrangements with other hospitals or other providers to receive patients in the event of limitations or cessation of operations to ensure continuity of services to hospital patients. TJC-accredited hospitals must plan for the sharing of resources and assets with other health care organizations (CAMH, Standard EC.4.14, EPs 7 and 8, p. EC–13d). However, we would not expect TJC-accredited hospitals to be substantially in compliance with the requirements we propose in § 482.15(b)(7) based on compliance with TJC accreditation standards alone.

Proposed § 482.15(b)(8) would require hospitals to have policies and procedures that address the hospital's role under an "1135 waiver" (that is, a waiver of some federal rules pursuant to § 1135 of the Social Security Act) in the provision of care and treatment at an ACS identified by emergency management officials. TJC-accredited hospitals must already have plans for transporting patients, as well as their associated information, medications, equipment, and staff to ACSs when the hospital cannot support their care, treatment, and services on site (CAMH, Standard EC.4.14, EPs 10 and 11, p. EC–13d). We expect that TJC-accredited hospitals would be in compliance with the requirements we propose in § 482.15(b)(8).

In summary, we expect that TJC-accredited hospitals have developed and are maintaining policies and procedures that would comply with the requirements in proposed § 482.15(b), except for proposed §§ 482.15(b)(3), (6), and (7). Later we will discuss the burden on TJC-accredited hospitals with respect to these provisions. We expect that any modifications that TJC-accredited hospitals would need to make to comply with the remaining proposed requirements would not impose a burden above that incurred as part of usual and customary business practices. Thus, with the exception of the proposed requirements set out at § 482.15(b)(3), (b)(6), and (b)(7), the proposed requirements would constitute usual and customary business practices and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The burden associated with proposed § 482.15(b)(3), (b)(6), and (b)(7) would be the resources required to develop written policies and procedures that comply with the proposed requirements. We expect that the risk management director would review the hospital's policies and procedures initially and make recommendations for revisions and development of additional policies or procedures. We expect that representatives from the hospital's major departments would make revisions or draft new policies and procedures based on the administrator's recommendation. The appropriate parties would then need to compile and disseminate these new policies and procedures.

We estimate that complying with these requirements would require 17 burden hours for each TJC-accredited hospital at a cost of $1,423. For all 3,410 TJC-accredited hospitals to comply with these requirements would require an estimated 57,970 burden hours (17 burden hours for each TJC-accredited hospital × 3,410 TJC-accredited hospitals = 57,970 burden hours) at a cost of $4,852,430 (1,423 estimated cost for each TJC-accredited hospital × 3,410 TJC-accredited hospitals = $4,852,430 estimated cost).

The 1,518 non TJC-accredited hospitals would need to review their policies and procedures, ensure that their policies and procedures accurately reflect their risk assessments, emergency preparedness plans, and communication plans, and incorporate any of our proposed requirements into their policies and procedures. We expect that the risk management director would coordinate the meetings, review and comment on the current policies and procedures, suggest revisions, coordinate comments, develop the policies and procedures, and ensure that the necessary parties approve it. We expect that the hospital administrator would spend more time reviewing the policies and procedures than most of the other individuals.

We estimate that complying with this requirement would require 33 burden hours for each non TJC-accredited hospital at an estimated cost of $2,623. Based on this estimate, for all 1,518 non TJC-accredited hospitals to comply with these requirements would require 50,094 burden hours (33 burden hours for each non TJC-accredited hospital × 1,518 non TJC-accredited hospitals = . 50,094 burden hours) at a cost of $3,981,714 ($2,623 estimated cost for each non TJC-accredited hospital × 1,518 non TJC-accredited hospitals = $3,981,714 estimated cost).

In addition, we expect that there would be a burden as a result of proposed § 482.15(b)(7). Proposed § 482.15(b)(7) would require hospitals to develop and maintain policies and procedures that address a hospital's development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure continuity of services to hospital patients. We expect that hospitals would base those arrangements on written agreements between the hospital and other hospitals and other providers. Thus, in addition to the burden related to developing the policies and procedures, hospitals would also sustain a burden related to developing the written agreements related to those arrangements.

All 4,928 hospitals would need to identify other hospitals and other providers with which they could have agreements, negotiate and draft the agreements, and obtain all necessary authorizations for the agreements. For the purpose of determining the burden, we will assume that hospitals would have written agreements with two other hospitals and other providers. Based on our experience with hospitals, we expect that complying with this requirement would primarily require the involvement of the hospital's administrator and risk management director. We also expect that a hospital attorney would assist with drafting the agreements and reviewing those documents for any legal implications. We estimate that complying with this requirement would require 8 burden hours for each hospital at an estimated cost of $719. Thus, it would require an estimated 39,424 burden hours (8 burden hours for each hospital × 4,928 hospitals = 39,512 burden hours) for all hospitals to comply with this requirement at a cost of $3,543,232 ($719 estimated cost for each hospital × 4,928 hospitals = $3,543,232 estimated cost).

Based upon the previous estimates, for all hospitals to be in compliance with all of the requirements in § 482.15(b) it would require 147,488 burden hours at a cost of $12,377,376.

Proposed § 482.15(b) would also require hospitals to review and update their emergency preparedness policies and procedures at least annually. We believe hospitals are already reviewing and updating their emergency preparedness policies and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for both TJC-accredited and non TJC-accredited hospitals and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(c) would require each hospital to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The plan would have to be reviewed and updated at least annually. The communication plan would have to include the information listed at § 482.15(c)(1) through (7).

We expect that all hospitals currently have some type of emergency preparedness communication plan. We expect that under this proposed rule, hospitals would review their current communication plans, compare them to their emergency preparedness plans and emergency policies and procedures, and revise their communication plans, as necessary.

It is standard practice for health care facilities to maintain contact information for staff and outside sources of assistance; have alternate means of communication in case there is an interruption in phone service to the facility; and have a method for sharing information and medical documentation with other health care providers to ensure continuity of care for patients. However, under this proposed rule, all hospitals would need to review and update their plans to ensure compliance with our proposed requirements.

The TJC-accredited hospitals are required to establish emergency communication strategies (CAMH, Standard EC.4.13, p. EC–13b). In addition, TJC-accredited hospitals are specifically required to ensure communication with staff, external authorities, patients, and their families (CAMH, Standard EC.4.13, EPs 1–5, p. EC–13c). TJC-accredited hospitals also are required to establish "back-up communications systems and technologies" for such activities (CAMH, Standard EC.4.13, EP 14, p. EC–13c). Moreover, TJC-accredited hospitals are required specifically to define "the circumstances and plans for communicating information about patients to third parties (such as other health care organizations) . . . " (CAMH, Standard EC.4.13, EP 12, p. EC–13c). Thus, we expect that that TJC-accredited hospitals would be in compliance with proposed § 482.15(c)(1) through (c)(4). In addition, the rationale for EC.4.13 states, "the hospital maintains reliable surveillance and communications capability to detect emergencies and communicate response efforts to hospital response personnel, patient and their families, and external agencies (CAMH, Standard EC.4.13, pp. EC–13b—13c). We expect that most, if not all, TJC-accredited hospitals would be in compliance with proposed § 482.15(c)(5) through (c)(7). Therefore, we expect that TJC-accredited hospitals already have developed and are currently maintaining emergency communication plans that would satisfy the requirements contained in proposed § 482.15(c). Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to PRA in accordance with 5 CFR 1320.3(b)(2).

Most, if not all, non TJC-accredited hospitals would be substantially in compliance with proposed § 482.15(c)(1) through (c)(4). Nevertheless, non TJC-accredited hospitals would need to review, update, and in some cases, develop new sections for their emergency communication plans to ensure they are in compliance with all of the proposed requirements in this subsection. We expect that this activity would require the involvement of the hospital's administrator, the risk management director, the facilities director, the health information services director, the security manager, and administrative support staff. We estimate that complying with this requirement would require 10 burden hours at a cost of $757 for each of the 1,518 non TJC-accredited hospitals. Therefore, based on this estimate, for non TJC-accredited hospitals to comply with this requirement would require 15,180 burden hours (10 burden hours for each non TJC-accredited hospital × 1,518 non TJC-accredited hospitals =15,180 burden hours) at a cost of $1,149,126 ($757 estimated cost for each non TJC-accredited hospital × 1,518 non TJC-accredited hospitals = $1,149,126 estimated cost).

Proposed § 482.15(c) also would require hospitals to review and update their emergency preparedness communication plans at least annually. We believe that hospitals are already reviewing and updating their emergency preparedness communication plans

periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(d) would require hospitals to develop and maintain emergency preparedness training and testing programs and review and update those plans at least annually. The hospital would be required to meet the requirements in § 482.15(d)(1) and (2).

Proposed § 482.15(d)(1) would require hospitals to provide initial and thereafter annual training on their emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. Hospitals must also maintain documentation of all of this training.

The burden for proposed § 482.15(d)(1) would be the time and effort necessary to develop a training program and the materials needed for the required initial and annual training. We expect that all hospitals would review their current training programs and compare them to their risk assessments, emergency plans, policies and procedures, and communication plans as set forth in § 482.15(a)(1), (a), (b), and (c), respectively. Hospitals would need to revise and, if necessary, develop new sections or material to ensure that their training programs comply with our proposed requirements.

The TJC-accredited hospitals are required to define staff roles and responsibilities in their EOP and train their staff for their assigned roles during emergencies (CAMH, EC.4.16, EPs 1–2, p. EC–13e). In addition, the TJC-accredited hospitals are required to provide an initial orientation, which includes information that the hospital has determined are key elements the staff need before they provide care, treatment, or services to patients (CAMH, Standard HR.2.10, EPs 1–2, CAMH Refreshed Core, January 2008. p. HR–10). We would expect that an orientation to the hospital's EOP would be part of this initial training. TJC-accredited hospitals also must provide on-going training to their staff, including training on specific job-related safety (CAMH, Standard HR–2.30, EP 4, CAMH Refreshed Core, January 2008, p. HR–11), and we expect that emergency preparedness is part of such on-going training.

Although TJC requirements do not specifically address training for individuals providing services under arrangement or training for volunteers consistent with their expected roles, it is standard practice for health care facilities to provide some type of training to all personnel, including those providing services under contract or arrangement and volunteers. If a hospital does not already provide such training, we would expect the additional burden to be negligible. Thus, for the TJC-accredited hospitals, the proposed requirements would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Based on our experience with non TJC-accredited hospitals, we expect that the non TJC-accredited hospitals have some type of emergency preparedness training program and provide training to their staff regarding their duties and responsibilities under their emergency plans. However, under this proposed rule, non TJC-accredited hospitals would need to compare their existing training programs with their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. They also would need to revise, update, and, if necessary, develop new sections and new material for their training programs.

To develop their training programs, hospitals could draw upon the resources of federal, state, and local emergency preparedness agencies, as well as state and national health care associations and organizations. In addition, hospitals could develop partnerships with other hospitals and health care facilities to develop the necessary training. Some hospitals might also choose to purchase off-the-shelf emergency training programs or hire consultants to develop the programs for them. However, for purposes of estimating a burden for these requirements, we will assume that hospitals would use their own staff.

Based on our experience with hospitals, we expect that complying with this requirement would require the involvement of the hospital administrator, the risk management director, a health care trainer, and administrative support staff. We estimate that it would require 40 burden hours for each hospital to develop an emergency preparedness training program at a cost of $2,094 for each non TJC-accredited hospital. We estimate that it would require 60,720 burden hours (40 burden hours for each non TJC-accredited hospital × 1,518 non TJC-accredited hospitals = 60,720 burden hours) to comply with this requirement at a cost of $3,178,692 ($2,094 estimated cost for each hospital × 1,518 non TJC-accredited hospitals = $3,178,692 estimated cost).

Proposed § 482.15(d) would also require hospitals to review and update their emergency preparedness training program at least annually. We believe that hospitals are already reviewing and updating their emergency preparedness training programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Hospitals also would be required to maintain documentation of their training. Based on our experience, we believe it is standard practice for hospitals to document the training they provide to their staff, individuals providing services under arrangement, and volunteers. Therefore, compliance with this requirement would constitute a usual and customary business practice for the hospitals and not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(d)(2) would also require hospitals to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, hospitals would have to conduct an individual, facility-based mock disaster drill. Hospitals also would be required to analyze their responses to, and maintain documentation of, all drills, exercises, and emergency events. If a hospital experienced an actual emergency which required activation of its emergency plan, it would be exempt from the requirement for a community or individual, facility-based disaster drill for 1 year following the onset of the emergency (proposed § 482.15(d)(2)(ii)). Thus, to satisfy the burden for these requirements, hospitals would need to develop a scenario for each drill and exercise, as well as the documentation necessary for recording what happened. If a hospital participated in a community mock disaster drill, it probably would not need to develop a scenario for that drill. However, for the purpose of determining the burden, we will assume that hospitals would need to develop at least two scenarios annually, one for a drill and one for an exercise.

The TJC-accredited hospitals are required to test their EOP twice a year (CAMH, Standard EC.4.20, EP 1, p. EC–14a). In addition, TJC-accredited hospitals must analyze all drills and exercises, identify deficiencies and areas for improvement, and modify their EOPs in response to the analysis of those tests (CAMH, Standard EC.4.20, EPs 15–17, p. EC–14b). Therefore, we expect that TJC-accredited hospitals have already developed scenarios for drills and have the documentation needed for the analysis of their

responses. Since tabletop exercises generally do not require as much preparation as drills and do not require different documentation than drills, we expect that any change a hospital needed to make to conduct a tabletop exercise would be minimal.

We expect that it would be a usual and customary business practice for the TJC-accredited hospitals to comply with the proposed requirement to prepare scenarios for emergency preparedness drills and exercises and to develop the necessary documentation. Thus, compliance with this requirement would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Based on our experience with non TJC-accredited hospitals, we expect that the remaining non TJC-accredited hospitals have some type of emergency preparedness training program and that most, if not all, of them already conduct some type of drill or exercise to test their emergency preparedness plans. In addition, many hospitals participate in mock drills and exercises held by their communities, counties, and states. We also expect that many of these hospitals have already developed the required documentation for recording the events, and analyzing their responses to, their drills, exercises, and emergency events. However, we do not believe that all non-TJC accredited hospitals would be in compliance with our proposed requirements. Thus, we will analyze the burden for non TJC-accredited hospitals.

The non TJC-accredited hospitals would be required to develop scenarios for a drill and an exercise and the documentation necessary to record and analyze their responses to drills, exercises, and emergency events. Based on our experience with hospitals, we expect that the same individuals who developed the emergency preparedness training program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the health care trainer would spend more time developing the scenarios and documentation. Thus, for each of the 1,518 non TJC-accredited hospitals to comply with these requirements, we estimate that it would require 9 burden hours at a cost of $523. Based on this estimate, for all 1,518 non TJC-accredited hospitals to comply would require 13,662 burden hours (9 burden hours for each non TJC-accredited hospital × 1,518 non TJC-accredited hospitals =13,662 burden hours) at a cost of $793,914 ($523 estimated cost for each non TJC-accredited hospital × 1,518 non TJC-accredited hospital = $793,914 estimated cost).

TABLE 7—BURDEN HOURS AND COST ESTIMATES FOR ALL 4,928 HOSPITALS TO COMPLY WITH THE ICRS CONTAINED IN § 482.15 CONDITION: EMERGENCY PREPAREDNESS

1800141075	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 482.15(a)(1)	0938—New	1,518	1,518	36	54,648	**	4,437,114	0	4,437,114
§ 482.15(a)(1)–(4)	0938—New	1,518	1,518	62	94,116	**	7,719,030	0	7,719,030
§ 482.15(b) (TJC-accredited)	0938—New	3,410	3,410	17	57,970	**	4,852,430	0	4,852,430
§ 482.15(b) (Non TJC-accredited)	0938—New	1,518	1,518	33	50,094	**	3,981,714	0	3,981,714
§ 482.15(b)(7)	0938—New	4,928	4,928	8	39,424	**	3,543,232	0	3,543,232
§ 482.15(c)	0938—New	1,518	1,518	10	15,180	**	1,449,126	0	1,449,126
§ 482.15(d)(1)	0938—New	1,518	1,518	40	60,720	**	3,178,692	0	3,178,692
§ 482.15(d)(2)	0938—New	1,518	1,518	9	13,662	**	793,914	0	793,914
Totals		4,928	17,446		385,814				29,655,252

** The hourly labor cost is blended between the wages for multiple staffing levels.

I. ICRs Regarding Condition of Participation: Emergency Preparedness for Transplant Centers (§ 482.78)

Proposed § 482.78 would require transplant centers to have policies and procedures that address emergency preparedness. Proposed § 482.78(a) would require transplant centers or the hospitals in which they operate to have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and related care for its patients during an emergency. We propose that the agreements must address, at a minimum, the circumstances under which the agreement would be activated and the types of services that would be provided during an emergency.

"Transplantation services and related care" would include all of a center's transplant-related activities, ranging from the evaluation of potential transplant recipients and living donors through post-operative care of transplant recipients and living donors. If the agreement does not include all services normally provided by the receiving transplant center, the agreement should state precisely what services the receiving transplant center would provide during an emergency.

We would also expect each transplant center to ensure that its agreement with another transplant center is sufficient to provide its patients with the care they would need during any period in which the transplant center could not provide its services due to an emergency. If not, we would expect the transplant center to make additional agreements, when possible, to ensure all services are available for its patients during an emergency.

For the purpose of determining a burden for this requirement, we expect that each transplant center would develop an agreement with one other transplant center to provide transplantation services and related care to its patients and living donors in an emergency.

Based on our experience with transplant centers, we expect that developing this agreement would require the involvement of an administrator, the transplant center medical director, the clinical transplant coordinator, and a hospital attorney. We believe the clinical transplant coordinator would be primarily responsible for initially identifying what types of services the center's patients would need to have provided by another transplant center during an emergency, as well as which transplant center(s) could provide such services. We expect that all of the individuals we have identified would have to attend an initial meeting to approve the list of services needed by the center's patients and the transplant center(s) to contact. The hospital attorney would be primarily responsible for drafting an agreement with input from the transplant center medical director. We estimate that it would require 15 burden hours for each transplant center to develop an agreement with another transplant center to provide services for its patients and living donors during an emergency, if applicable; at a cost of $1,388.

According to CMS' Center for Medicaid, Children's Health Insurance Program (CHIP), and Survey and Certification (CMCS), there are currently

770 transplant programs or transplant centers. CMS uses the terms transplant centers and transplant programs interchangeably (70 FR 6145 and 72 FR 15210). Therefore, based on the previous estimate, for all 770 transplant centers to comply with the requirement for an agreement, it would require 11,550 burden hours (15 burden hours for each transplant center × 770 transplant centers = 11,550 burden hours) at a cost of $1,068,760 ($1,388 estimated cost for each transplant center × 770 transplant centers = $1,068,760 estimated cost).

Proposed § 482.78(b) would require a transplant center to ensure that the written agreement between the hospital in which it is located and the hospital's designated OPO as required under § 482.100 addresses the duties and responsibilities of the hospital and the OPO during an emergency. We expect that transplant centers would propose language; review any language proposed by the hospital, the OPO, or both; and approve the final agreement.

The burden associated with ensuring that the duties and responsibilities of the hospital and OPO during an emergency are addressed in the agreement would be the resources needed to draft, review, revise, and approve the language. Based on our experience with transplant centers, we expect that accomplishing these tasks would require the involvement of an administrator, the transplant center medical director, the clinical transplant coordinator, and a hospital attorney. We expect that the medical director and the clinical transplant coordinator would be primarily responsible for drafting, reviewing, revising, and approving the language of the agreement. A hospital attorney would be primarily responsible for drafting and reviewing any proposed language before the agreement was approved. The attorney would also brief the administrator and the administrator would approve the language. Thus, we estimate that it would require 15 burden hours for each transplant center to comply with the requirement to ensure that the duties and responsibilities of the hospital and OPO are identified in these agreements at a cost of $1,388. A hospital can have multiple transplant centers, but the agreement is between the hospital and the OPO. Therefore, we will use 238 hospitals for this burden analysis. This is the number of hospitals, according to CASPER, that have transplant programs. Based on this estimate, for 238 hospitals to comply with this requirement would require 3,570 burden hours (15 burden hours for each hospital × 238 hospitals= 3,570 burden hours) at a cost of $330,344 ($1,388 estimated cost for each hospital × 238 hospitals = $330,344 estimated cost).

TABLE 8—BURDEN HOURS AND COST ESTIMATES FOR ALL 770 TRANSPLANT CENTERS TO COMPLY WITH THE ICRS CONTAINED IN § 482.78 CONDITION: EMERGENCY PREPAREDNESS FOR TRANSPLANT CENTERS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total Labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 482.78(a)		770	770	15	11,550	**	1,068,760	0	1,068,760
§ 482.78(b)		238	238	15	3,570	**	330,344	0	330,344
Totals		770	1008		15,120				1,399,104

** The hourly labor cost is blended between the wages for multiple staffing levels.

J. ICRs Regarding Emergency Preparedness (§ 483.73)

Proposed § 483.73 sets forth the emergency preparedness requirements for long term care (LTC) facilities. LTC facilities would be required to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually (§ 483.73(a)). The emergency plan would have to include and be based upon a documented, facility-based and community based risk assessment that utilizes an all-hazards approach and must address missing residents (§ 483.73(a)(1)). LTC facilities would be required to develop and maintain emergency preparedness policies and procedures based on their emergency preparedness plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan that is required in paragraph (c) of this section (§ 483.73(b)). Proposed § 483.73(d) would require LTC facilities to develop and maintain emergency preparedness training and testing programs.

We would usually be required to estimate the information collection requirements (ICRs) for these proposed requirements in accordance with chapter 35 of title 44, United States Code. However, sections 4204(b) and 4214(d), which cover skilled nursing facilities (SNFs) and nursing facilities (NFs), respectively, of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) provide for a waiver of Paperwork Reduction Act (PRA) requirements for the regulations that implement the OBRA '87 requirements. Section 1819(d), as implemented by section 4201 of OBRA '87, requires that SNFs "be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident (consistent with requirements established under subsection (f)(5))." Section 1819(f)(5)(C) of the Act, requires the Secretary to establish criteria for assessing a SNF's compliance with the requirement in subsection (d) with respect for disaster preparedness. Nursing facilities have the same requirement in sections 1919(d) and (f)(5)(C), as implemented by OBRA '87.

All of the proposed requirements in this rule relate to disaster preparedness. We believe this waiver still applies to those revisions we have proposed to existing requirements in part 483 subpart B. Thus, the ICRs for the proposed requirements in § 483.73 are not subject to the PRA.

K. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 483.475)

Proposed § 483.475(a) would require Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) to develop and maintain an emergency preparedness plan that would have to be reviewed and updated at least annually. We propose that the plan would include the elements set out at § 483.475(a)(1) through (4). We will discuss the burden for these activities individually beginning with the risk assessment.

Proposed § 483.475(a)(1) would require each ICFs/IID to develop a documented, facility-based and community-based risk assessment utilizing an all-hazard approach, including missing clients. We expect an ICF/IID to identify the medical and non-medical emergency events it could experience in the facility and the community in which it is located and determine the likelihood of the facility experiencing an emergency due to the identified hazards. In performing the

risk assessment, we expect that an ICF/IID would need to consider its physical location, the geographical area in which it is located, and its client population.

The burden associated with this requirement would be the time and effort necessary to perform a thorough risk assessment. The current CoPs for ICFs/IID already require ICFs/IID to "develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fires, severe weather, and missing clients" (42 CFR 483.470(h)(1)). During the process of developing these detailed written plans and procedures, we expect that all ICFs/IID have already performed some type of risk assessment. However, as discussed earlier in the preamble, the current requirement is primarily designed to ensure the health and safety of the ICF/IID clients during emergencies that are within the facility or in the facility's local area. We do not expect that this requirement would be sufficient to protect the health and safety of clients during more widespread local, state, or national emergencies. In addition, an ICF/IID current risk assessment may not address all of the elements required in proposed § 483.475(a). Therefore, all ICFs/IID would have to conduct a thorough review of their current risk assessments, if they have them, and then perform the necessary tasks to ensure that their risk assessments comply with the requirements of this section.

We have not designated any specific process or format for ICFs/IID to use in conducting their risk assessments because we expect ICFs/IID would need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect that in the process of developing a risk assessment, an ICF/IID would include representatives from, or obtain input from, all of the major departments in their facilities. Based on our experience with ICFs/IID, we expect that conducting the risk assessment would require the involvement of the ICF/IID administrator and a professional staff person, such as a registered nurse. We expect that both individuals would attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review, and approve the risk assessment. We expect that the administrator would coordinate the meetings, perform an initial review of the current risk assessment, critique the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. We also expect that the administrator would spend more time reviewing and working on the risk assessment. Thus, we estimate that complying with this requirement would require 10 burden hours to complete at a cost of $461. There are currently 6,442 ICFs/IID. Therefore, it would require an estimated 51,536 burden hours (8 burden hours for each ICF/IID × 6,442 ICFs/IID = 51,536 burden hours) for all ICFs/IID to comply with this requirement at a cost of $2,969,762 ($461 estimated cost for each ICF/IID × 6,442 ICFs/IID = $2,969,762 estimated cost).

Under this proposed rule, ICFs/IID would be required to develop emergency preparedness plans that addressed the emergency events that could affect not only their facilities but also the communities in which they are located. An ICF/IID current disaster plan might not address all of the medical and non-medical emergency events identified by its risk assessment, include strategies for addressing those emergency events, or address its patient population. It may not specify the type of services the ICF/IID has the ability to provide in an emergency, or continuity of operations, including delegation of authority and succession plans. Thus, we expect that each ICFs/IID would have to review its current plans and compare them to its risk assessments. Each ICF/IID would then need to update, revise, and, in some cases, develop new sections to comply with our proposed requirements.

The burden associated with this requirement would be the resources needed to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with ICFs/IID, we expect that the same individuals who were involved in the risk assessment would be involved in developing the facility's new emergency preparedness plan. We also expect that developing the plan would require more time to complete than the risk assessment. We estimate that it would require 9 burden hours at a cost of $525 for each ICF/IID to develop an emergency plan that complied with the requirements in this section. Based on this estimate, it would require 57,978 burden hours (9 burden hours for each ICF/IID × 6,442 ICFs/IID = 57,978 burden hours) to complete the plan at a cost of $3,382,050 ($525 estimated cost for each ICF/IID × 6,442 ICFs/IID = $3,382,050 estimated cost).

The ICF/IID also would be required to review and update its emergency preparedness plan at least annually. We believe that ICFs/IID already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(b) would require each ICF/IID to develop and implement emergency preparedness policies and procedures, based on its emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. We would also require the ICF/IID to review and update these policies and procedures at least annually. At a minimum, the ICF/IID policies and procedures would be required to address the requirements listed at § 483.475(b)(1) through (8).

We expect all ICFs/IID to compare their current emergency preparedness policies and procedures to their emergency preparedness plans, risk assessments, and communication plans. They would then need to revise and, if necessary, develop new policies and procedures to ensure they comply with the requirements in this section.

We expect that all ICFs/II already have some emergency preparedness policies and procedures. As discussed earlier, the current CoPs for ICFs/IID require them to have "written . . . procedures to meet all potential emergencies and disasters" (§ 483.470(h)(1)). In addition, we expect that all ICFs/IID already have procedures that comply with some of the other proposed requirements in this section. For example, as will be discussed later, current regulations require ICFs/IID to perform drills, evaluate the effectiveness of those drills, and take corrective action for any problems they detect (§ 483.470(i)). We expect that all ICFs/IID have developed procedures for safe evacuation from and return to the ICF/IID (§ 483.475(b)(4)) and a process to document and analyze drills and revise their emergency plan when they detect problems.

We expect that each ICF/IID would need to review its current disaster policies and procedures and assess whether they incorporate all of the elements we are proposing. Each ICF/IID also would need to revise, and, if needed, develop new policies and procedures.

The burden incurred by reviewing, revising, updating and, if necessary, developing new emergency policies and procedures would be the resources needed to ensure that the ICF/IID policies and procedures complied with the proposed requirements of this subsection. We expect that these tasks

would involve the ICF/IID administrator and a registered nurse. We estimate that for each ICF/IID to comply would require 9 burden hours at a cost of $525. Based on this estimate, for all 6,442 ICFs/IID to comply with this requirement would require 57,978 burden hours (9 burden hours for each ICF/IID × 6,442 ICFs/IID = 57,978 burden hours) at a cost of $3,382,050 ($525 estimated cost for each ICF/IID × 6,442 ICFs/IID = $3,382,050 estimated cost).

We expect ICFs/IID to review and update their emergency preparedness policies and procedures at least annually. We believe that ICFs/IID already review their policies and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(c) would require each ICF/IID to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The ICF/IID would also have to review and update the plan at least annually. The communication plan must include the information set out at § 483.475(c)(1) through (7).

We expect all ICFs/IID to compare their current emergency preparedness communications plans, if they have them, to the requirements in this section. ICFs/IID also would need to perform any tasks necessary to ensure that they document their communication plans and that those plans comply with the proposed requirements of this subsection.

We expect that all ICFs/IID have some type of emergency preparedness communication plan. The current CoPs require ICFs/IID to have written disaster plans and procedures for all potential emergencies (§ 483.470(h)(1)). We expect that an integral part of these plans and procedures would include communication. Further, it is standard practice for health care organizations to maintain contact information for both staff and outside sources of assistance; have alternate means of communication in case there is an interruption in phone service to the facility (for example, cell phones); and have a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their clients. However, many ICFs/IID may not have a formal, written emergency preparedness communication plan, or their plan may not comply with all the elements we are requiring.

The burden associated with complying with this requirement would be the resources required to ensure that the ICF/IID emergency communication plan complied with the proposed requirements. Based upon our experience with ICFs/IID, we anticipate that meeting the requirements in this section would primarily require the involvement of the ICF/IID administrator and a registered nurse. We estimate that for each ICF/IID to comply with the proposed requirement would require 6 burden hours at a cost of $350. Therefore, for all 6,442 ICFs/IID to comply with this requirement would require an estimated 38,652 burden hours (6 burden hours for each ICF/IID × 6,442 ICFs/IID = 38,652 burden hours) at a cost of $2,254,700 ($350 estimated cost for each ICF/IID × 6,442 ICFs/IID = $2,254,700 estimated cost).

ICFs/IID would also have to review and update their emergency preparedness communication plans at least annually. We believe that ICFs/IID already review their plans, policies, and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(d) would require ICFs/IID to develop and maintain emergency preparedness training and testing programs that would have to be reviewed and updated at least annually. Each ICF/IID would also have to meet the requirements for evacuation drills and training at § 483.470(i).

To comply with the requirements at § 483.475(d)(1), an ICF/IID would have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the ICF/IID would have to provide emergency preparedness training at least annually.

The ICFs/IID would need to compare their current emergency preparedness training programs' contents to their risk assessments and updated emergency preparedness plans, policies and procedures, and communication plans and then revise and, if necessary, develop new sections for their training programs to ensure they complied with the proposed requirements. The current ICFs/IID CoPs require ICFs/IID to periodically review and provide training to their staff on the facility's emergency plan (§ 483.470(h)(2)). In addition, staff on all shifts must be trained to perform the tasks to which they are assigned for evacuations (§ 483.470(i)(1)(i)). We expect that all ICFs/IID have emergency preparedness training programs for their staff. However, under this proposed rule, each ICF/IID would need to review its current training program and compare its contents to its updated emergency preparedness plan, policies and procedures, and communications plan. Each ICF/IID also would need to revise and, if necessary, develop new sections for their training program to ensure it complied with the proposed requirements.

The burden would be the time and effort necessary to comply with the proposed requirements. We expect that a registered nurse would be primarily involved in reviewing the ICF/IID current training program and the ICF/IID updated emergency preparedness plan, policies and procedures, and communication plan; determining what tasks would need to be performed to comply with the proposed requirements of this subsection; accomplishing those tasks, and developing an updated training program. We expect the administrator would work with the registered nurse to update the training program. We estimate that it would require 7 burden hours for each ICF/IID to develop an emergency training program at a cost of $363. Therefore, it would require an estimated 45,094 burden hours (7 burden hours for each ICF/IID × 6,442 ICFs/IID = 45,094 burden hours) to comply with this requirement at a cost of $2,338,446 ($363 estimated cost for each ICF/IID × 6,442 ICFs/IID = $2,338,446 estimated cost).

ICFs/IID would have to review and update their emergency preparedness training program at least annually. We believe that ICFs/IID already review their emergency preparedness training programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(d)(2) would require ICFs/IID to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. The ICFs/IID would also be required to analyze their responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. If an ICF/IID experienced an actual natural or man-made emergency that required activation of its emergency plan, the ICF/IID would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year

following the onset of the actual event. To comply with this requirement, an ICF/IID would need to develop scenarios for each drill and exercise. An ICF/IID also would have to develop the required documentation.

The current ICF/IID CoPs require them to "hold evacuation drills at least quarterly for each shift and under varied conditions to . . . evaluate the effectiveness of emergency and disaster plans and procedures" (§ 483.470(i)(1)). In addition, ICFs/IID must "actually evacuate clients during at least one drill each year on each shift . . . file a report and evaluation on each evacuation drill . . . and investigate all problems with evacuation drills, including accidents, and take corrective action" (42 CFR 483.470(i)(2)). Thus, all 6,450 ICFs/IID already conduct quarterly drills. However, the current CoPs do not indicate the type of drills ICFs/IID must perform. In addition, although the CoPs require that a report and evaluation be filed, this requirement does not ensure that ICFs/IID have developed the type of paperwork we propose requiring or that scenarios are used for each drill or table top exercise. For the purpose of determining a burden for these requirements, all ICFs/IID would have to develop scenarios, one for the drill and one for the table top exercise, and all ICFs/IID would have to develop the necessary documentation.

The burden associated with these requirements would be the resources the ICF/IID would need to comply with the proposed requirements. We expect that complying with these requirements would likely require the involvement of a registered nurse. We expect that the registered nurse would develop the required documentation. We also expect that the registered nurse would develop the scenarios for the drill and exercise. We estimate that these tasks would require 4 burden hours at a cost of $188. Based on this estimate, for all 6,442 ICFs/IID to comply, it would require 25,768 burden hours (4 burden hours for each ICF/IID × 6,442 ICFs/IID = 25,768 burden hours) at a cost of $1,211,096 ($188 estimated cost for each ICF/IID × 6,442 ICFs/IID = $1,211,096 estimated cost).

TABLE 9—BURDEN HOURS AND COST ESTIMATES FOR ALL 6,442 ICFS/IID TO COMPLY WITH THE ICRS CONTAINED IN § 485.475 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 483.475(a)(1)		6,442	6,442	8	51,536	**	2,969,762	0	2,969,762
§ 483.475(a)(1)–(4)		6,442	6,442	9	57,978	**	3,382,050	0	3,382,050
§ 483.475(b)		6,442	6,442	9	57,978	**	3,382,050	0	3,382,050
§ 483.475(c)		6,442	6,442	6	38,652	**	2,254,700	0	2,254,700
§ 483.475(d)(1)		6,442	6,442	7	45,094	**	2,338,446	0	2,338,446
§ 483.475(d)(2)		6,442	6,442	4	25,768	**	1,211,096	0	1,211,096
Totals		6,442	38,652		277,006				15,538,104

** The hourly labor cost is blended between the wages for multiple staffing levels.

L. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 484.22)

Proposed § 484.22(a) would require home health agencies (HHAs) to develop and maintain emergency preparedness plans. Each HHA also would be required to review and update the plan at least annually. Specifically, we propose that the plan meet the requirements listed at § 484.22(a)(1) through (4). We will discuss the burden for these activities individually, beginning with the risk assessment.

Accreditation may substantially affect the burden a HHA would experience under this proposed rule. HHAs are accredited by three different accrediting organizations (AOs): The Joint Commission (TJC), The Community Health Accreditation Program (CHAP), and the Accreditation Commission for Health Care, Inc. (ACHC). After reviewing the accreditation standards for all three AOs, neither the standards for CHAP nor the ones for ACHC appeared to ensure substantial compliance with our proposed requirements in this rule. Therefore, the HHAs accredited by CHAP and ACHC will be included with the non-accredited HHAs for the purposed of determining the burden for this proposed rule.

There are currently 12,349 HHAs. There are 1,734 TJC-accredited HHAs. A review of TJC deeming standards indicates that the 1,734 TJC-accredited HHAs already perform certain tasks or activities that would partially or completely satisfy our proposed requirements. Therefore, since TJC accreditation is a significant factor in determining the burden, we will analyze the burden for the 1,734 TJC-accredited HHAs separately from the 10,615 non TJC-accredited HHAs (12,349 HHAs—1,734 TJC-accredited HHAs = 10,615 non TJC-accredited HHAs), as appropriate. Note that we obtain data on the number of HHAs, both accredited and non-accredited, from the CMS CASPER data system, which is updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited HHAs may not equal the total number of HHAs.

Section 484.22(a)(1) would require that HHAs develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. To perform this risk assessment, an HHA would need to identify the medical and non-medical emergency events the HHA could experience and how the HHA's essential business functions and ability to provide services could be impacted by those emergency events based on the risks to the facility itself and the community in which it is located. We would expect HHAs to consider the extent of their service area, including the location of any branch offices. An HHA with an existing risk assessment would need to review, revise and update it to comply with our proposed requirements.

For TJC accreditation standards, we used TJC's CAMHC Refreshed Core, January 2008 pages from the Comprehensive Accreditation Manual for Home Care 2008 (CAMHC). In the chapter entitled, "Environmental Safety and Equipment Management" (EC), TJC accreditation standards require HHAs to conduct proactive risk assessments to "evaluate the potential adverse impact of the external environment and the services provided on the security of patients, staff, and other people coming to the organization's facilities" (CAMHC, Standard EC.2.10, EP 3, p. EC–7). These proactive risk assessments should evaluate the risk to the entire organization, and the HHA should conduct one of these assessments whenever it identifies any new external risk factors or begins a new service

(CAMHC, Standard EC.2.10, p. EC–7). Moreover, TJC-accredited HHAs are required to develop and maintain "a written emergency management plan describing the process for disaster readiness and emergency management . . . " (CAMHC, Standard EC.4.10, EP 3, p. EC–9). In addition, TJC requires that these plans provide for "processes for managing . . . activities related to care, treatment, and services (for example, scheduling, modifying, or discontinuing services; controlling information about patients; referrals; transporting patients) . . . logistics relating to critical supplies . . . communicating with patient" during an emergency (CAMHC, Standard EC.4.10, EP 10, p. EC–9–10). We expect that any HHA that has conducted a proactive risk assessment and developed an emergency management plan that satisfies the previously described TJC accreditation requirements has already conducted a risk assessment that would satisfy our proposed requirements. Any tasks needed to comply with our proposed requirements would not result in any additional burden. Thus, for the 1,734 TJC-accredited HHAs, the risk assessment requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

It is standard practice for health care facilities to prepare for common internal and external medical and non-medical emergencies, based on their location, structure, and the services they provide. We believe that the 10,615 non TJC-accredited HHAs have conducted some type of risk assessment. However, those risk assessments are unlikely to satisfy all of our proposed requirements. Therefore, we will analyze the burden for the 10,615 non TJC-accredited HHAs to comply.

We have not designated any specific process or format for HHAs to use in conducting their risk assessments because we believe that HHAs need the flexibility to determine the best way to accomplish this task. However, we expect that HHAs would include representatives from or input from all of their major departments. Based on our experience working with HHAs, we expect that conducting the risk assessment would require the involvement of an HHA administrator, the director of nursing, director of rehabilitation, and the office manager. We expect that these individuals would attend an initial meeting, review relevant sections of the current assessment, prepare and forward their comments to the administrator and the director of nursing, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the director of nursing would coordinate the meetings, review the current risk assessment, provide suggestions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the director of nursing would spend more time developing the facility's new risk assessment than the other individuals. We estimate that the risk assessment would require 11 burden hours for each non TJC-accredited HHA to complete at a cost of $605. There are currently about 10,615 non TJC-accredited HHAs. We estimate that for all non TJC-accredited HHAs to comply with this requirement would require 116,765 burden hours (11 burden hours for each non TJC-accredited HHA × 10,615 non TJC-accredited HHAs = 116,765 burden hours) at a cost of $6,422,075 ($605 estimated cost for each non TJC-accredited HHA × 10,615 non TJC-accredited HHAs = $6,422,075 estimated cost).

After conducting a risk assessment, HHAs would have to develop an emergency preparedness plan that complied with § 484.22(a)(1) through (4). As discussed earlier, TJC already has accreditation standards similar to the requirements we propose at § 484.22(a). Thus, we expect that TJC-accredited HHAs have an emergency preparedness plan that would satisfy most of our proposed requirements. Although the current HHA CoPs require that there be a qualified person who "is authorized in writing to act in the absence of the administrator" (§ 484.14(c)), the TJC standards do not specifically address delegations of authority or succession plans. Furthermore, TJC standards do not address persons-at-risk. Therefore, we expect that the 1,734 TJC-accredited HHAs would incur some burden due to reviewing, revising, and in some cases, developing new sections for their emergency preparedness plans. However, we will analyze the burden for TJC-accredited HHAs separately from the 10,615 non TJC-accredited HHAs because we expect the burden for TJC-accredited HHAs to be substantially less.

We expect that the 10,615 non TJC-accredited HHAs already have some type of emergency preparedness plan, as well as delegations of authority and succession plans. However, we also expect that their plans do not comply with all of our proposed requirements. Thus, all non TJC-accredited HHAs would need to review their current plans and compare them to their risk assessments. They also would need to update, revise, and, in some cases, develop new sections for their emergency plans.

Based on our experience with HHAs, we expect that the same individuals who were involved in the risk assessment would be involved in developing the emergency preparedness plan. We estimate that complying with this requirement would require 10 burden hours for each TJC-accredited HHA at a cost of $546. Therefore, for all 1,734 TJC-accredited HHAs to comply would require an estimated 17,340 burden hours (10 burden hours for each TJC-accredited HHA × 1,734 TJC-accredited HHAs = 17,340 burden hours) at a cost of $946,764 ($546 estimated cost for each HHA × 1,734 TJC-accredited HHAs = $946,764 estimated cost).

We estimate that complying with this requirement would require 15 burden hours for each of the 10,615 non TJC-accredited HHAs at a cost of $819. Therefore, for all 10,615 non TJC-accredited HHAs to comply would require an estimated 159,225 burden hours (15 burden hours for each non TJC-accredited HHA × 10,615 non TJC-accredited HHAs = 159,225 burden hours) at a cost of $8,693,685 ($819 estimated cost for each non TJC-accredited HHA × 10,615 non TJC-accredited HHAs = $8,693,685 estimated cost).

Based on these estimates, for all 12,349 HHAs to develop an emergency preparedness plan that complies with our proposed requirements would require 176,565 burden hours at a cost of $9,640,449.

We would also require HHAs to review and update their emergency preparedness plans at least annually. We believe that HHAs are already reviewing and updating their emergency preparedness plans periodically. Hence, compliance with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 484.22(b) would require each HHA to develop and implement emergency preparedness policies and procedures based on the emergency plan, risk assessment, communication plan as set forth in § 484.22(a), (a)(1), and (c), respectively. The HHA would also have to review and update its policies and procedures at least annually. We would require that, at a minimum, these policies and procedures address the requirements listed at § 484.22(b)(1) through (6).

We expect that HHAs would review their emergency preparedness policies

and procedures and compare them to their risk assessments, emergency preparedness plans, and emergency communication plans. HHAs would need to revise or, in some cases, develop new policies and procedures to ensure they complied with all of the proposed requirements.

In the chapter entitled, "Leadership," TJC accreditation standards require that each HHA's "leaders develop policies and procedures that guide and support patient care, treatment, and services" (CAMHC, Standard LD.3.90, EP 1, p. LD–13). In addition, TJC accreditation standards and EPs specifically require each HHA to develop and maintain an emergency management plan that provides processes for managing activities related to care, treatment, and services, including scheduling, modifying, or discontinuing services (CAMHC, Standard EC.4.10, EP 10, EC–9); identify backup communication systems in the event of failure due to an emergency event (CAMHC, Standard EC.4.10, EP 18, EC–10); and develop processes for critiquing tests of its emergency preparedness plan and modifying the plan in response to those critiques (CAMHC, Standard EC.4.20, EPs 15–17, p. EC–11).

We expect that the 1,734 TJC-accredited HHAs already have emergency preparedness policies and procedures that address some of the proposed requirements at § 484.22(b). However, we do not believe that TJC accreditation requirements ensure that TJC-accredited HHAs' policies and procedures address all of our proposed requirements for emergency policies and procedures. Thus, we will include the 1,734 TJC-accredited HHAs with the 10,615 non TJC-accredited HHAs in our analysis of the burden for proposed § 484.22(b).

Under proposed § 484.22(b)(1), the HHA's individual plans for patients during a natural or man-made disaster would be included as part of the comprehensive patient assessment, which would be conducted according to the provisions at § 484.55. We expect that HHAs already collect data during the comprehensive patient assessment that they would need to develop for each patient's emergency plan. At § 484.22(b)(2), we propose requiring each HHA to have procedures to inform state and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patients' medical and psychiatric condition and home environment.

Existing HHA regulations already address some aspects of proposed § 484.22(b)(1) and (b)(2). For example, regulations at § 484.18 make it clear that HHAs are expected to accept patients only on the basis of a reasonable expectation that they can provide for the patients' medical, nursing, and social needs in the patients' home. Moreover, the plan of care for each patient must cover any safety measures necessary to protect the patient from injury § 484.18(a). Thus, the activities necessary to be in compliance with § 484.22(b)(1) and (2) would constitute usual and customary business practices for HHA and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

We expect that all 12,349 HHAs (1,734 TJC-accredited HHAs + 10,615 non TJC-accredited HHAs = 12,349 HHAs) have some emergency preparedness policies and procedures. However, we also expect that all HHAs would need to review their policies and procedures and revise and, if necessary, develop new policies and procedures that complied with our proposed requirements set out at § 484.22(3) through (6). We expect that a professional staff person, most likely the director of nursing, would review the HHA's policies and procedures and make recommendations for changes or development of additional policies and procedures. The administrator or director of nursing would brief representatives of most of the HHA's major departments and assign staff to make necessary revisions and draft any new policies and procedures. We estimate that complying with this requirement would require 18 burden hours for each HHA at a cost of $996. Thus, for all 12,349 HHAs to comply with all of our proposed requirements would require an estimated 222,282 burden hours (18 burden hours for each HHA × 12,349 HHAs = 222,282 burden hours) at a cost of $12,299,604 ($996 estimated cost for each HHA × 12,349 HHAs = $12,299,604 estimated cost).

We are also proposing that HHAs review and update their emergency preparedness policies and procedures at least annually. The current HHA CoPs already require that "a group of professional personnel . . . reviews the agency's policies governing scope of services offered" (42 CFR 484.16). Thus, we believe that complying with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

In proposed § 484.22(c), each HHA would be required to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. We propose that each HHA review and update its communication plan at least annually. We would require that the emergency communication plan include the information listed at § 484.22(c)(1) through (6).

It is standard practice for health care facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method of sharing information and medical documentation with other health care providers to ensure continuity of care for patients.

All TJC-accredited HHAs are required to identify backup communication systems for both internal and external communication in case of failure due to an emergency (CAMHC, Standard EC.4.10, EP 18, p. EC–10). They are required to have processes for notifying their staff when the HHA initiates its emergency plan (CAMHC, Standard EC.4.10, EP 7, p. EC–9); identifying and assigning staff to ensure that essential functions are covered during emergencies (CAMHC, Standard EC.4.10, EP 9, p. EC–9); and activities related to care, treatment, and services, such as controlling information about their patients (CAMHC, Standard EC.4.10, EP 10, p. EC–9). However, we do not believe these requirements ensure that all TJC-accredited HHAs are already in compliance with our proposed requirements. Thus, we will include the 1,734 TJC-accredited HHAs with the 10,615 non TJC-accredited HHAs in assessing the burden for this requirement.

We expect that all 12,349 HHAs maintain some contact information, an alternate means of communication, and a method for sharing information with other health care facilities. However, this would not ensure that all HHAs would be in compliance with our proposed requirements for communication plans. Thus, we will analyze the burden for this requirement for all 12,349 HHAs.

The burden associated with complying with this requirement would be the time and effort necessary for each HHA to review its existing communication plan, if any, and revise it; and, if necessary, to develop new sections for the emergency preparedness communication plan to ensure that it complied with our proposed requirements. Based on our experience with HHAs, we expect that these activities would require the involvement of the HHA's administrator, director of nursing, director of rehabilitation, and office

manager. We estimate that complying with this requirement would require 10 burden hours for each HHA at a cost of $520. Thus, for all 12,349 HHAs to comply with these requirements would require an estimated 123,490 burden hours (10 burden hours for each HHA × 12,349 HHAs = 123,490 burden hours) at a cost of $6,421,480 ($520 estimated cost for each HHA × 12,349 HHAs = $6,421,480 estimated cost).

We propose requiring HHAs to review and update their emergency preparedness communication plans at least annually. We believe that HHAs already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Section 484.22(d) would require each HHA to develop and maintain an emergency preparedness training and testing program. Each HHA would also have to review and update its training and testing program at least annually. We propose requiring that each HHA meet the requirements listed at § 484.22(d)(1) and (2).

Proposed § 484.22(d)(1) states that each HHA would have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the HHA would have to provide emergency preparedness training at least annually. Each HHA would also have to ensure that their staff could demonstrate knowledge of their emergency procedures.

Based on our experience with HHAs, we expect that all 12,349 HHAs have some type of emergency preparedness training program. The 1,734 TJC-accredited HHAs are already required to provide both an initial orientation to their staff before they can provide care, treatment, or services (CAMHC, Standard HR.2.10, EP 2, p. HR–6) and "ongoing in-services, training or other staff activities [that] emphasize job-related aspects of safety . . ." (CAMHC, Standard HR.2.30, EP 4, p. HR–8). Since emergency preparedness is a critical aspect of job-related safety, we expect that TJC-accredited HHAs would ensure that their orientations and ongoing staff training would include the facility's emergency preparedness policies and procedures.

However, we expect that under proposed § 484.22(d), all HHAs would need to compare their training and testing programs with their risk assessments, emergency preparedness plans, emergency policies and procedures, and emergency communication plans. We expect that most HHAs would need to revise and, in some cases, develop new sections for their training programs to ensure that they complied with our proposed requirements. In addition, HHAs would need to provide an orientation and annual training in their facilities' emergency preparedness policies and procedures to individuals providing services under arrangement and volunteers, consistent with their expected roles. Hence, we will analyze the burden of these proposed requirements for all 12,349 HHAs.

Based on our experience with HHAs, we expect that complying with this requirement would require the involvement of an administrator, the director of training, director of nursing, director of rehabilitation, and the office manager. We expect that the director of training would spend more time reviewing, revising or developing new sections for the training program than the other individuals. We estimate that it would require 16 burden hours for each HHA to develop an emergency preparedness training and testing program at a cost of $756. Thus, for all 12,349 HHAs to comply would require an estimated 197,584 burden hours (16 burden hours for each HHA × 12,349 HHAs = 197,584 burden hours) at a cost of $9,335,844 ($756 estimated cost for each HHA × 12,349 HHAs = $9,335,844 estimated cost).

We also propose requiring HHAs to review and update their emergency preparedness training programs at least annually. We believe that HHAs already review their training and testing programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 484.22(d)(2) would require each HHA to conduct drills and exercises to test its emergency plan. Each HHA would have to participate in a community mock disaster drill and conduct a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, each HHA would have to conduct an individual, facility-based mock disaster drill at least annually. If an HHA experienced an actual natural or man-made emergency that required activation of the emergency plan, it would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. Each HHA would also be required to analyze its responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise its emergency plan as needed. For the purposes of determining the burden for these requirements, we expect that all HHAs would have to comply with all of the proposed requirements.

The burden associated with complying with this requirement would be the time and effort necessary to develop the scenarios for the drill and the exercise and the required documentation. All TJC-accredited HHAs are required to test their emergency management plan once a year; the test cannot be a tabletop exercise (CAMHC, Standard EC.4.20, EP 1 and Note 1, p. EC–11). The TJC also requires HHAs to critique the drills and modify their emergency management plans in response to those critiques (CAMHC, Standard EC.4.20, EPs 15–17, p. EC–11). Therefore, TJC-accredited HHAs already prepare scenarios for drills, develop documentation to record the events during drills, critique them, and modify their emergency preparedness plans in response. However, TJC standards do not describe what type of drill HHAs must conduct or require a tabletop exercise annually. Thus, TJC accreditation standards would not ensure that TJC-accredited HHAs would be in compliance with our proposed requirements. Therefore, we will include the 1,734 TJC-accredited HHAs with the 10,615 non TJC-accredited HHAs in our analysis of the burden for these requirements.

Based on our experience with HHAs, we expect that the same individuals who are responsible for developing the HHA's training and testing program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the director of nursing would spend more time on these activities than would the other individuals. We estimate that it would require 8 burden hours for each HHA to comply with the proposed requirements at an estimated cost of $373. Thus, for all 12,349 HHAs to comply with the requirements in this section would require an estimated 98,792 burden hours (8 burden hours for each HHA x 12,349 HHAs = 98,792 burden hours) at a cost of $4,606,177 ($373 estimated cost for each HHA x 12,349 HHAs = $4,606,177 estimated cost).

Based upon the previous analysis, we estimate that it would require 909,855 burden hours for all HHAs to comply with the ICRs contained in this proposed rule at a cost of $51,034,965.

TABLE 10—BURDEN HOURS AND COST ESTIMATES FOR ALL 12,349 HHAS TO COMPLY WITH THE ICRS CONTAINED IN § 484.22 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 484.22(a)(1)	0938—New	10,615	10,615	11	116,765	**	6,422,075	0	6,422,075
§ 484.22(a)(1)–(4) (TJC-accredited)	0938—New	1,734	1,734	10	17,340	**	946,764	0	946,764
§ 484.22(a)(1)–(4) (Non TJC-accredited)	0938—New	10,615	10,615	18	159,225	**	8,693,685	0	8,693,685
§ 484.22(b)	0938—New	12,349	12,349	18	222,282	**	12,299,604	0	12,299,604
§ 484.22(c)	0938—New	12,349	12,349	10	123,490	**	6,421,480	0	6,421,480
§ 484.22(d)(1)	0938—New	12,349	12,349	16	197,584	**	9,335,844	0	9,335,844
§ 484.22(d)(2)	0938—New	12,349	12,349	8	98,792	**	4,606,177	0	4,606,177
Total					935,478				48,725,629

** The hourly labor cost is blended between the wages for multiple staffing levels.

M. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.68)

Proposed § 485.68(a) would require all Comprehensive Outpatient Rehabilitation Facilities (CORFs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We propose that the plan meet the requirements listed at § 485.68(a)(1) through (5).

Proposed § 485.68(a)(1) would require a CORF to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. The CORFs would need to identify the medical and non-medical emergency events they could experience. The current CoPs for CORFs already require CORFs to have "written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters" (§ 485.64). We expect that all CORFs have performed some type of risk assessment during the process of developing their disaster policies and procedures. However, their risk assessments may not meet our proposed requirements. Therefore, we expect that all CORFs would need to review their existing risk assessments and perform the tasks necessary to ensure that those assessments meet our proposed requirements.

We have not designated any specific process or format for CORFs to use in conducting their risk assessments because we believe they need the flexibility to determine how best to accomplish this task. However, we expect that CORFs would obtain input from all of their major departments.

Based on our experience with CORFs, we expect that conducting the risk assessment would require the involvement of the CORF's administrator and a therapist. The type of therapists at each CORF varies, depending upon the services offered by the facility. For the purposes of determining the burden, we will assume that the therapist is a physical therapist. We expect that both the administrator and the therapist would attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator would coordinate the meetings, review and critique the risk assessment, coordinate comments, develop the new risk assessment, and ensure that it was approved.

We estimate that complying with this requirement would require 8 burden hours at a cost of $485. There are currently 272 CORFs. Therefore, it would require an estimated 2,176 burden hours (8 burden hours for each CORF × 272 CORFs = 2,176 burden hours) for all CORFs to comply at a cost of $131,920 ($485 estimated cost for each CORF × 272 CORFs = $131,920 estimated cost).

After conducting the risk assessment, each CORF would need to review, revise, and, if necessary, develop new sections for its emergency plan so that it complied with our proposed requirements. The current CoPs for CORFs require them to have a written disaster plan (§ 485.64) that must be developed and maintained with the assistance of appropriate experts and address, among other things, procedures concerning the transfer of casualties and records, notification of outside emergency personnel, and evacuation routes (§ 485.64(a)). Thus, we expect that all CORFs have some type of emergency preparedness plan. However, we also expect that all CORFs would need to review, revise, and develop new sections for their plans to ensure that their plans complied with all of our proposed requirements.

Based on our experience with CORFs, we expect that the administrator and physical therapist who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect that it would require more time to complete the emergency plan than to complete the risk assessment. We estimate that complying with this requirement would require 11 burden hours at a cost of $677 for each CORF. Therefore, it would require an estimated 2,992 burden hours (11 burden hours for each CORF × 272 CORFs = 2,992 burden hours) for all CORFs to complete an emergency preparedness plan at a cost of $184,144 ($677 estimated cost for each CORF × 272 CORFs = $184,144 estimated cost).

The CORF also would be required to review and update its emergency preparedness plan at least annually. We believe that CORFs already review their plans periodically. Therefore, compliance with the requirement for an annual review of the emergency preparedness plan would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(b) would require CORFs to develop and implement emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 485.68(a), (a)(1), and (c), respectively. We would also require CORFs to review and update these policies and procedures at least annually. We would require that a CORF's policies and procedures address, at a minimum, the requirements listed at § 485.68(b)(1) through (4).

We expect that all CORFs have some emergency preparedness policies and procedures. As discussed earlier, the current CoPs for CORFs already require CORFs to have "written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters" (42 CFR 485.64). However, all CORFs would need to review their policies and procedures and compare them to their risk assessments, emergency

preparedness plans, and communication plans. Most CORFs would need to revise their existing policies and procedures or develop new policies and procedures to ensure they complied with all of our proposed requirements.

We expect that both the administrator and the therapist would attend an initial meeting, review relevant policies and procedures, make recommendations for changes, attend a follow-up meeting, perform a final review, and approve the policies and procedures. We expect that the administrator would coordinate the meetings, coordinate the comments, and ensure that they are approved.

We estimate that it would take 9 burden hours for each CORF to comply with this requirement at a cost of $549. Therefore, it would take all CORFs 2,448 burden hours (9 burden hours for each CORF × 272 CORFs = 2,448 burden hours) to comply with this requirement at a cost of $149,328 ($549 estimated cost for each CORF × 272 CORFs = $149,328 estimated cost).

Proposed § 485.68(b) also proposes that CORFs review and update their emergency preparedness policies and procedures at least annually. We believe that CORFs already review their policies and procedures periodically. Therefore, we believe that complying with this requirement would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(c) would require CORFs to develop and maintain emergency preparedness communication plans that complied with both federal and state law and that would be reviewed and updated at least annually. We propose that a CORF's communication plan include the information listed in § 485.68(c)(1) through (5). Current CoPs require CORFs to have a written disaster plan that must include, among other things, "procedures for notifying community emergency personnel" (§ 486.64(a)(2)). In addition, it is standard practice in the health care industry to maintain contact information for staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many CORFs may not have formal, written emergency preparedness communication plans. Therefore, we expect that all CORFs would need to review, update, and in some cases, develop new sections for their plans to ensure they complied with all of our proposed requirements.

Based on our experience with CORFs, we anticipate that satisfying the requirements in this section would primarily require the involvement of the CORF's administrator with the assistance of a physical therapist to review, revise, and, if needed, develop new sections for the CORF's emergency preparedness communication plan. We estimate that it would take 8 burden hours for each CORF to comply with this requirement at a cost of $485. Therefore, it would take 2,176 burden hours (8 burden hours for each CORF × 272 CORFs = 2,176 burden hours) for all CORFs to comply at a cost of $131,920 ($485 estimated cost for each CORF × 272 CORFs = $131,920 estimated cost).

We propose that each CORF would also have to review and update its emergency preparedness communication plan at least annually. We believe that compliance with this requirement would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(d) would require CORFs to develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. We propose that each CORF would have to satisfy the requirements listed at § 485.68(d)(1) and (2).

Proposed § 485.68(d)(1) would require that each CORF provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, each CORF would have to provide emergency preparedness training at least annually. Each CORF would also have to ensure that its staff could demonstrate knowledge of its emergency procedures. All new personnel would have to be oriented and assigned specific responsibilities regarding the CORF's emergency plan within two weeks of their first workday. In addition, the training program would have to include instruction in the location and use of alarm systems and signals and firefighting equipment.

The current CORF CoPs at § 485.64 require CORFs to ensure that all personnel are knowledgeable, trained, and assigned specific responsibilities regarding the facility's disaster procedures. Section § 485.64(b)(1) specifies that CORFs must also "provide ongoing training . . . for all personnel associated with the facility in all aspects of disaster preparedness". In addition, § 485.64(b)(2) specifies that "all new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within 2 weeks of their first workday".

In evaluating the requirement for proposed § 485.68(d)(1), we expect that all CORFs have an emergency preparedness training program for new employees, as well as ongoing training for all staff. However, under this proposed rule, all CORFs would need to compare their current training programs to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. CORFs would then need to revise, and in some cases, develop new material for their training programs.

We expect that these tasks would require the involvement of an administrator and a physical therapist. We expect that the administrator would review the CORF's current training program to identify necessary changes and additions to the program. We expect that the physical therapist would work with the administrator to develop the revised and updated training program. We estimate it would require 8 burden hours for each CORF to develop an emergency training program at a cost of $485. Therefore, for all CORFs to comply would require an estimated 2,176 burden hours (8 burden hours for each CORF × 272 CORFs = 2,176 burden hours) at a cost of $131,920 ($485 estimated cost for each CORF × 272 CORFs = $131,920 estimated cost).

We also propose that each CORF review and update its emergency preparedness training program at least annually. We believe that CORFs already review their training programs periodically. Thus, complying with the requirement for an annual review of the emergency preparedness training program would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(d)(2) would require CORFs to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, the CORF would have to conduct an individual, facility-based mock disaster drill at least annually. If a CORF experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. CORFs would also be required to analyze their responses to and maintain

documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, a CORF would need to develop scenarios for these drills and exercises. The current CoPs at § 485.64(b)(1) require CORFs to "provide ongoing . . . drills for all personnel associated with the facility in all aspects of disaster preparedness". However, the current CoPs do not specify the type of drill, how often the CORF must conduct drills, or that a CORF must use scenarios for their drills and tabletop exercises.

Based on our experience with CORFs, we expect that the same individuals who develop the emergency preparedness training program would develop the scenarios for the drills and exercises, as well as the accompanying documentation. We expect that the administrator would spend more time on these tasks than the physical therapist. We estimate that for each CORF to comply with the proposed requirements would require 6 burden hours at a cost of $366. Therefore, for all 272 CORFs to comply would require an estimated 1,632 burden hours (6 burden hours for each CORF × 272 CORFs = 1,632 burden hours) at a cost of $99,552 ($366 estimated cost for each CORF × 272 CORFs = $99,552 estimated cost).

Based on the previous analysis, for all 272 CORFs to comply with the ICRs contained in this proposed rule would require 13,600 total burden hours at a total cost of $828,784.

TABLE 11—BURDEN HOURS AND COST ESTIMATES FOR ALL 272 CORFS TO COMPLY WITH THE ICRS CONTAINED IN § 485.68 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 485.68(a)(1)	0938—New	272	272	8	2,176	**	131,920	0	131,920
§ 485.68(a)(2–(4)	0938—New	272	272	11	2,992	**	184,144	0	184,144
§ 485.68(b)	0938—New	272	272	9	2,448	**	149,328	0	149,328
§ 485.68(c)	0938—New	272	272	8	2,176	**	131,920	0	131,920
§ 485.68(d)(1)	0938—New	272	272	8	2,176	**	131,920	0	131,920
§ 485.68(d)(2)	0938—New	272	272	6	1,632	**	99,552	0	99,552
Totals		272	1,632		13,600				828,784

** The hourly labor cost is blended between the wages for multiple staffing levels.

N. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.625)

Proposed § 485.625(a) would require critical access hospitals (CAHs) to develop and maintain a comprehensive emergency preparedness program that utilizes an all-hazards approach and would have to be reviewed and updated at least annually. Each CAH's emergency plan would have to include the elements listed at § 485.625(a)(1) through (4).

Proposed § 485.625(a)(1) would require each CAH to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. CAHs would need to review their existing risk assessments and perform any tasks necessary to ensure that it complied with our proposed requirements.

There are approximately 1,322 CAHs. CAHs with distinct part units were included in the hospital burden analysis. Approximately 402 CAHs are accredited either by TJC (370) or by the AOA (32); the remainder are non-accredited CAHs. Many of the TJC and AOA accreditation standards for CAHs are similar to the requirements in this proposed rule. For purposes of determining the burden, we have analyzed the burden for the 370 TJC-accredited and 32 AOA-accredited CAHs separately from the non-accredited CAHs. Note that we obtain data on the number of CAHs, both accredited and non-accredited, from the CMS CASPER database, which is updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited CAHs may not equal the total number of CAHs.

For purposes of determining the burden for TJC-accredited CAHs, we used TJC's Comprehensive Accreditation Manual for Critical Access Hospitals: The Official Handbook 2008 (CAMCAH). In the chapter entitled, "Management of the Environment of Care" (EC), Standard EC.4.11 requires CAHs to plan for managing the consequences of emergency events (CAMCAH, Standard EC.4.11, CAMCAH Refreshed Care, January 2008, pp. EC–10—EC–11). CAHs are required to perform a hazard vulnerability analysis (HVA), which requires each CAH to, among other things, "identify events that could affect demand for its services or its ability to provide those services, the likelihood of those events occurring, and the consequences of those events" (Standard EC.4.11, EP 2, p. EC–10a). The HVA "should identify potential hazards, threats, and adverse events, and assess their impact on the care, treatment, and services [the CAH] must sustain during an emergency," and the HVA "is designed to assist [CAHs] in gaining a realistic understanding of their vulnerabilities, and to help focus their resources and planning efforts" (CAMCAH, Emergency Management, Introduction, p. EC–10). Thus, we expect that TJC-accredited CAHs already conduct a risk assessment that would comply with the requirements we propose. Thus, for the 370 TJC-accredited CAHs, the risk assessment requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

For purposes of determining the burden for AOA-accredited CAHs, we used the AOA's Healthcare Facilities Accreditation Program: Accreditation Requirements for Critical Access CAHs 2007 (ARCAH). In Chapter 11 entitled, "Physical Environment," CAHs are required to have disaster plans, external disaster plans that include triaging victims, and weapons of mass destruction response plans (ARCAH, Standards 11.07.01, 11.07.02, and 11.07.05–6, pp. 11–38 through 11–41, respectively). In addition, AOA-accredited CAHs must "coordinate with federal, state, and local emergency preparedness and health authorities to identify likely risks for their area . . . and to develop appropriate responses" (ARCAH, Standard 11.02.02, p. 11–5). Thus, we believe that to develop their plans, AOA-accredited CAHs already perform some type of risk assessment. However, the AOA standards do not require a documented facility-based and community-based risk assessment, as we propose. Therefore, we will include the 32 AOA-accredited CAHs with non-

accredited CAHs in determining the burden for our proposed risk assessment requirement.

The CAH CoPs currently require CAHs to assure the safety of their patients in non-medical emergencies (§ 485.623) and to take appropriate measures that are consistent with the particular conditions in the area in which the CAH is located (42 CFR 485.623(c)(4)). To satisfy this requirement in the CoPs, we expect that CAHs have already conducted some type of risk assessment. However, that requirement does not ensure that CAHs have conducted a documented, facility-based, and community-based risk assessment that would satisfy our proposed requirements.

We believe that under this proposed rule, the 952 non TJC-accredited CAHs (1,322 CAHs − 370 TJC-accredited CAHs = 952 non TJC-accredited CAHs) would need to review, revise, and, in some cases, develop new sections for their current risk assessments to ensure compliance with all of our requirements.

We have not designated any specific process or format for CAHs to use in conducting their risk assessments because we believe that CAHs need the flexibility to determine the best way to accomplish this task. However, we expect that CAHs would include representatives from or obtain input from all of their major departments in the process of developing their risk assessments.

Based on our experience with CAHs, we expect that these activities would require the involvement of a CAH's administrator, medical director, director of nursing, facilities director, and food services director. We expect that these individuals would attend an initial meeting, review relevant sections of the current risk assessment, provide comments, attend a follow-up meeting, perform a final review, and approve the new or updated risk assessment. We expect the administrator would coordinate the meetings, perform an initial review of the current risk assessment, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approved it.

We estimate that the risk assessment requirement would require 15 burden hours to complete at a cost of $949. We estimate that for the 952 non TJC-accredited CAHs to comply with the proposed risk assessment requirement would require 14,280 burden hours (15 burden hours for each CAH × 952 non TJC-accredited CAHs = 14,280 burden hours) at a cost of $903,448 ($949 estimated cost for each non TJC-accredited CAH × 952 non TJC-accredited CAHs = $903,448 estimated cost).

After conducting the risk assessment, CAHs would have to develop and maintain emergency preparedness plans that complied with proposed § 485.625(a)(1) through (4). We would expect all CAHs to compare their emergency plans to their risk assessments and then revise and, if necessary, develop new sections for their emergency plans to ensure that they complied with our proposed requirements.

The TJC-accredited CAHs must develop and maintain an Emergency Operations Plan (EOP) (CAMCAH Standard EC.4.12, p. EC–10a). The EOP must cover the management of six critical areas during emergencies: communications, resources and assets, safety and security, staff roles and responsibilities, utilities, and patient clinical and support activities (CAMCAH, Standards EC.4.12 through 4.18, pp. EC–10a–EC–10g). In addition, as discussed earlier, TJC-accredited CAHs also are required to conduct an HVA (CAMCAH, Standard EC.4.11, EP 2, p. EC–10a). Therefore, we expect that the 370 TJC-accredited CAHs already have emergency preparedness plans that would satisfy our proposed requirements. If a CAH needed to complete additional tasks to comply with the proposed requirement, the burden would be negligible. Thus, for the 370 TJC-accredited CAHs, this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The AOA-accredited CAHs must work with federal, state, and local emergency preparedness authorities to identify the likely risks for their location and geographical area and develop appropriate responses to assure the safety of their patients (ARCAH, Standard 11.02.02, p. 11–5). Among the elements that AOA-accredited CAHs must specifically consider are the special needs of their patient population, availability of medical and non-medical supplies, both internal and external communications, and the transfer of patients to home or other health care settings (ARCAH, Standard 11.02.02, p. 11–5). In addition, there are requirements for disaster and disaster response plans (ARCAH, Standards 11.07.01, 11.07.02, and 11.07.06, pp. 11–38 through 11–40). There also are specific requirements for plans for responses to weapons of mass destruction, including chemical, nuclear, and biological weapons; communicable diseases, and chemical exposures (ARCAH, Standards 11.07.02 and 11.07.05–11.07.06, pp. 11–39 through 11–41). However, the AOA accreditation requirements require only that CAHs assess their most likely risks (ARCAH, Standard 11–02.02, p. 11–5), and we are proposing that CAHs be required to conduct a risk assessment utilizing an all-hazards approach. Thus, we expect that AOA-accredited CAHs would have to compare their risk assessments they conducted in accordance with proposed § 485.625(a)(1) to their current plans and then revise, and in some cases develop new sections for, their plans. Therefore, we will assess the burden for these 32 AOA-accredited CAHs with the non-accredited CAHs.

The CAH CoPs require all CAHs to ensure the safety of their patients during non-medical emergencies (§ 485.623). They are also required to provide, among other things, for evacuation of patients, cooperation with disaster authorities, emergency power and lighting in their emergency rooms and for flashlights and battery lamps in other areas, an emergency water and fuel supply, and any other appropriate measures that are consistent with their particular location (§ 485.623). Thus, we believe that all CAHs have developed some type of emergency preparedness plan. However, we also expect that the 920 non-accredited CAHs would have to review their current plans and compare them to their risk assessments and revise and, in some cases, develop new sections for their current plans to ensure that their plans would satisfy our proposed requirements.

Based on our experience with CAHs, we expect that the same individuals who were involved in conducting the risk assessment would be involved in developing the emergency preparedness plan. We expect that these individuals would attend an initial meeting, review relevant sections of the current emergency preparedness plan(s), prepare and send their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the new plan. We expect that the administrator would coordinate the meetings, perform an initial review, coordinate comments, revise the plan, and ensure that the necessary parties approve the new plan. We estimate that complying with this requirement would require 26 burden hours at a cost of $1,620. Therefore, we estimate that for all 952 non TJC-accredited CAHs (920 non-accredited CAHs + 32 AOA-accredited CAHs = 952 non TJC-accredited CAHs) to comply with this requirement would require 24,752 burden hours (26 burden hours for each

non TJC-accredited CAH × 952 non TJC-accredited CAHs = 24,752 burden hours) at a cost of $1,542,240 ($1,620 estimated cost for each non TJC-accredited CAH × 952 non TJC-accredited CAHs = $1,542,240 estimated cost).

Under this proposed rule, CAHs also would be required to review and update their emergency preparedness plans at least annually. The CAH CoPs already require CAHs to perform a periodic evaluation of their total program at least once a year (§ 485.641(a)(1)). Hence, all CAHs should already have an individual or team responsible that is for the periodic review of their total program. Therefore, we believe that this requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Under proposed § 485.625(b), we would require CAHs to develop and maintain emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 485.625(a), (a)(1), and (c), respectively. We would also require CAHs to review and update these policies and procedures at least annually. These policies and procedures would have to address, at a minimum, the requirements listed at § 485.625(b)(1) through (8).

We expect that all CAHs would review their policies and procedures and compare them to their risk assessments, emergency preparedness plans, and emergency communication plans. The CAHs would need to revise, and, in some cases, develop new policies and procedures to incorporate all of the provisions previously noted and address all of our proposed requirements.

The CAMCAH chapter entitled, "Leadership" (LD), requires TJC-accredited CAH leaders to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMCAH, Standard LC.3.90, EP 1, CAMCAH Refreshed Core, January 2008, p. LD–11). Thus, we expect that TJC-accredited CAHs already have some policies and procedures for the activities and processes required for accreditation, including their EOP. As discussed later, many of the required elements we propose have a corresponding requirement in the CAH TJC accreditation standards.

We propose at § 485.625(b)(1) that CAHs have policies and procedures that address the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place. TJC-accredited CAHs must make plans for obtaining and replenishing medical and non-medical supplies, including food, water, and fuel for generators and transportation vehicles (CAMCAH, Standard EC.4.14, EPs 1–4, p. EC–10d). In addition, they must identify alternative means of providing electricity, water, fuel, and other essential utility needs in cases where their usual supply is disrupted or compromised (CAMCAH, Standard EC.4.17, EPs 1–5, p. EC–10f). We expect that TJC-accredited CAHs that comply with these requirements would be in compliance with our proposed requirement concerning subsistence needs at § 485.625(b)(1).

We are proposing at § 485.625(b)(2) that CAHs have policies and procedures for a system to track the location of staff and patients in the CAH's care both during and after an emergency. TJC-accredited CAHs must plan for communicating with their staff, as well as patients and their families, at the beginning of and during an emergency (CAMCAH, Standard EC.4.13, EPs 1, 2, and 5, p. EC–10c). We expect that TJC-accredited CAHs that comply with these requirements would be in compliance with our proposed requirement.

Proposed § 485.625(b)(3) would require CAHs to have a plan for the safe evacuation from the CAH. TJC-accredited CAHs are required to make plans to evacuate patients as part of managing their clinical activities (CAMCAH, Standard EC.4.18, EP 1, p. EC–10g). They also must plan for the evacuation and transport of patients, their information, medications, supplies, and equipment to alternative care sites (ACSs) when the CAH cannot provide care, treatment, and services in its facility (CAMCAH, Standard EC.4.14, EPs 9–11, p. EC–10d). We expect that TJC-accredited CAHs that comply with these requirements would be in compliance with our proposed requirement.

We are proposing at § 485.625(b)(4) that CAHs have policies and procedures for a means to shelter in place for patients, staff, and volunteers who remain in the facility. The rationale for CAMCAH Standard EC.4.18 states, "[a] catastrophic emergency may result in the decision to keep all patients on the premises in the interest of safety" (CAMCAH, Standard EC.4.18, p. EC–10f). Therefore, we expect that TJC-accredited CAHs would be substantially in compliance with our proposed requirement.

Proposed § 485.625(b)(5) would require CAHs to have policies and procedures that address a system of medical documentation that preserves patient information, protects the confidentiality of patient information, and ensures that records are secure and readily available. The CAMCAH chapter entitled "Management of Information" (IM), requires TJC-accredited CAHs to have storage and retrieval systems for their clinical/service and CAH-specific information (CAMCAH, Standard IM.3.10, EP 5, CAMCAH Refreshed Core, January 2008, p. IM–11), as well as to ensure the continuity of their critical information for patient care, treatment, and services (CAMCAH, Standard IM.2.30, CAMCAH Refreshed Core, January 2008, p. IM–9). They also must ensure the privacy and confidentiality of patient information (CAMCAH, Standard IM.2.10, CAMCAH Refreshed Core, January 2008, p. IM–7). In addition, TJC-accredited CAHs must have plans for transporting patients and their clinical information, including transferring information to ACSs (CAMCAH Standard EC.4.14, EP 10 and 11, p. EC–10d and Standard EC.4.18, EP 6, pp. EC–10g, respectively). Therefore, we expect that TJC-accredited CAHs would be substantially in compliance with proposed § 485.625(b)(5).

Proposed § 485.625(b)(6) would require CAHs to have policies and procedures that addressed the use of volunteers in an emergency or other emergency staffing strategies. TJC-accredited CAHs must define staff roles and responsibilities in their EOP and ensure that they train their staff for their assigned roles (CAMCAH, Standard EC.4.16, EPs 1 and 2, p. EC–10e). Also, the rationale for Standard EC.4.15 indicates that the CAH "determines the type of access and movement to be allowed by . . . emergency volunteers . . . when emergency measures are initiated" (CAMCAH, Standard EC.4.15, Rationale, p. EC–10d). In addition, in the chapter entitled "Medical Staff" (MS), CAHs "may grant disaster privileges to volunteers that are eligible to be licensed independent practitioners" (CAMCAH, Standard MS.4.110, CAMCAH Refreshed Care, January 2008, p. MS–20). Finally, in the chapter entitled "Management of Human Resources" (HR), CAHs "may assign disaster responsibilities to volunteer practitioners" (CAMCAH, Standard HR.1.25, CAMCAH Refreshed Core, January 2008, p. HR–6). Although the TJC accreditation requirements address some of our proposed requirements, we do not believe TJC-accredited CAHs would be in compliance with all requirements in proposed § 485.625(b)(6).

Based upon the previous discussion, we expect that the activities required for compliance by TJC-accredited CAHs

with § 485.625(b)(1) through (b)(5) constitutes usual and customary business practices for PRAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

However, we do not believe TJC-accredited CAHs would be substantially in compliance with proposed § 485.625(b)(6) through (8). We will discuss the burden for TJC-accredited CAHs to comply with these requirements later in this section.

The AOA accreditation standards also contain requirements for policies and procedures related to safety and disaster preparedness. The AOA-accredited CAHs are required to maintain plans and performance standards for disaster preparedness (ARCAH, Standard 11.00.02 Required Plans and Performance Standards, p. 11–2). They also must have "written procedures for possible situations to be followed by each department and service within the CAH and for each building used for patient treatment or housing" (ARCAH, Standard 11.07.01 Disaster Plans, Explanation, p.11–38). AOA-accredited CAHs also are required to have a safety team or committee that is responsible for all issues related to safety within the CAH (ARCAH, Standard 11.02.03, p. 11–7). The individuals or team would be responsible for all policies and procedures related to safety in the CAH (ARCAH, Standard 11.02.03, Explanation, p. 11–7). We expect that these performance standards and procedures are similar to some of our proposed requirements for policies and procedures.

In regard to proposed § 485.625(b)(1), AOA-accredited CAHs are required to consider "pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations" and "provisions if gas, water, electricity supply is shut off to the community" when they are developing their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Elements 5 and 11, pp. 11–5 and 11–6, respectively). In addition, CAHs are required "to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care" (ARCAH, Standard 11.03.22 Emergency Gas and Water, p. 11–22 through 11–23). However, these standards do not specifically address all of the proposed requirements in this subsection.

In regard to proposed § 485.625(b)(2), AOA-accredited CAHs are required to consider how they will communicate with their staff within the CAH when developing their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Element 7, p. 11–6). They also are required to have a "call tree" in their external disaster plan that must be updated at least annually (ARCAH, Standard 11.07.04 Staff Call Tree, p. 11–40). However, these requirements do not sufficiently cover the requirements to track the location of staff and patients during and after an emergency.

In regard to proposed § 485.625(b)(3), which requires policies and procedures regarding the safe evacuation from the facility, AOA-accredited CAHs are required to consider the "transfer or discharge of patients to home, other healthcare settings, or other CAHs" and the "transfer of patients with CAH equipment to another CAH or healthcare setting" (ARCAH, Standard 11.02.02 Building Safety, Elements 12 and 13, p. 11–6). AOA-accredited CAHs also are required to consider in their emergency plans how to maintain communication with external entities should their telephones and computers either cease to operate or become overloaded (ARCAH, Standard 11.02.02, Element 6, p. 11–6). AOA-accredited CAHs must also "develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations" (ARCAH, Standard 11.02.02 Building Safety, pp. 11–4 through 11–7). However, we do not believe these requirements are detailed enough to ensure that AOA-accredited CAHs are compliant with our proposed requirements.

In regard to proposed § 485.625(b)(4), AOA-accredited CAHs are required to consider the special needs of their patient population and the security of those patients and others that come to them for care when they develop their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Elements 2 and 3, p. 11–5). In addition, as described earlier, they also must consider the food, pharmaceuticals, and other supplies and equipment they may need during an emergency in developing their emergency plan (ARCAH, Standard 11.02.02, Element 5, p. 11–5). However, these requirements do not specifically mention volunteers and CAHs are required only to consider these elements in developing their plans.

Therefore, we believe that AOA-accredited CAHs have likely already incorporated many of the elements necessary to satisfy the requirements in proposed § 485.625(b); however, they would need to thoroughly review their current policies and procedures and perform whatever tasks are necessary to ensure that they complied with all of our proposed requirements for emergency policies and procedures. Because we expect that AOA-accredited CAHs already comply with many of our proposed requirements, we will include the AOA-accredited CAHs with the TJC-accredited CAHs in determining the burden.

The burden for the 32 AOA-accredited CAHs and the 370 TJC-accredited CAHs to comply with all of the requirements in proposed § 485.625(b) would be the resources required to develop written policies and procedures that comply with all of our proposed requirements for emergency policies and procedures. Based on our experience working with CAHs, we expect that accomplishing these activities would require the involvement of an administrator, the medical director, director of nursing, facilities director, and food services director. We expect that the administrator would review the policies and procedures and make recommendations for necessary changes or additional policies or procedures. The CAH administrator would brief other staff and assign staff to make necessary revisions or draft new policies and procedures and disseminate them to the appropriate parties. We estimate that complying with this requirement would require 10 burden hours for each TJC and AOA-accredited CAH at a cost of $624. For all 402 TJC and AOA-accredited CAHs to comply with these requirements would require an estimated 4,020 burden hours (10 burden hours for each TJC or AOA-accredited CAH × 402 TJC and AOA-accredited CAHs = 4,020 burden hours) at a cost of $327,228 ($814 estimated cost for each TJC or AOA-accredited CAH × 402 TJC and AOA-accredited CAHs = $327,228 estimated cost).

We expect that the 920 non-accredited CAHs already have developed some emergency preparedness policies and procedures. The current CAH CoPs require CAHs to develop, maintain, and review policies to ensure quality care and a safe environment for their patients (§ 485.627(a), § 485.635(a), and § 485.641(a)(1)(iii)). In addition, certain activities associated with our proposed requirements are addressed in the current CAH CoPs. For example, all CAHs are required to have agreements or arrangements with one or more providers or suppliers, as appropriate, to provide services to their patients (§ 485.635(c)).

The burden associated with the development of emergency policies and procedures would be the resources needed to review, revise, and if needed, develop emergency preparedness policies and procedures that include our proposed requirements. We believe the

individuals and tasks would be the same as described earlier for the TJC and AOA-accredited CAHs. However, the non-accredited CAHs would require more time to accomplish these activities. We estimate that a non-accredited CAH's compliance would require 14 burden hours at a cost of $860. For all 920 unaccredited CAHs to comply with this requirement would require an estimated 12,880 burden hours (14 burden hours for each non-accredited CAHs × 920 non-accredited CAHs = 12,880 burden hours) at a cost of $791,200 ($860 estimated cost for each non-accredited CAH × 920 non-accredited CAHs = $791,200 estimated cost).

Thus, for all 1,322 CAH to comply with the requirements in proposed § 485.625(b) would require 16,900 burden hours at a cost of $1,118,428.

Proposed § 485.625(b) would also require CAHs to review and update their emergency preparedness policies and procedures at least annually. As discussed earlier, TJC and AOA-accredited CAHs already periodically review their policies and procedures. In addition, the existing CAH CoPs require periodic reviews of the CAH's health care policies (§ 485.627(a), § 485.635(a), and § 485.641(a)(1)(iii)). Thus, compliance with this requirement would constitute a usual and customary business practice for all CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.625(c) would require CAHs to develop and maintain emergency preparedness communication plans that complied with both federal and state law. We propose that CAHs review and update these plans at least annually. We propose that these communication plans include the information listed at § 485.625(c)(1) through (7).

We expect that all CAHs would review their emergency preparedness communication plans and compare them to their risk assessments and emergency plans. We also expect that CAHs would revise and, if necessary, develop new sections that would comply with our proposed requirements. Based on our experience with CAHs, they generally have some type of emergency preparedness communication plan. Further, it is standard practice for health care facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. Thus, we believe that most, if not all, CAHs are already in compliance with proposed § 485.625(c)(1) through (3).

However, all CAHs would need to review and, if needed, revise and update their plans to ensure compliance with proposed § 485.625(c)(4) through (7). The TJC-accredited CAHs are required to establish strategies or plans for emergency communications (CAMCAH, Standard 4.13, p. EC–10b–10c). These plans must cover both internal and external communications and include back-up technologies and communication systems (CAMCAH, Standard 4.13, and EPs 1–14, p. EC–10b–EC–10c). However, we do not believe that these standards would ensure compliance with proposed § 485.625(c)(4) through (7). Thus, we will include the 365 TJC-accredited CAHs in the burden below.

The AOA-accredited CAHs must develop and implement communication plans to ensure the safety of their patients during emergencies (AOA Standard 11.02.02). These plans must specifically include both internal and external communications (AOA Standard 11.02.02, Elements 6, 7, and 10). Based on these standards, we do not believe they ensure compliance with proposed § 485.625(c)(4) through (7). Thus, we will include these 32 AOA-accredited CAHs in the burden below.

The burden associated with complying with this requirement would be the resources required to develop a communication plan that complied with the requirements of this section. Based on our experience with CAHs, we expect that accomplishing these activities would require the involvement of an administrator, director of nursing, and the facilities director. We expect that the administrator would review the communication plan and make recommendations for necessary changes or additions. The director of nursing and the facilities director would meet with the administrator to discuss and revise or draft new sections for the CAH's existing emergency communication plan. We estimate that complying with this requirement would require 9 burden hours for each CAH at a cost of $519. We estimate that for all 1,322 CAHs to comply with the requirements for an emergency preparedness communication plan would require 11,898 burden hours (9 burden hours for each CAH × 1,322 CAHs = 11,898 burden hours) at a cost of $686,118 ($519 estimated cost for each CAH × 1,322 CAHs = $686,118 estimated cost).

Proposed § 485.625(c) also would require CAHs to review and update their emergency preparedness communication plans at least annually. All CAHs are required to evaluate their entire program at least annually (§ 485.641(a)). Therefore, compliance with this requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.625(d) would require CAHs to develop and maintain emergency preparedness training and testing programs. We would also require CAHs to review and update their training and testing programs at least annually. We propose that a CAH comply with the requirements listed at § 485.625(d)(1) and (2).

Regarding § 485.625(d)(1), CAHs would have to provide initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the CAH would have to provide emergency preparedness training at least annually.

We expect that all CAHs would review their current training programs and compare them to their risk assessments and emergency preparedness plans, emergency policies and procedures, and emergency communication plans. The CAHs would need to revise and, if necessary, develop new sections or materials to ensure their training and testing programs complied with our proposed requirements.

Current CoPs require CAHs to train their staffs on how to handle emergencies (§ 485.623(c)(1)). However, this training primarily addresses internal emergencies, such as a fire inside the facility. In addition, both TJC and AOA require CAHs to provide their staff with training. TJC-accredited CAHs are required to provide their staff with both an initial orientation and on-going training (CAMCAH, Standards HR.2.10 and 2.30, pp. HR–8 and HR–9, respectively). On-going training must also be documented (CAMCAH, Standard HR.2.30, EP 8, p. HR–10). The AOA-accredited CAHs are required to provide an education program for their staff and physicians for the CAH's emergency response preparedness (AOA Standard 11.07.01). Each CAH also must

provide an education program specifically for the CAH's response plan for weapons of mass destruction (AOA Standard 11.07.07).

Thus, we expect that all CAHs provide some emergency preparedness training for their staff. However, neither the current CoPs nor the TJC and AOA accreditation standards ensure compliance with all our proposed requirements. All CAHs would need to review their risk assessments, emergency preparedness plans, policies and procedures, and communication plans and then revise or, in some cases, develop new sections for their training programs to ensure compliance with our proposed requirements. They also would need to revise, update, or, in some cases, develop new materials for the initial and ongoing training.

Based on our experience with CAHs, we expect that complying with our proposed requirement would require the involvement of an administrator, the director of nursing, and the facilities director. We expect that the director of nursing would perform the initial review of the training program, brief the administrator and the director of facilities, and revise or develop new sections for the training program, based on the group's decisions. We estimate that each CAH would require 14 burden hours to develop an emergency preparedness training program at a cost of $834. Therefore, for all 1,322 CAHs to comply with this requirement would require an estimated 18,508 burden hours (14 burden hours for each CAH × 1,322 CAHs = 18,508 burden hours) at a cost of $1,102,548 ($834 estimated cost for each CAH × 1,322 CAHs = $1,102,548 estimated cost).

Proposed § 485.625(d)(1) also would require CAHs to review and update their emergency preparedness training programs at least annually. Existing regulations require all CAHs to evaluate their entire program at least annually (§ 485.641(a)). Therefore, compliance with this proposed requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The CAHs also would be required to maintain documentation of their training. Based on our experience with CAHs, it is standard practice for them to document the training they provide to staff and other individuals. If a CAH needed to make any changes to their normal business practices to comply with this requirement, the burden would be negligible. Thus, compliance with this requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.625(d)(2) would require CAHs to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, the CAH would have to conduct an individual, facility-based mock disaster drill at least annually. CAHs also would be required to analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed. If a CAH experienced an actual natural or man-made emergency that required activation of the emergency plan, it would be exempt from the proposed requirement for an annual community or individual, facility-based mock disaster drill for 1 year following the onset of the emergency (proposed § 485.625(d)(2)(ii)). Thus, to meet these requirements, CAHs would need to develop scenarios for each drill and exercise and develop the required documentation.

If a CAH participated in a community mock disaster drill, it would likely not need to develop the scenario for that drill. However, for the purpose of determining the burden, we will assume that CAHs need to develop scenarios for both the drill and the exercise annually.

The TJC-accredited CAHs are required to test their EOP twice a year, either as a planned exercise or in response to an emergency (CAMCAH, Standard EC.4.20, EP 1, p. EC–12). These tests must be monitored, documented, and analyzed (CAMCAH, Standard EC.4.20, EPs 8–19, pp. EC–12—EC–13). Thus, we believe that TJC-accredited CAHs already develop scenarios for these tests. We also expect that they also have developed the documentation necessary to record and analyze their tests and responses to actual emergency events. Therefore, compliance with this requirement would constitute a usual and customary business practice for TJC-accredited CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The AOA-accredited CAHs are required to conduct two disaster drills annually (AOA Standard 11.07.03). In addition, AOA-accredited CAHs are required to participate in weapons of mass destruction drills, as appropriate (AOA Standard 11.07.09). We expect that since AOA-accredited CAHs already conduct disaster drills, they also develop scenarios for the drills. In addition, it is standard practice in the health care industry to document and analyze tests that a facility conducts. Thus, compliance with this requirement would constitute a usual and customary business practice for AOA-accredited CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Based on our experience with CAHs, we expect that the 831 non-accredited CAHs already have some type of emergency preparedness training program and conduct some type of drills or exercises to test their emergency preparedness plans. However, this does not ensure that most CAHs already perform the activities needed to comply with our proposed requirements. Thus, we will analyze the burden for these requirements for the 920 non-accredited CAHs.

The 920 non-accredited CAHs would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the documentation necessary to record and later analyze the events that occurred during these tests and actual emergency events. Based on our experience with CAHs, we believe that the same individuals who developed the emergency preparedness training program would develop the scenarios for the tests and the accompanying documentation. We expect that the director of nursing would spend more time than would the other individuals developing the scenarios and the accompanying documentation. We estimate that it would require 8 burden hours for the 920 non-accredited CAHs to comply with these proposed requirements at a cost of $488. Therefore, for all 920 non-accredited CAHs to comply with these requirements would require an estimated 7,360 burden hours (8 burden hours for each non-accredited CAH × 920 non-accredited CAHs = 7,360 burden hours) at a cost of $448,960 ($488 estimated cost for each non-accredited CAH × 920 non-accredited CAHs = $448,960 estimated cost).

TABLE 12—BURDEN HOURS AND COST ESTIMATES FOR ALL 1,322 CAHS TO COMPLY WITH THE ICRS CONTAINED IN § 485.625 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 485.625(a)(1)	0938—New	952	952	15	14,280	**	903,448	0	903,448
§ 485.625(a)(2)–(4)	0938—New	952	952	26	24,752	**	1,542,240	0	1,542,240
§ 485.625(b) (TJC and AOA-Accredited)	0938—New	402	402	10	4,020	**	327,228	0	327,228
§ 485.625(b) (Non-accredited)	0938—New	920	920	14	12,880	**	791,200	0	791,200
§ 485.625(c)	0938—New	1322	1322	9	11,898	**	686,118	0	686,118
§ 485.625(d)(1)	0938—New	1322	1322	14	18,508	**	1,102,548	0	1,102,548
§ 485.625(d)(2)	0938—New	920	920	8	7,360	**	448,960	0	448,960
Total			6,790		93,698				5,801,742

** The hourly labor cost is blended between the wages for multiple staffing levels.

O. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.727)

Proposed § 485.727(a) would require clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (organizations) to develop and maintain emergency preparedness plans and review and update the plan at least annually. We are proposing that the plan comply with the requirements listed at § 485.727(a)(1) through (6).

Proposed § 485.727(a)(1) would require organizations to develop documented, facility-based and community-based risk assessment utilizing an all-hazards approach. Organizations would need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area.

The current CoPs for Organizations require these providers to have "a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster" (§ 485.727(a)). To comply with this CoP, we expect that all of these providers have already performed some type of risk assessment during the process of developing their disaster plans and policies and procedures. However, these providers would need to review their current risk assessments and make any revisions to ensure they complied with our proposed requirements.

We have not designated any specific process or format for these providers to use in conducting their risk assessments because we believe that they need the flexibility to determine the best way to accomplish this task. Providers of physical therapy and speech therapy services should include input from all of their major departments in the process of developing their risk assessments. Based on our experience with these providers, we expect that conducting the risk assessment would require the involvement of the organization's administrator and a therapist. The types of therapists at each Organization vary depending upon the services offered by the facility. For the purposes of determining the PRA burden, we will assume that the therapist is a physical therapist. We expect that both the administrator and the therapist would attend an initial meeting, review the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator would coordinate the meetings, review and critique the current risk assessment initially, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We also expect that the administrator would spend more time reviewing and working on the risk assessment than the physical therapist. We estimate that complying with this requirement would require 9 burden hours at a cost of $549. We estimate that it would require 20,034 burden hours (9 burden hours for each organization × 2,256 organizations = 20,304 burden hours) for all organizations to comply with this requirement at a cost of $1,238,544 ($549 estimated cost for each organization × 2,256 organizations = $1,238,544 estimated cost).

After conducting the risk assessment, each organization would need to develop and maintain an emergency preparedness plan and review and update it at least annually. Current CoPs require these providers to have a written disaster plan with accompanying procedures for fires, explosions, and other disasters (§ 485.727(a)). The plan must include or address the transfer of casualties and records, the location and use of alarm systems and signals, methods of containing fire, notification of appropriate persons, and evacuation routes and procedures (§ 485.727(a)). Thus, we expect that all of these organizations have some type of emergency preparedness plan and that these plans address many of our proposed requirements. However, all organizations would need to review their current plans and compare them to their risk assessments. Each organization would need to revise, update, and, in some cases, develop new sections to complete a comprehensive emergency preparedness plan that complied with our proposed requirements.

Based on our experience with these organizations, we expect that the administrator and physical therapist who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect it would require more time to complete the plan and that the administrator would be the most heavily involved in reviewing and developing the organization's emergency preparedness plan. We estimate that for each organization to comply would require 12 burden hours at a cost of $741. We estimate that it would require 27,072 burden hours (12 burden hours for each organization × 2,256 organizations = 27,072 burden hours) to complete the plan at a cost of $1,671,696 ($741 estimated cost for each organization × 2,256 organizations = $1,671,696 estimated cost).

Each organization would also be required to review and update its emergency preparedness plan at least annually. We believe that these organizations already review their plans periodically. Thus, complying with this requirement would constitute a usual and customary business practice for organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(b) would require organizations to develop and implement emergency preparedness policies and procedures based on their risk assessments, emergency plans, communication plans as set forth in

§ 485.727(a)(1), (a), and (c), respectively. It would also require organizations to review and update these policies and procedures at least annually. At a minimum, we would require that an organization's policies and procedures address the requirements listed at § 485.727(b)(1) through (4).

We expect that all organizations have emergency preparedness policies and procedures. As discussed earlier, the current CoPs require organizations to have procedures within their written disaster plan to be followed for fires, explosions, or other disasters (§ 485.727(a)). In addition, we expect that those procedures already address some of the specific elements required in this section. For example, the current requirements at § 485.727(a)(1) through (4) are similar to our proposed requirements at § 485.727(a)(1) through (5). However, all organizations would need to review their policies and procedures, assess whether their policies and procedures incorporate all of the necessary elements of their emergency preparedness program, and, if necessary, take the appropriate steps to ensure that their policies and procedures are in compliance with our proposed requirements.

We expect that the administrator and the physical therapist would be primarily involved with reviewing and revising the current policies and procedures and, if needed, developing new policies and procedures. We estimate that it would require 10 burden hours for each organization to comply at a cost of $613. We estimate that for all organizations to comply would require 22,560 burden hours (10 burden hours for each organization × 2,256 organizations = 23,550 burden hours) at a cost of $1,382,928 ($622 estimated cost for each organization × 2,256 organizations = $1,382,928 estimated cost).

We would require organizations to review and update their emergency preparedness policies and procedures at least annually. We believe that these providers already review their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(c) would require organizations to develop and maintain emergency preparedness communication plans that complied with both federal and state law and would be reviewed and updated at least annually. The communication plan would have to include the information listed at § 485.727(c)(1) through (5).

We expect that all organizations have some type of emergency preparedness communication plan. Current CoPs for these organizations already require them to have a written disaster plan with procedures that must include, among other things, "notification of appropriate persons" (§ 485.727(a)(4)). Thus, we expect that each organization has the contact information they would need to comply with this proposed requirement. In addition, it is standard practice for health care facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many organizations may not have formal, written emergency preparedness communication plans or their plans may not be fully compliant with our proposed requirements. Therefore, we expect that all organizations would need to review, update, and, in some cases, develop new sections for their plans.

Based on our experience with these organizations, we anticipate that satisfying the requirements in this section would primarily require the involvement of the organization's administrator with the assistance of a physical therapist. We estimate that for each organization to comply would require 8 burden hours at a cost of $494. We estimate that for all 2,256 organizations to comply would require 18,048 burden hours (8 burden hours for each organizations × 2,256 organizations = 18,048 burden hours) at a cost of $1,114,464 ($494 estimated cost for each organization × 2,256 organizations = $1,114,464 estimated cost).

We are proposing that organizations must review and update their emergency preparedness communication plans at least annually. We believe that these organizations already review their emergency communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(d) would require organizations to develop and maintain emergency preparedness training and testing programs and review and update these programs at least annually. Specifically, we are proposing that organizations comply with the requirements listed at § 485.727(d)(1) and (2).

With respect to § 485.727(d)(1), organizations would have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the CAH would have to provide emergency preparedness training at least annually.

Current CoPs require organizations to ensure that "all employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures . . ."(42 CFR 485.727(b)). Thus, we expect that organizations already have an emergency preparedness training program for new employees, as well as ongoing training for all staff. However, organizations would need to review their current training programs and compare them to their risk assessments and emergency preparedness plans, policies and procedures, and communication plans. Organizations would need to review, revise, and, in some cases, develop new material for their training programs so that they comply with our proposed requirements.

We expect that complying with this requirement would require the involvement of an administrator and a physical therapist. We expect that the administrator would primarily be involved in reviewing the organization's current training program and the current emergency preparedness program; determining what tasks would need to be performed and what materials would need to be developed to comply with our proposed requirements; and developing the materials for the training program. We expect that the physical therapist would work with the administrator to develop the revised and updated training program. We estimate that it would require 8 burden hours for each organization to develop a comprehensive emergency training program at a cost of $494. Therefore, it would require an estimated 18,048 burden hours (8 burden hours for each organization × 2,256 organizations = 18,048 burden hours) to comply with this requirement at a cost of $1,114,464 ($494 estimated cost for each organization × 2,256 organizations = $1,114,464 estimated cost).

In § 485.727(d)(1), we also propose requiring that an organization must review and update its emergency

preparedness training program at least annually. We believe that these providers already review their emergency preparedness training programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(d)(2) would require organizations to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, the organization would have to conduct an individual, facility-based mock disaster drill at least annually. If an organization experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. Organizations also would be required to analyze their response to and maintain documentation of all the drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed. To comply with this requirement, an organization would need to develop scenarios for their drills and exercises. An organization also would have to develop the documentation necessary for recording and analyzing their responses to drills, exercises, and actual emergency events.

The current CoPs require organizations to have a written disaster plan that is "periodically rehearsed" and have "ongoing . . . drills" (§ 485.727(a) and (b)). Thus, we expect that all 2,256 organizations currently conduct some type of drill or exercise of their disaster plan. However, the current organizations CoPs do not specify the type of drill, how they are to conduct the drills, or whether the drills should be community-based. In addition, there is no requirement for a paper-based, tabletop exercise. Thus, these requirements do not ensure that organizations would be in compliance with our proposed requirements. Therefore, we will analyze the burden from these requirements for all organizations.

The 2,256 organizations would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the necessary documentation. Based on our experience with organizations, we expect that the same individuals who develop the emergency preparedness training program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the administrator would spend more time than the physical therapist developing the scenarios and the documentation. We estimate that for each organization to comply would require 3 burden hours at a cost of $183. Based on that estimate, it would require 6,768 burden hours (3 burden hours for each organization × 2,256 organizations = 6,768 burden hours) at a cost of $417,360 ($183 estimated cost for each organization × 2,256 organizations = $417,360 estimate cost).

TABLE 13—BURDEN HOURS AND COST ESTIMATES FOR ALL 2,256 ORGANIZATIONS TO COMPLY WITH THE ICRS CONTAINED IN § 485.727 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 485.727(a)(1)	0938—New	2,256	2,256	9	20,304	**	1,238,544	0	1,238,544
§ 485.727(a)(2)–(4)	0938—New	2,256	2,256	12	27,072	**	1,671,696	0	1,671,696
§ 485.727(b)	0938—New	2,256	2,256	10	22,560	**	1,382,928	0	1,382,928
§ 485.727(c)	0938—New	2,256	2,256	8	18,048	**	1,114,464	0	1,114,464
§ 485.727(d)(1)	0938—New	2,256	2,256	8	18,048	**	1,114,464	0	1,114,464
§ 485.727(d)(2)	0938—New	2,256	2,256	3	6,768	**	417,360	0	417,360
Totals		2,256	13,536		112,800				6,939,456

** The hourly labor cost is blended between the wages for multiple staffing levels.

P. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.920)

Proposed § 485.920(a) would require Community Mental Health Centers (CMHCs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. Specifically, we propose that the plan must meet the requirements listed at § 485.920(a)(1) through (4).

We expect all CMHCs to identify the likely medical and non-medical emergency events they could experience within the facility and the community in which it is located and determine the likelihood of the facility experiencing an emergency due to the identified hazards. We expect that in performing the risk assessment, a CMHC would need to consider its physical location, the geographical area in which it is located and its patient population.

The burden associated with this proposed requirement would be the time and effort necessary to perform a thorough risk assessment. We expect that most, if not all, CMHCs have already performed at least some of the work needed for a risk assessment because it is standard practice for health care organizations to prepare for common emergencies, such as fires, interruptions in communication and power, and storms. However, many CMHCs may not have performed a risk assessment that complies with the proposed requirements. Therefore, we expect that most, if not all, CMHCs would have to perform a thorough review of their current risk assessment and perform the tasks necessary to ensure that the facility's risk assessment complies with the proposed requirements.

We do not propose designating any specific process or format for CMHCs to use in conducting their risk assessments because we believe CMHCs need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect that in the process of developing a risk assessment, health care organizations would include representatives from or obtain input from all major departments. Based on our experience with CMHCs, we expect that conducting the risk assessment would require the involvement of the CMHC administrator, a psychiatric registered nurse, and a clinical social worker or mental health counselor. We expect that most of these individuals would attend an initial meeting, review relevant sections of the current assessment, prepare and forward their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the risk assessment. We expect that the administrator would coordinate the meetings, do an initial review of the current risk assessment, critique the risk assessment, offer suggested revisions,

coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. It is likely that the CMHC administrator would spend more time reviewing and working on the risk assessment than the other individuals. We estimate that complying with the proposed requirement to conduct a risk assessment would require 10 burden hours for a cost of $470. There are currently 207 CMHCs. Therefore, it would require an estimated 2,070 burden hours (10 burden hours for each CMHC × 207 CMHCs = 2,070 burden hours) for all CMHCs to comply with this requirement at a cost of $97,290 ($470 estimated cost for each CMHC × 207 CMHCs = $97,290 estimated cost).

After conducting the risk assessment, CMHCs would need to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. CMHCs would need to compare their current emergency plan, if they have one, to their risk assessment. They would then need to revise and, if necessary, develop new sections of their plan to ensure it complies with the proposed requirements.

It is standard practice for health care organizations to make plans for common disasters they may confront, such as fires, interruptions in communication and power, and storms. Thus, we expect that all CMHCs have some type of emergency preparedness plan. However, their plan may not address all likely medical and non-medical emergency events identified by the risk assessment. Further, their plans may not include strategies for addressing likely emergency events or address their patient population, the type of services they have the ability to provide in an emergency, or continuity of operation, including delegations of authority and succession plans. We expect that CMHCs would have to review their current plan and compare it to their risk assessment, as well as to the other requirements in proposed § 485.920(a). We expect that most CMHCs would need to update and revise their existing emergency plan and, in some cases, develop new sections to comply with our proposed requirements.

The burden associated with this requirement would be due to the resources needed to develop an emergency preparedness plan or to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with CMHCs, we expect that the same individuals who were involved in the risk assessment would be involved in developing the emergency preparedness plan. We also expect that developing the plan would require more time to complete than the risk assessment. We expect that the administrator and a psychiatric nurse would spend more time reviewing and developing the CMHC's emergency preparedness plan. We expect that the clinical social worker or mental health counselor would review the plan and provide comments on it to the administrator. We estimate that it would require 15 burden hours for a CMHC to develop its emergency plan at a cost of $750. Based on this estimate, it would require 3,105 burden hours (15 burden hours for each CMHC × 207 CMHCs = 3,105 burden hours) for all CMHCs to complete their plans at a cost of $155,250 ($750 estimated cost for each CMHC × 207 CMHCs = $155,250 estimated cost).

The CMHC would be required to review and update its emergency preparedness plan at least annually. For the purpose of determining the burden for this proposed requirement, we expect that the CMHCs will review and update their plans annually.

We expect that all CMHCs have an administrator that is responsible for the day-to-day operation of the CMHC. This would include ensuring that all of the CMHC's plans are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. In addition, it is standard practice in the health care industry for facilities to have a professional staff person, generally an administrator, who periodically reviews their plans and procedures. We expect that complying with the requirement for an annual review of the emergency preparedness plan would constitute a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(b) would require CMHCs to develop and maintain emergency preparedness policies and procedures based on the emergency plan, the communication plan, and the risk assessment. We also propose requiring CMHCs to review and update these policies and procedures at least annually. The CMHC's policies and procedures would be required to address, at a minimum, the requirements listed at § 485.920(b)(1) through (7).

We expect that all CMHCs would compare their current emergency preparedness policies and procedures to their emergency preparedness plan, communication plan, and their training and testing program. They would need to review, revise and, if necessary, develop new policies and procedure to ensure they comply with the proposed requirements. The burden associated with reviewing, revising, and updating the CMHC's emergency policies and procedures would be due to the resources needed to ensure they comply with the proposed requirements. We expect that the administrator and the psychiatric registered nurse would be involved with reviewing, revising and, if needed, developing any new policies and procedures. We estimate that for a CMHC to comply with this proposed requirement would require 12 burden hours at a cost of $630. Therefore, for all 207 CMHCs to comply with this proposed requirement would require an estimated 2,484 burden hours (12 burden hours for each CMHC × 207 CMHCs = 2,484 burden hours) at a cost of $130,410 ($630 estimated cost for each CMHC × 207 CMHCs = $130,410 estimated cost).

The CMHCs would be required to review and update their emergency preparedness policies and procedures at least annually. For the purpose of determining the burden for this requirement, we expect that CMHCs would review their policies and procedures annually. We expect that all CMHCs have an administrator who is responsible for the day-to-day operation of the CMHC, which includes ensuring that all of the CMHC's policies and procedures are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. We also expect that the administrator is responsible for periodically reviewing the emergency preparedness policies and procedures as part of his or her responsibilities. We expect that complying with the requirement for an annual review of the emergency preparedness policies and procedures would constitute a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(c) would require CMHCs to develop and maintain an emergency preparedness communications plan that complies with both federal and state law. The CMHC also would have to review and update this plan at least annually. The communication plan must include the information listed in § 485.920(c)(1) through (7).

We expect that all CMHCs would compare their current emergency

preparedness communications plan, if they have one, to the proposed requirements. CMHCs would need to perform any tasks necessary to ensure that their communication plans were documented and in compliance with the proposed requirements.

We expect that all CMHCs have some type of emergency preparedness communications plan. However, their emergency communications plan may not be thoroughly documented or comply with all of the elements we are requiring. It is standard practice for health care organizations to maintain contact information for their staff and for outside sources of assistance; alternate means of communication in case there is a disruption in phone service to the facility (for example, cell phones); and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, we expect that all CMHCs would need to review, update, and in some cases, develop new sections for their plans to ensure that those plans include all of the elements we are requiring for CMHC communications plans.

The burden associated with complying with this proposed requirement would be due to the resources required to ensure that the CMHC's emergency communication plan complies with the requirements. Based upon our experience with CMHCs, we expect the involvement of the CMHC's administrator and the psychiatric registered nurse. For each CMHC, we estimate that complying with this requirement would require 8 burden hours at a cost of $415. Therefore, for all of the CMHCs to comply with this proposed requirement would require an estimated 1,656 burden hours (8 burden hours for each CMHC × 207 CMHCs = 1,656 burden hours) at a cost of $85,905 ($415 estimated cost for each CMHC × 207 CMHCs = $85,905 estimated cost).

We expect that CMHCs must also review and update their emergency preparedness communication plan at least annually. For the purpose of determining the burden for this proposed requirement, we expect that CMHCs would review their policies and procedures annually. We expect that all CMHCs have an administrator who is responsible for the day-to-day operation of the CMHC. This includes ensuring that all of the CMHC's policies and procedures are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. We expect that the administrator is responsible for periodically reviewing the CMHC's plans, policies, and procedures as part of his or her responsibilities. In addition, we expect that an annual review of the communication plan would require only a negligible burden. Complying with the proposed requirement for an annual review of the emergency preparedness communications plan constitutes a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(d) would require CMHCs to develop and maintain an emergency preparedness training program that must be reviewed and updated at least annually. We would require the CMHC to meet the requirements contained in § 485.920(d)(1) and (2).

We expect that CMHCs would develop a comprehensive emergency preparedness training program. The CMHCs would need to compare their current emergency preparedness training program and compare its contents to the risk assessment and updated emergency preparedness plan, policies and procedures, and communications plan and review, revise, and, if necessary, develop new sections for their training program to ensure it complies with the proposed requirements.

The burden would be due to the resources the CMHC would need to comply with the proposed requirements. We expect that complying with this requirement would include the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse would be primarily involved in reviewing the CMHC's current training program, determining what tasks need to be performed or what materials need to be developed, and developing the materials for the training program. We estimate that it would require 10 burden hours for each CMHC to develop a comprehensive emergency training program at a cost of $414. Therefore, it would require an estimated 2,070 burden hours (10 burden hours for each CMHC × 207 CMHCs = 2,070 burden hours) to comply with this proposed requirement at a cost of $85,698 ($414 estimated cost for each CMHC × 207 CMHCs = $85,698 estimated cost).

Proposed § 485.920(d)(1) would also require the CMHCs to review and update their emergency preparedness training program at least annually. For the purpose of determining the burden for this proposed requirement, we will expect that CMHCs would review their emergency preparedness training program annually. We expect that all CMHCs have a professional staff person, probably a psychiatric registered nurse, who is responsible for periodically reviewing their training program to ensure that it is up-to-date and complies with the relevant federal, state, and local laws, regulations, and ordinances. In addition, we expect that an annual review of the CMHC's emergency preparedness training program would require only a negligible burden. Thus, we expect that complying with the proposed requirement for an annual review of the emergency preparedness training program constitutes a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(d)(2) would require CMHCs to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. CMHCs would be required to document the drills and the exercises. To comply with this proposed requirement, a CMHC would need to develop a specific scenario for each drill and exercise. A CMHC would have to develop the documentation necessary to record what happened during the drills and exercises.

Based on our experience with CMHCs, we expect that all 207 CMHCs have some type of emergency preparedness training program and most, if not all, of these CMHCs already conduct some type of drill or exercise to test their emergency preparedness plans. However, we do not know what type of drills or exercises they typically conduct or how often they are performed. We also do not know how, or if, they are documenting and analyzing their responses to these drills and tests. For the purpose of determining a burden for these proposed requirements, we will expect that all CMHCs need to develop two scenarios, one for the drill and one for the exercise, and develop the documentation necessary to record the facility's responses.

The associated burden would be the time and effort necessary to comply with the requirement. We expect that complying with this proposed requirement would likely require the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse would develop the documentation necessary for both

during the drill and the exercise and for the subsequent analysis of the CMHC's response. The psychiatric registered nurse would also develop the two scenarios for the drill and exercise. We estimate that these tasks would require 4 burden hours at a cost of $166. For all 207 CMHCs to comply with this proposed requirement would require an estimated 828 burden hours (4 burden hours for each CMHC × 207 CMHCs = 828 burden hours) at a cost of $34,362 ($166 estimated cost for each CMHC × 207 CMHCs = $34,362 estimated cost).

TABLE 14—BURDEN HOURS AND COST ESTIMATES FOR ALL 207 CMHCS TO COMPLY WITH THE ICRS CONTAINED IN § 485.920 EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 485.920(a)(1)	0938—New	207	207	10	2,070	**	97,290	97,290
§ 485.920(a)(1)–(4)	0938—New	207	207	15	3,105	**	155,250	155,250
§ 485.920(b)	0938—New	207	207	12	2,484	**	130,410	130,410
§ 485.920(c)	0938—New	207	207	8	1,656	**	85,905	85,905
§ 485.920(d)(1)	0938—New	207	207	10	2,070	**	85,698	85,698
§ 485.920(d)(2)	0938—New	207	207	4	828	**	34,362	34,362
Totals		207	1,242		12,213			588,915

Q. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 486.360)

Proposed § 486.360(a) would require Organ Procurement Organizations (OPOs) to develop and maintain emergency preparedness plans that would have to be reviewed and updated at least annually. These plans would have to comply with the requirements listed in § 486.360(a)(1) through (4).

The current OPO Conditions for Coverage (CfCs) are located at 42 CFR 486.301 through 486.348. These CfCs do not contain any specific emergency preparedness requirements. Thus, for the purpose of determining the burden, we have analyzed the burden for all 58 OPOs for all of the ICRs contained in this proposed rule.

Proposed § 486.360(a)(1) would require OPOs to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. OPOs would need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area, including branch offices and hospitals in their donation services areas.

The burden associated with this requirement would be the time and effort necessary to perform a thorough risk assessment. Based on our experience with OPOs, we believe that all 58 OPOs have already performed at least some of the work needed for their risk assessments. However, these risk assessments may not be documented or may not address all of the elements required under proposed § 486.360(a). Therefore, we expect that all 58 OPOs would have to perform a thorough review of their current risk assessments and perform the necessary tasks to ensure that their risk assessment complied with the requirements of this proposed rule. Based on our experience with OPOs, we believe that conducting a risk assessment would require the involvement of the OPO's director, medical director, quality assessment and performance improvement (QAPI) director, and an organ procurement coordinator (OPC). We expect that these individuals would attend an initial meeting; review relevant sections of the current assessment, prepare and send their comments to the QAPI director; attend a follow-up meeting; perform a final review; and approve the new risk assessment. We estimate that the QAPI Director probably would coordinate the meetings, review the current risk assessment, critique the risk assessment, coordinate comments, develop the new risk assessment, and assure that the necessary parties approved it. We estimate that it would require 10 burden hours for each OPO to conduct a risk assessment at a cost of $822. Therefore, for all 58 OPOs to comply with the risk assessment requirement in this section would require an estimated 580 burden hours (10 burden hours for each OPO × 58 OPOs = 580 burden hours) at a cost of $47,676 ($822 estimated cost for each OPO × 58 OPOs = $47,676 estimated cost).

After conducting the risk assessment, OPOs would then have to develop emergency preparedness plans. The burden associated with this requirement would be the resources needed to develop an emergency preparedness plan that complied with the requirements in proposed § 486.360(a)(1) through (4). We expect that all OPOs have some type of emergency preparedness plan because it is standard practice in the health care industry to have a plan to address common emergencies, such as fires. In addition, based on our experience with OPOs (including the performance of the Louisiana OPO during the Katrina disaster), OPOs already have plans to ensure that services will continue to be provided in their donation service areas (DSAs) during an emergency. However, we do not expect that all OPOs would have emergency preparedness plans that would satisfy the requirements of this section. Therefore, we expect that all OPOs would need to review their current emergency preparedness plans and compare their plans to their risk assessments. Most OPOs would need to revise, and in some cases develop, new sections to ensure their plan satisfied the proposed requirements.

We expect that the same individuals who were involved in the risk assessment would be involved in developing the emergency preparedness plan. We expect that these individuals would attend an initial meeting, review relevant sections of the OPO's current emergency preparedness plan, prepare and send their comments to the QAPI director, attend a follow-up meeting, perform a final review, and approve the new plan. We expect that the QAPI Director would coordinate the meetings, perform an initial review of the current emergency preparedness plan, critique the emergency preparedness plan, coordinate comments, ensure that the appropriate individuals revise the plan, and ensure that the necessary parties approve the new plan.

Thus, we estimate that it would require 22 burden hours for each OPO to develop an emergency preparedness plan that complied with the requirements of this section at a cost of $1,772. Therefore, for all 58 OPOs to comply with this requirement would require an estimated 1,276 burden hours (22 burden hours for each OPO × 58 OPOs = 1,276 burden hours) at a cost of $102,776 ($1,772 estimated cost for each

OPO × 58 OPOs = $102,776 estimated cost).

OPOs would also be required to review and update their emergency preparedness plans at least annually. We believe that all of the OPOs already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for OPOs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(b) would require OPOs to develop and maintain emergency preparedness policies and procedures based on their risk assessments, emergency preparedness plans, emergency communication plan as set forth in proposed § 486.360(a)(1), (a), and (c), respectively. It would also require OPOs to review and update these policies and procedures at least annually. The OPO's policies and procedures must address the requirements listed at § 486.360(b)(1) and (2).

The OPO CfCs already require the OPOs' governing boards to "develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including . . . the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for those services" (§ 486.324(e)). Thus, we expect that OPOs already have developed and implemented policies and procedures for their effective administration. However, since the current CfCs have no specific requirement that these policies and procedures address emergency preparedness, we do not believe that the OPOs have developed or implemented all of the policies and procedures that would be needed to comply with the requirements of this section.

The burden associated with the development of the emergency preparedness policies and procedures would be the resources needed to develop emergency preparedness policies and procedures that would include, but would not be limited to, the specific elements identified in this requirement. We expect that all OPOs would need to review their current policies and procedures and compare them to their risk assessments, emergency preparedness plans, emergency communication plans, and agreements and protocols, they have developed as required by this proposed rule. Following their reviews, OPOs would need to develop and implement the policies and procedures necessary to ensure that they initiate and maintain their emergency preparedness plans, agreements, and protocols.

Based on our experience with OPOs, we expect that accomplishing these activities would require the involvement of the OPO's director, medical director, QAPI director, and an Organ Procurement Coordinator (OPC). We expect that all of these individuals would review the OPO's current policies and procedures; compare them to the risk assessment, emergency preparedness plan, agreements and protocols they have established with hospitals, other OPOs, and transplant programs; provide an analysis or comments; and participate in developing the final version of the policies and procedures.

We expect that the QAPI director would likely coordinate the meetings; coordinate and incorporate comments; draft the revised or new policies and procedures; and obtain the necessary signatures for final approval. We estimate that it would require 20 burden hours for each OPO to comply with the requirement to develop emergency preparedness policies and procedures at a cost of $1,482. Therefore, for all 58 OPOs to comply with this requirement would require an estimated 1,160 burden hours (20 burden hours for each OPO × 58 OPOs = 1,160 burden hours) at a cost of $85,956 (estimated cost for each OPO of $1,482 × 58 OPOs = $85,956 estimated cost).

OPOs also would be required to review and update their emergency preparedness policies and procedures at least annually. We believe that OPOs already review their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(c) would require OPOs to develop and maintain emergency preparedness communication plans that complied with both federal and state law. The OPOs would have to review and update their plans at least annually. The communication plans would have to include the information listed in § 486.360(c)(1) through (3).

OPOs must operate 24 hours a day, seven days a week. OPOs conduct much of their work away from their office(s) at various hospitals within their DSAs. To function effectively, OPOs must ensure that they and their staff at these multiple locations can communicate with the OPO's office(s), other OPO staff members, transplant and donor hospitals, transplant programs, the Organ Procurement and Transplantation Network (OPTN), other healthcare providers, other OPOs, and potential and actual donors' next-of-kin.

Thus, we expect that the nature of their work would ensure that all OPOs have already addressed at least some of the elements that would be required by this section. For example, due to the necessity of communication with so many other entities, we expect that all OPOs would have compiled names and contact information for staff, other OPOs, and transplant programs.

We also expect that all OPOs would have alternate means of communication for their staffs. However, we do not believe that all OPOs have developed formal plans that include all of the proposed elements contained in this requirement. The burden would be the resources needed to develop an emergency preparedness communications plan that would include, but not be limited to, the specific elements identified in this section. We expect that this would require the involvement of the OPO director, medical director, QAPI director, and OPC. We expect that all of these individuals would need to review the OPO's current plans, policies, and procedures related to communications and compare them to the OPO's risk assessment, emergency plan, and the agreements and protocols the OPO developed in accordance with proposed § 486.360(e), and the OPO's emergency preparedness policies and procedures. We expect that these individuals would review the materials described earlier, submit comments to the QAPI director, review revisions and additions, and give a final recommendation or approval for the new emergency preparedness communication plan. We also expect that the QAPI director would coordinate the meetings; compile comments; incorporate comments into a new communications plan, as appropriate; and ensure that the necessary individuals review and approve the new plan.

We estimate that it would require 14 burden hours to develop an emergency preparedness communication plan at a cost of $1,078. Therefore, it would require an estimated 812 burden hours (14 burden hours for each OPO × 58 OPOs = 812 burden hours) at a cost of $62,524 ($1,078 estimated cost for each OPO × 58 OPOs = $62,524 estimated cost).

We propose that OPOs must review and update their emergency preparedness communication plans at least annually. We believe that all of the OPOs already review their emergency preparedness communication plans

periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for OPOs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(d) would require OPOs to develop and maintain emergency preparedness training and testing programs. OPOs also would be required to review and update these programs at least annually. In addition, OPOs must meet the requirements listed in § 486.360(d)(1) and (2).

In § 486.360(d)(1), we are proposing that OPOs be required to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of that training. OPOs must also ensure that their staff can demonstrate knowledge of their emergency procedures. Thereafter, OPOs would have to provide emergency preparedness training at least annually.

Under existing regulations, OPOs are required to provide their staffs with the training and education necessary for them to furnish the services the OPO is required to provide, including applicable organizational policies and procedures and QAPI activities (§ 486.326(c)). However, since there are no specific emergency preparedness requirements in the current OPO CfCs, we do not believe that the content of their existing training would comply with the proposed requirements.

We expect that OPOs would develop a comprehensive emergency preparedness training program for their staffs. Based upon our experience with OPOs, we expect that complying with this proposed requirement would require the OPO director, medical director, the QAPI director, an OPC, and the education coordinator. We expect that the QAPI director and the education coordinator would review the OPO's risk assessment, emergency preparedness plan, policies and procedures, and communication plan and make recommendations regarding revisions or new sections necessary to ensure that all appropriate information is included in the OPO's emergency preparedness training. We believe that the OPO director, medical director, and OPC would meet with the QAPI director and education coordinator and assist in the review, provide comments, and approve the new emergency preparedness training program.

We estimate that it would require 40 burden hours for each OPO to develop an emergency preparedness training program that complied with these requirements at a cost of $2,406. Therefore, we estimate that for all 58 OPOs to comply with this requirement would require 2,320 burden hours (40 burden hours for each OPO × 58 OPOs = 2,320 burden hours) at a cost of $139,548 ($2,406 estimated cost for each OPO × 58 OPOs = $139,548 estimated cost).

We propose that OPOs must review and update their emergency preparedness training programs at least annually. We believe that all of the OPOs already review their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for OPOs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(d)(2) would require OPOs to conduct a paper-based, tabletop exercise at least annually. OPOs also would be required to analyze their responses to and maintain documentation of all tabletop exercises and actual emergency events, and revise their emergency plans, as needed. To comply with this requirement, OPOs would have to develop scenarios for each tabletop exercise and the necessary documentation.

The OPO CfCs do not currently contain a requirement for OPOs to conduct a paper-based, tabletop exercise. However, OPOs are required to evaluate their staffs' performance and provide training to improve individual and overall staff performance and effectiveness (42 CFR 486.326(c)). Therefore, we expect that OPOs periodically conduct some type of exercise to test their plans, policies, and procedures, which would include developing a scenario for and documenting the exercise. Thus, compliance with these requirements would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

We expect that the QAPI director and the education coordinator would work together to develop the scenario for the exercise and the necessary documentation. We expect that the QAPI director would likely spend more time on these activities. We estimate that these tasks would require 5 burden hours for each OPO at a cost of $278. For all 58 OPOs to comply with these requirements would require an estimated 290 burden hours (5 burden hours for each OPO × 58 OPOs = 290 burden hours) at a cost of $16,124 ($278 estimated cost for each OPO × 58 OPOs = $16,124 estimated cost).

Proposed § 486.360(e) would require each OPO to have an agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's DSA in the event that the OPO cannot provide such services due to an emergency. This section would also require each OPO to include in the hospital agreements required under § 486.322(a), and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

The burden associated with the development of an agreement with another OPO and with the hospitals in the OPO's DSA would be the resources needed to negotiate, draft, and approve the agreement. For the purpose of determining a burden for this requirement, we will assume that each OPO would need to develop an agreement with one other OPO.

We expect that the OPO director, medical director, QAPI director, OPC, and an attorney would be involved in completing the tasks necessary to develop these agreements. We expect that all of these individuals would be involved in assessing the OPO's need for coverage of its DSA during emergencies and deciding with which OPO to negotiate an agreement. We also expect that the OPO director, QAPI director, and an attorney would be involved in negotiating the agreements and ensuring that the appropriate parties sign the agreements. The attorney would be responsible for drafting the agreement and making any necessary revisions.

We estimate that it would require 22 burden hours for each OPO to develop an agreement with another OPO to provide essential organ procurement services to all or a portion of its DSA during an emergency at a cost of $1,658. Therefore, it would require an estimated 1,276 burden hours (22 burden hours for each OPO × 58 OPOs = 1,276 burden hours) for all 58 OPOs to comply with this requirement at a cost of $96,164 ($1,658 estimated cost for each OPO × 58 OPOs = $96,164 estimated cost).

Proposed § 486.360(e) would also require OPOs to include in the agreements with hospitals required under § 486.322(a), and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant center, and the OPO in the event of an emergency. The current OPO CfCs do not contain a requirement for emergency preparedness to be covered in these agreements and protocols. However, based on our experience with

OPOs, hospitals, and transplant centers, we expect that most, if not all of these agreements and protocols already address roles and responsibilities during an emergency.

Thus, for the purpose of determining an ICR burden for these requirements, we will assume that all 58 OPOs would need to draft a limited amount of new language for their agreements with hospitals and the protocols with transplant centers. We expect that an attorney would be primarily responsible for drafting the language for these agreements and protocols and making any necessary revisions required by the parties. The number of hospitals and transplant programs in each DSA would vary widely between the OPOs. However, we expect that the attorney would draft standard language for both types of documents. In addition, we expect that the OPO director, medical director, QAPI director, and OPC would work with the attorney in developing this standard language.

We estimate that it would require 13 burden hours for each OPO to comply with these requirements at a cost of $969. Therefore, it would require 754 burden hours (13 burden hours for each OPO × 58 OPOs = 754 burden hours) at a cost of $56,202 ($969 estimated cost for each OPO × 58 OPOs = $56,202 estimated cost).

Based on the previous analysis, for all 58 OPOs to comply with all of the ICRs in proposed § 486.360 would require 8,468 burden hours at a cost of $606,970.

TABLE 15—BURDEN HOURS AND COST ESTIMATES FOR ALL 58 OPOS TO COMPLY WITH THE ICRS CONTAINED IN § 486.360 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total Capital/ Maintenance Costs ($)	Total cost ($)
§ 486.360(a)(1)	0938—New	58	58	10	580	**	47,676	0	47,676
§ 486.360(a)(2)–(4)	0938—New	58	58	22	1,276	**	102,776	0	102,776
§ 486.360(b)	0938—New	58	58	20	1,160	**	85,956	0	85,956
§ 486.360(c)	0938—New	58	58	14	812	**	62,524	0	62,524
§ 486.360(d)(1)	0938—New	58	58	40	2,320	**	139,548	0	139,548
§ 486.360(d)(2)	0938—New	58	58	5	290	**	16,124	0	16,124
§ 486.360(e)	0938—New	58	58	35	2,030	**	152,366	0	152,366
Totals		58	406	146	8,468				606,970

R. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 491.12)

Proposed § 491.12(a) would require Rural Health Clinics (RHCs) and Federally Qualified Health Clinics (FQHCs) to develop and maintain emergency preparedness plans. The RHCs and FQHCs would also have to review and update their plans at least annually. We propose that the plan must meet the requirements listed at § 491.12(a)(1) through (4).

Proposed § 491.12(a)(1) would require RHCs/FQHCs to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. RHCs/FQHCs would need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area. RHCs/FQHCs would need to review any existing risk assessments and then update and revise those assessments or develop new sections for them so that those assessments complied with our proposed requirements.

We obtained the total number of RHCs and FQHCs used in this burden analysis from the CMS CASPER data system, which the states update periodically. Due to variations in the timeliness of the data submission, all numbers in this analysis are approximate. There are currently 4,013 RHCs and 5,534 FQHCs. Thus, there are 9,547 RHC/FQHCs (4,013 RHCs + 5,534 FQHCs = 9,547 RHCs/FQHCs). Unlike RHCs, FQHCs are grantees under Section 330 of the Public Health Service Act. In 2007, the Health Resources and Services Administration (HRSA) issued a Policy Information Notice (PIN) entitled "Health Center Emergency Management Program Expectations," that detailed the expectations HRSA has for section 330 grantees related to emergency management ("Health Center Emergency Management Program Expectations," Policy Information Notice (PIN), Document Number 2007–15, HRSA, August 22, 2007) (Emergency Management PIN). A review of the Emergency Management PIN indicates that some of its expectations are very similar to the requirements in this proposed rule. Therefore, since the expectations in the Emergency Management PIN are a significant factor in determining the burden for FQHCs, we will analyze the burden for the 5,534 FQHCs separately from the 4,013 RHCs where the burden would be significantly different.

Based on our experience with RHCs, we expect that all 4,013 RHCs have already performed at least some of the work needed to conduct a risk assessment. It is standard practice for health care facilities to prepare for common emergencies, such as fires, power outages, and storms. In addition, the current Rural Health Clinic Conditions for Certification and the FQHC Conditions for Coverage (RHC/FQHC CfCs) already require each RHC and FQHC to assure "the safety of patients in case of non-medical emergencies by . . . taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located" (§ 491.6(c)(3)).

Further, in accordance with the Emergency Management PIN, FQHCs should have initiated their "emergency management planning by conducting a risk assessment such as a Hazard Vulnerability Analysis" (HVA) (Emergency Management PIN, p. 5). The HVA should identify potential emergencies or risks and potential direct and indirect effects on the facility's operations and demands on their services and prioritize the risks based on the likelihood of each risk occurring and the impact or severity the facility would experience if the risk occurs (Emergency Management PIN, p. 5). FQHCs are also "encouraged to participate in community level risk assessments and integrate their own risk assessment with the local community" (Emergency Management PIN, p. 5).

Despite these expectations and the existing Medicare regulations for RHCs/FQHCs, some RHC/FQHC risk assessments may not comply with all proposed requirements. For example, the expectations for FQHCs do not specifically address our proposed requirement to address likely medical and non-medical emergencies. In addition, participation in a community-based risk assessment is only

encouraged, not required. We expect that all 4,013 RHCs and 5,534 FQHCs will need to compare their current risk assessments with our proposed requirements and accomplish the tasks necessary to ensure their risk assessments comply with our proposed requirements. However, we expect that FQHCs would not be subject to as many burden hours as RHCs.

We have not designated any specific process or format for RHCs or FQHCs to use in conducting their risk assessments because we believe that RHCs and FQHCs need flexibility to determine the best way to accomplish this task. However, we expect that these health care facilities would include input from all of their major departments. Based on our experience with RHCs/FQHCs, we expect that conducting the risk assessment would require the involvement of the RHC/FQHC's administrator, a physician, a nurse practitioner or physician assistant, and a registered nurse. We expect that these individuals would attend an initial meeting, review the current risk assessment, prepare and forward their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator would coordinate the meetings, review the current risk assessment, provide an analysis of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We also expect that the administrator would spend more time reviewing the risk assessment than the other individuals.

We estimate that it would require 10 burden hours for each RHC to conduct a risk assessment that complied with the requirements in this section at a cost of $712. We estimate that for all RHCs to comply with our proposed requirements would require 40,130 burden hours (10 burden hours for each RHC × 4,013 RHCs = 39,410 burden hours) at a cost of $2,857,256 ($712 estimated cost for each RHC × 4,013 RHCs = $2,857,256 estimated cost).

We estimate that it would require 5 burden hours for each FQHC to conduct a risk assessment that complied with our proposed requirements at a cost of $356. We estimate that for all 5,534 FQHCs to comply would require 27,670 burden hours (5 burden hours for each FQHC × 5,534 FQHCs = 27,670 burden hours) at a cost of $1,970,104 ($356 estimated cost for each FQHC × 5,534 FQHCs = $1,970,104 estimated cost).

Based on those estimates, compliance with this proposed requirement for all RHCs and FQHCs would require 67,800 burden hours at a cost of $4,827,360.

After conducting the risk assessment, RHCs/FQHCs would have to develop and maintain emergency preparedness plans that complied with proposed § 491.12(a)(1) through (4) and review and update them annually. It is standard practice for healthcare facilities to plan for common emergencies, such as fires, hurricanes, and snowstorms. In addition, as discussed earlier, we require all RHCs/FQHCs to take appropriate measures to ensure the safety of their patients in non-medical emergencies, based on the particular conditions present in the area in which they are located (§ 491.6(c)(3)). Thus, we expect that all RHCs/FQHCs have developed some type of emergency preparedness plan. However, under this proposed rule, all RHCs/FQHCs would have to review their current plans and compare them to their risk assessments. The RHCs/FQHCs would need to update, revise, and, in some cases, develop new sections to complete their emergency preparedness plans that meet our proposed requirements.

The Emergency Management PIN contains many expectations for an FQHC's emergency management plan (EMP). For example, it states that the FQHC's EMP "is necessary to ensure the continuity of patient care" during an emergency (Emergency Management PIN, p. 6) and should contain plans for "assuring access for special populations (Emergency Management PIN, p. 7). The FQHC's EMP also should address continuity of operations, as appropriate (Emergency Management PIN, p. 6). In addition, FQHCs should use an "all-hazards approach" so that these facilities can respond to all of the risks they identified in their risk assessment (Emergency Management PIN, p. 6). Based on the expectations in the Emergency Management PIN, we expect that FQHCs likely have developed emergency preparedness plans that comply with many, if not all, of the elements with which their plans would need to comply under this proposed rule. However, we expect that FQHCs would need to compare their current EMP to our proposed requirements and, if necessary, revise or develop new sections for their EMP to bring it into compliance. We expect that FQHCs would have less of a burden than RHCs.

Based on our experience with RHCs/FQHCs, we expect that the same individuals who were involved in developing the risk assessments would be involved in developing the emergency preparedness plans. However, we expect that it would require more time to complete the plans than the risk assessments. We expect that the administrator would have primary responsibility for reviewing and developing the RHC/FQHC's EMP. We expect that the physician, nurse practitioner, and registered nurse would review the draft plan and provide comments to the administrator. We estimate that for each RHC to comply with this requirement would require 14 burden hours at a cost of $949. Therefore, it would require an estimated 56,182 burden hours (14 burden hours for each RHC × 4,013 RHCs = 56,182 burden hours) to complete the plan at a cost of $3,808,337 ($949 estimated cost for each RHC × 4,013 RHCs = $3,808,337 estimated cost).

We estimate that it would require 8 burden hours for each FQHC to comply with our proposed requirements at a cost of $530. Based on that estimate, it would require 44,272 burden hours (8 burden hours for each FQHC × 5,534 FQHCs = 44,272 burden hours) to complete the plan at a cost of $2,933,020 ($530 estimated cost for each FQHC × 5,534 FQHCs = $2,933,020 estimated cost).

Based on the previous estimates, for all RHCs and FQHCs to develop an emergency preparedness plan that complies with our proposed requirements would require 100,454 burden hours at a cost of $6,741,357.

Each RHC/FQHC also would be required to review and update its emergency preparedness plan at least annually. We believe that RHCs and FQHCs already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for RHCs and FQHCs and would not subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(b) would require RHCs/FQHCs to develop and implement emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 491.12(a), (a)(1), and (c), respectively. We would also require RHCs/FQHCs to review and update these policies and procedures at least annually. At a minimum, we would require that the RHC/FQHC's policies and procedures address the requirements listed at § 491.12(b)(1) through (4).

We expect that all RHCs/FQHCs have some emergency preparedness policies and procedures. All RHCs and FQHCs are required to have emergency procedures related to the safety of their patients in non-medical emergencies (§ 491.6(c)). They also must set forth in writing their organization's policies (§ 491.7(a)(2)). In addition, current

regulations require that a physician, in conjunction with a nurse practitioner or physician's assistant, develop the facility's written policies (§ 491.8(b)(ii) and (c)(i)). However, we expect that all RHCs/FQHCs would need to review their policies and procedures, assess whether their policies and procedures incorporate their risk assessments and emergency preparedness plans and make any changes necessary to comply with our proposed requirements.

We expect that FQHCs already have policies and procedures that would comply with some of our proposed requirements. Several of the expectations of the Emergency Management PIN address specific elements in proposed § 491.12(b). For example, the PIN states that FQHCs should address, as appropriate, continuity of operations, staffing, surge patients, medical and non-medical supplies, evacuation, power supply, water and sanitation, communications, transportation, and the access to and security of medical records (Emergency Management PIN, p. 6). In addition, FQHCs should also continually evaluate their EMPs and make changes to their EMPs as necessary (Emergency Management PIN, p. 7). These expectations also indicate that FQHCs should be working with and integrating their planning with their state and local communities' plans, as well as other key organizations and other relationships (Emergency Management PIN, p. 8). Thus, we expect that burden for FQHCs from the requirement for emergency preparedness policies and procedures would be less than the burden for RHCs.

The burden associated with our proposed requirements would be reviewing, revising, and, if needed, developing new emergency preparedness policies and procedures. We expect that a physician and a nurse practitioner would primarily be involved with these tasks and that an administrator would assist them. We estimate that for each RHC to comply with our proposed requirements would require 12 burden hours at a cost of $968. Based on that estimate, for all 4,013 RHCs to comply with these requirements would require 48,156 burden hours (12 burden hours for each RHC × 4,013 RHCs = 48,156 burden hours) at a cost of $3,884,584 ($968 estimated cost for each RHC × 4,013 RHCs = $3,884,584 estimated cost).

As discussed earlier, we expect that FQHCs would have less of a burden from developing their emergency preparedness policies and procedures due to the expectations set out in the Emergency Management PIN. Thus, we estimate that for each FQHC to comply with the proposed requirements would require 8 burden hours at a cost of $608. Based on that estimate, for all 5,534 FQHCs to comply with these requirements would require 44,272 burden hours (8 burden hours for each FQHC × 5,534 FQHCs = 44,272 burden hours) at a cost of $3,364,672 ($608 estimated cost for each FQHC × 5,534 FQHCs = $3,364,672 estimated cost).

Based on the previous estimates, for all RHCs and FQHCs to develop emergency preparedness policies and procedures that comply with our proposed requirements would require 92,428 burden hours at a cost of $7,249,256.

We propose that RHCs/FQHCs review and update their emergency preparedness policies and procedures at least annually. We believe that RHCs and FQHCs already review their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for RHCs/FQHCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(c) would require RHCs/FQHCs to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. RHCs/FQHCs would also have to review and update these plans at least annually. We propose that the communication plan must include the information listed in § 491.12(c)(1) through (5).

We expect that all RHCs/FQHCs have some type of emergency preparedness communication plan. It is standard practice for health care facilities to maintain contact information for staff and outside sources of assistance; alternate means of communication in case there is an interruption in the facility's phone services; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for patients. As discussed earlier, RHCs and FQHCs are required to take appropriate measures to ensure the safety of their patients during non-medical emergencies (§ 491.6(c)). We expect that an emergency preparedness communication plan would be an essential element in any emergency preparedness preparations. However, some RHCs/FQHCs may not have a formal, written emergency preparedness communication plan or their plan may not include all the requirements we propose.

The Emergency Management PIN contains specific expectations for communications and information sharing (Emergency Management PIN, pp. 8–9). "A well-defined communication plan is an important component of an effective EMP" (Emergency Management PIN, p. 8). In addition, FQHCs are expected to have policies and procedures for communicating with both internal stakeholders (such as patients and staff) and external stakeholders (such as federal, tribal, state, and local agencies), and for identifying who will do the communicating and what type of information will be communicated (Emergency Management PIN, p. 8). FQHCs should also identify alternate communications systems in the event that their standard communications systems become unavailable, and the FQHC should identify these alternate systems in their EMP (Emergency Management PIN, p. 9). Thus, we expect that all FQHCs would have a formal communication plan for emergencies and that those plans would contain some of our proposed requirements. However, we expect that all FQHCs would need to review, revise, and, if needed, develop new sections for their emergency preparedness communication plans to ensure that their plans are in compliance. We expect that these tasks will require less of a burden for FQHCs than for the RHCs.

The burden associated with complying with this requirement would be the resources required to review, revise, and, if needed, develop new sections for the RHC/FQHC's emergency preparedness communication plan. Based on our experience with RHCs/FQHCs, as well as the requirements in current regulations for a physician to work in conjunction with a nurse practitioner or a physician assistant to develop policies, we anticipate that satisfying the requirements in this section would require the involvement of the RHC/FQHC's administrator, a physician, and a nurse practitioner or physician assistant. We expect that the administrator and the nurse practitioner or physician assistant would be primarily involved in reviewing, revising, and if needed, developing new sections for the RHC/FQHC's emergency preparedness communication plan.

We estimate that for each RHC to comply with the proposed requirements would require 10 burden hours at a cost of $734. Based on that estimate, for all 4,013 RHCs to comply would require 40,130 burden hours (10 burden hours for each RHC × 4,013 RHCs = 40,130 burden hours) at a cost of $3,443,154 ($734 estimated cost for each RHC × 4,013 RHCs = $3,443,154 estimated cost).

We estimate that for a FQHC to comply with the proposed requirements would require 5 burden hours at a cost of $367. Based on this estimate, for all 5,534 FQHCs to comply would require 27,670 burden hours (5 burden hours for each FQHC × 5,534 FQHCs = 27,670 burden hours) at a cost of $2,030,978 ($367 estimated cost for each FQHC × 5,534 FQHCs = $2,030,978 estimated cost).

We propose that RHCs/FQHCs also review and update their emergency preparedness communication plans at least annually. We believe that RHCs/FQHCs already review their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for RHCs/FQHCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(d) would require RHCs/FQHCs to develop and maintain emergency preparedness training and testing programs and review and update these programs at least annually. We propose that an RHC/FQHC would have to comply with the requirements listed in § 491.12(d)(1) and (2).

Proposed § 491.12(d)(1) would require each RHC and FQHC to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of that training. Each RHC and FQHC would also have to ensure that its staff could demonstrate knowledge of those emergency procedures. Thereafter, each RHC and FQHC would be required to provide emergency preparedness training annually.

Based on our experience with RHCs and FQHCs, we expect that all 9,045 RHC/FQHCs already have some type of emergency preparedness training program. The current RHC/FQHC regulations require RHCs and FQHCs to provide training to their staffs on handling emergencies (§ 491.6(c)(1)). In addition, FQHCs are expected to provide ongoing training in emergency management and their facilities' EMP to all of their employees (Emergency Management PIN, p. 7). However, neither the current regulations nor the PIN's expectations for FQHCs address initial training and ongoing training, frequency of training, or requirements that individuals providing services under arrangement and volunteers be included in the training. RHCs/FQHCs would need to review their current training programs; compare their contents to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans and then take the necessary steps to ensure that their training programs comply with our proposed requirements.

We expect that each RHC and FQHC has a professional staff person who is responsible for ensuring that the facility's training program is up-to-date and complies with all federal, state, and local laws and regulations. This individual would likely be an administrator. We expect that the administrator would be primarily involved in reviewing the RHC/FQHC's emergency preparedness program; determining what tasks need to be performed and what materials need to be developed to bring the training program into compliance with our proposed requirements; and making changes to current training materials and developing new training materials. We expect that the administrator would work with a registered nurse to develop the revised and updated training program. We estimate that it would require 10 burden hours for each RHC or FQHC to develop a comprehensive emergency training program at a cost of $526. Therefore, it would require an estimated 95,470 burden hours (10 burden hours for each RHC/FQHC × 9,547 RHCs/FQHCs = 95,470 burden hours) to comply with this requirement at a cost of $5,021,722 ($526 estimated cost for each RHC/FQHC × 9,547 RHCs/FQHCs = $5,021,722 estimated cost).

Proposed § 491.12(d) would also require that RHCs/FQHCs develop and maintain emergency preparedness training and testing programs that would be reviewed and updated at least annually. We believe that RHCs/FQHCs already review their emergency preparedness programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for RHCs/FQHCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(d)(2) would require RHCs/FQHCs to participate in a community mock disaster drill and conduct a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, RHCs/FQHCs would have to conduct an individual, facility-based mock disaster drill at least annually. RHCs/FQHCs would also be required to analyze their responses to and maintain documentation of drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. If an RHC or FQHC experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from the requirement for a community or individual, facility-based mock drill for 1 year following the onset of the actual event. However, for purposes of determining the burden for these requirements, we will assume that all RHCs/FQHCs would have to comply with all of these proposed requirements.

The burden associated with complying with these requirements would be the resources the RHC or FQHC would need to develop the scenarios for the drill and exercise and the documentation necessary for analyzing and documenting their drills, tabletop exercises, as well as any emergency events.

Based on our experience with RHCs/FQHCs, we expect that most of the 9,547 RHCs/FQHCs already conduct some type of testing of their emergency preparedness plans and develop scenarios and documentation for their testing and emergency events. For example, FQHCs are expected to conduct some type of testing of their EMP at least annually (Emergency Management PIN, p. 7). However, we do not believe that all RHCs/FQHCs have the appropriate documentation for drills, exercises, and emergency events or that they conduct both a drill and a tabletop exercise annually. Thus, we will analyze the burden associated with these requirements for all 9,547 RHCs/FQHCs.

Based on our experience with RHCs/FQHCs, we expect that the same individuals who are responsible for developing the RHC/FQHC's training and testing program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the administrator and a registered nurse would be primarily involved in accomplishing these tasks. We estimate that for each RHC/FQHC to comply with the requirements in this section would require 5 burden hours at a cost of $276. Based on this estimate, for all 9,547 RHCs/FQHCs to comply with the requirements in this section would require 47,735 burden hours (5 burden hours for each RHC/FQHC × 9,547 RHCs/FQHCs = 47,735 burden hours) at a cost of $2,634,972 ($276 estimated cost for each RHC/FQHC × 9,547 RHC/FQHCs = $2,634,972 estimated cost).

TABLE 16—BURDEN HOURS AND COST ESTIMATES FOR ALL 9,547 RHC/FQHCS TO COMPLY WITH THE ICRS CONTAINED IN § 491.12 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total Capital/ Maintenance Costs ($)	Total cost ($)
§ 491.12(a)(1) (RHCs)	0938—New	4,013	4,013	10	40,130	**	2,857,256	0	2,857,256
§ 491.12(a)(1) (FQHCs)	0938—New	5,534	5,534	5	27,670	**	1,970,104	0	1,970,104
§ 491.12(a)(1)–(4) (RHCs)	0938—New	4,013	4,013	14	56,182	**	3,808,337	0	3,808,337
§ 491(a)(1)–(4) (FQHCs)	0938—New	5,534	5,534	8	44,272	**	2,933,020	0	2,933,020
§ 491.12(b) (RHCs)	0938—New	4,013	4,013	12	48,156	**	3,884,584	0	3,884,584
§ 491.12(b) (FQHCs)	0938—New	5,534	5,534	8	44,272	**	3,364,672	0	3,364,672
§ 491.12(c) (RHCs)	0938—New	4,013	4,013	10	40,130	**	3,443,154	0	3,443,154
§ 491.12(c) (FQHCs)	0938—New	5,534	5,534	5	27,670	**	2,030,978	0	2,030,978
§ 491.12(d)(1)	0938—New	9,547	9,547	10	95,470	**	5,021,722	0	5,021,722
§ 491.12(d)(2)	0938—New	9,547	9,547	5	47,735	**	2,634,972	0	2,634,972
Totals			57,282		471,687				31,948,799

** The hourly labor cost is blended between the wages for multiple staffing levels.

S. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 494.62)

Proposed § 494.62(a) would require dialysis facilities to develop and maintain emergency preparedness plans that would have to reviewed and updated at least annually. Proposed § 494.62 would require that the plan include the elements set out at § 494.62(a)(1) through (4).

Proposed § 494.62(a)(1) would require dialysis facilities to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. The risk assessment should address the medical and non-medical emergency events the facility could experience both within the facility and within the surrounding area. The dialysis facility would have to consider its location and geographical area; patient population, including, but not limited to, persons-at-risk; and the types of services the dialysis facility has the ability to provide in an emergency. The dialysis facility also would need to identify the measures it would need to take to ensure the continuity of its operations, including delegations of authority and succession plans.

The burden associated with this requirement would be the resources needed to perform a thorough risk assessment. The current CfCs already require dialysis facilities to "implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failure, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area" (§ 494.60(d)). Thus, to be in compliance with this CfC, we believe that all dialysis facilities would have already performed some type of risk assessment during the process of developing their emergency preparedness processes and procedures. However, these risk assessments may not be as thorough or address all of the elements required in proposed § 494.62(a). For example, the current CfCs do not require dialysis facilities to plan for man-made disasters. Therefore, we believe that all dialysis facilities would have to conduct a thorough review of their current risk assessments and then perform the necessary tasks to ensure that their facilities' risk assessments complied with the requirements of this section.

Based on our experience with dialysis facilities, we expect that conducting the risk assessment would require the involvement of the dialysis facility's chief executive officer or administrator, medical director, nurse manager, social worker, and a PCT. We believe that all of these individuals would attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review and approve the risk assessment. We believe that the administrator would probably coordinate the meetings, do an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. We also believe that the administrator would probably spend more time reviewing and working on the risk assessment than the other individuals involved in performing the risk assessment. Thus, we estimate that complying with this requirement to conduct and develop a risk assessment would require 12 burden hours at a cost of $838. There are currently 5,923 dialysis facilities. Therefore, it would require an estimated 71,076 burden hours (12 burden hours for each dialysis facility × 5,923 dialysis facilities = 71,076 burden hours) for all dialysis facilities to comply with this requirement at a cost of $4,963,474 ($838 estimated cost for each dialysis facility × 5,923 dialysis facilities = $4,963,474 estimated cost).

After conducting the risk assessment, each dialysis facility would then have to develop and maintain an emergency preparedness plan that the facility must evaluate and update at least annually. This emergency plan would have to comply with the requirements at proposed § 494.62(a)(1) through (4).

Current CfCs already require dialysis facilities to "have a plan to obtain emergency medical system assistance when needed . . . " and "evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary" (§ 494.60(d)(4)). Thus, we expect that all dialysis facilities have some type of emergency preparedness or disaster plan. In addition, dialysis facilities must also "implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area" (§ 494.60(d)). We expect that the facility would incorporate many, if not all, of these processes and procedures into its emergency preparedness plan. We expect that each dialysis facility has some type of emergency preparedness plan and that plan should already address many of these requirements. However, all of the dialysis facilities would have to review their current plans and compare them to the risk assessment they performed pursuant to

proposed § 494.62(a)(1). The dialysis facility would then need to update, revise, and, in some cases, develop new sections to complete an emergency preparedness plan that addressed the risks identified in their risk assessment and the specific requirements contained in this subsection. The plan would also address how the dialysis facility would continue providing its essential services, which are the services that the dialysis facility would continue to provide despite an emergency. The dialysis facility would also need to review, revise, and, in some cases, develop delegations of authority or succession plans that the dialysis facility determined were necessary for the appropriate initiation and management of their emergency preparedness plan.

The burden associated with this requirement would be the time and effort necessary to develop the emergency preparedness plan. Based upon our experience with dialysis facilities, we expect that developing the emergency preparedness plan would require the involvement of the dialysis facility's chief executive officer or administrator, medical director, nurse manager, social worker, and a PCT. We believe that all of these individuals would probably have to attend an initial meeting, review relevant sections of the facility's current emergency preparedness or disaster plan(s), develop comments and recommendations for changes to the assessment, attend a follow-up meeting, and then perform a final review and approve the risk assessment. We believe that the administrator would probably coordinate the meetings, do an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approved the new risk assessment. We also believe that the administrator, medical director, and nurse manager would probably spend more time reviewing and working on the risk assessment than the other individuals involved in developing the plan. The social worker and PCT would likely just review the plan or relevant sections of it. In addition, since the medical director's responsibilities include participation in the development of patient care policies and procedures (42 CFR 494.150(c)), we expect that the medical director would be involved in the development of the emergency preparedness plan. We estimate that complying with this requirement would require 10 burden hours at a cost of $776 for each dialysis facility. There are 5,923 dialysis facilities. Therefore, it would require an estimated 59,230 burden hours (10 burden hours for each dialysis facility × 5,923 dialysis facilities = 59,230 burden hours) to complete the plan at a cost of $4,596,248 ($776 estimated cost for each dialysis facility × 5,923 dialysis facilities = $4,596,248 estimated cost).

Each dialysis facility would also be required to review and update its emergency preparedness plan at least annually. We believe that dialysis facilities already review their emergency preparedness plans periodically. The current CfCs already requires dialysis facilities to evaluate the effectiveness of their emergency and disaster plans and update them as necessary (42 CFR 494.60(d)(4)(ii)). Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(b) would require dialysis facilities to develop and implement emergency preparedness policies and procedures based on the emergency plan, the risk assessment, and communication plan as set forth in § 494.62(a), (a)(1), and (c), respectively. These emergencies would include, but would not be limited to, fire, equipment or power failures, care-related emergencies, water supply interruptions, and natural and man-made disasters that are likely to occur in the facility's geographical area. Dialysis facilities would also have to review and update these policies and procedures at least annually. The policies and procedures would be required to address, at a minimum, the requirements listed at § 494.62(b)(1) through (9).

We expect that all dialysis facilities have some emergency preparedness policies and procedures. The current CfCs at 42 CFR 494.60(d) already require dialysis facilities to have and "implement processes and procedures to manage medical and nonmedical emergencies . . . [that] include, but not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area". In addition, we expect that dialysis facilities already have procedures that would satisfy some of the requirements in this section. For example, each dialysis facility is already required at 42 CFR 494.60(d)(4)(iii) to "contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency". However, all dialysis facilities would need to review their policies and procedures, assess whether their policies and procedures incorporated all of the necessary elements of their emergency preparedness program, and then, if necessary, take the appropriate steps to ensure that their policies and procedures encompassed these requirements.

The burden associated with the development of these emergency policies and procedures would be the time and effort necessary to comply with these requirements. We expect the administrator, medical director, and the nurse manager would be primarily involved with reviewing, revising, and if needed, developing any new policies and procedures that were needed. The remaining individuals would likely review the sections of the policies and procedures that directly affect their areas of expertise. Therefore, we estimate that complying with this requirement would require 10 burden hours at a cost of $776 for each dialysis facility. There are 5,923 dialysis facilities. Therefore, it would require an estimated 59,230 burden hours (10 burden hours for each dialysis facility × 5,923 dialysis facilities = 59,230 burden hours) to complete the plan at a cost of $4,596,248 ($768 estimated cost for each dialysis facility × 5,923 dialysis facilities = $4,596,248 estimated cost).

The dialysis facility must also review and update its emergency preparedness policies and procedures at least annually. We believe that dialysis facilities already review their emergency preparedness policies and procedures periodically. In addition, the current CfCs already require (at 42 CFR 494.150(c)(1)) the medical director to participate in a periodic review of patient care policies and procedures. Thus, compliance with this requirement would constitute a usual and customary business practice for dialysis facilities and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(c) would require dialysis facilities to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The dialysis facility must also review and update this plan at least annually. The communication plan must include the information listed at § 494.62(c)(1) through (7).

We expect that all dialysis facilities have some type of emergency preparedness communication plan. A communication plan would be an integral part of any emergency preparedness plan. Current CfCs already require dialysis facilities to have a written disaster plan (42 CFR

494.60(d)(4)). Thus, each dialysis facility should already have some of the contact information they would need to have in order to comply with this section. In addition, we expect that it is standard practice in the healthcare industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones or text-messaging devices; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many dialysis facilities may not have formal, written emergency preparedness communication plans. Therefore, we expect that all dialysis facilities would need to review, update, and in some cases, develop new sections for their plans to ensure that those plans included all of the previously-described required elements in their emergency preparedness communication plan.

The burden associated with complying with this requirement would be the resources required to review and revise the dialysis facility's emergency preparedness communication plan to ensure that it complied with these requirements. Based upon our experience with dialysis facilities, we anticipate that satisfying these requirements would primarily require the involvement of the dialysis facility's administrator, medical director, and nurse manager. For each dialysis facility, we estimate that complying with this requirement would require 4 burden hours at a cost of $357. Therefore, for all of the dialysis facilities to comply with this requirement would require an estimated 23,692 burden hours (4 burden hours for each dialysis facility × 5,923 dialysis facilities = 23,692 burden hours) at a cost of $2,114,511 ($357 estimated cost for each dialysis facility × 5,923 dialysis facilities = $2,114,511 estimated cost).

Each dialysis facility would also have to review and update its emergency preparedness communication plan at least annually. For the purpose of determining the burden for this requirement, we would expect that dialysis facilities would review their emergency preparedness communication plans annually. We believe that all dialysis facilities have an administrator that would be primarily responsible for the day-to-day operation of the dialysis facility. This would include ensuring that all of the dialysis facility's policies, procedures, and plans were up-to-date and complied with the relevant federal, state, and local laws, regulations, and ordinances. We expect that the administrator would be responsible for periodically reviewing the dialysis facility's plans, policies, and procedures as part of his or her work responsibilities. Therefore, we expect that complying with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(d) would require dialysis facilities to develop and maintain emergency preparedness training, testing and patient orientation programs that would have to be evaluated and updated at least annually. The dialysis facility would have to comply with the requirements located at § 494.62(d)(1) through (3).

Proposed § 494.62(d)(1) would require that dialysis facilities provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the dialysis facility would have to provide emergency preparedness training at least annually.

Current CfCs already require dialysis facilities to "provide training and orientation in emergency preparedness to the staff" (42 CFR 494.60(d)(1)) and "provide appropriate orientation and training to patients . . ." in emergency preparedness (42 CFR 494.60(d)(2)). In addition, the dialysis facility's patient instruction would have to include the same matters that are specified in the current CfCs (42 CFR 494.60(d)(2)). Thus, dialysis facilities should already have an emergency preparedness training program for new employees, as well as ongoing training for all their staff and patients. However, all dialysis facilities would need to review their current training programs and compare their contents to their updated emergency preparedness programs, that is, the risk assessment, emergency preparedness plan, policies and procedures, and communications plans that they developed pursuant to proposed § 494.62(a) through (c). Dialysis facilities would then need to review, revise, and in some cases, develop new material for their training programs so that they complied with these requirements.

The burden associated with complying with this requirement would be the time and effort necessary to develop the required training program. We expect that complying with this requirement would require the involvement of the administrator, medical director, and the nurse manager. In fact, the medical director's responsibilities include, among other things, staff education and training (42 CFR 494.150(b)). We estimate that it would require 7 burden hours for each dialysis facility to develop an emergency training program at a cost of $559. Therefore, it would require an estimated 41,461 burden hours (7 burden hours for each dialysis facility × 5,923 dialysis facilities = 41,461 burden hours) to comply with this requirement at a cost of ($559 estimated cost for each dialysis facility × 5,923 dialysis facilities = $3,310,957 estimated cost).

The dialysis facility must also review and update its emergency preparedness training program at least annually. We believe that dialysis facilities already review their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(d)(2) requires dialysis facilities to participate in a mock disaster drill and conduct a paper-based; tabletop exercise at least annually. If a community mock disaster drill was not available, the dialysis facility would have to conduct an individual, facility-based mock disaster drill at least annually. If the dialysis facility experienced an actual natural or man-made emergency that required activation of their emergency plan, the dialysis facility would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. Dialysis facilities would also be required to analyze their responses to and maintain document of all drills, tabletop exercises, and emergency events. To comply with this requirement, a dialysis facility would need to develop scenarios for each drill and exercise. A dialysis facility would also have to develop the documentation necessary for recording and analyzing the drills, tabletop exercises, and emergency events.

The current CfCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (42 CFR 494.60(d)(4)(ii)). Thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency plans. Although the current CfCs do not specify the type of drill or test, dialysis facilities should have already been developing scenarios for testing their plans. Thus, complying with this requirement would constitute a usual and customary business practice and

would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(d)(3) would require dialysis facilities to provide appropriate orientation and training to patients, including the areas specified in proposed § 494.62(d)(1). Proposed § 494.62(d)(1) specifically would require that staff demonstrate knowledge of emergency procedures including the emergency information they must give to their patients. Thus, the burden associated with this section would already be included in the burden estimate for § 494.62(d)(1).

TABLE 17—BURDEN HOURS AND COST ESTIMATES FOR ALL 5,923 DIALYSIS FACILITIES TO COMPLY WITH THE ICRS CONTAINED IN § 494.62 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB control no.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ mintenance costs ($)	Total cost ($)
§ 494.62(a)(1)	0938—New	5,923	5,923	12	71,076	**	4,963,474	0	4,834,422
§ 494.62(a)(2)–(4)	0938—New	5,923	5,923	10	59,230	**	4,596,248	0	4,476,744
§ 494.62(b)	0938—New	5,923	5,923	10	59,230	**	4,596,248	0	4,476,744
§ 494.62(c)	0938—New	5,923	5,923	4	23,692	**	2,114,511	0	2,059,533
§ 494.62(d)	0938—New	5,923	5,923	7	41,461	**	3,310,957	0	3,224,871
Totals		5,923	29,615		254,689				19,581,438

** The hourly labor cost is blended between the wages for multiple staffing levels.

T. Summary of Information Collection Burden

Based on the previous analysis, the first year's burden for complying with all of the requirements in this proposed rule would be 3,018,124 burden hours at a cost of $185,908,673. For subsequent years, if there is any additional burden, it would be negligible.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced earlier, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410–786–1326.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William Parham, (CMS–3178–P), Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, CMS–3178–P, Fax (202) 395–6974.

IV. Regulatory Impact Analysis

A. Statement of Need

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

In response to past terrorist attacks, natural disasters, and the subsequent national need to refine the nation's strategy to handle emergency situations, there continues to be a coordinated effort across federal agencies to establish a foundation for development and expansion of emergency preparedness systems. There are two Presidential Directives, HSPD–5 and HSPD–21, instructing agencies to coordinate their emergency preparedness activities with each other. Although these directives do not specifically require Medicare providers and suppliers to adopt measures, they have set the stage for what we expect from our providers and suppliers in regard to their roles in a more unified emergency preparedness system.

Homeland Security Presidential Directive (HSPD–5): Management of Domestic Incidents authorizes the Department of Homeland to develop and administer the National Incident Management System (NIMS).

Homeland Security Presidential Directive (HSPD–21) addresses public health and medical preparedness. The directive establishes a National Strategy for Public Health and Medical Preparedness (Strategy), which builds upon principles set forth in "Biodefense for the 21st Century (April 2004), "National Strategy for Homeland Security" (October 2007), and the "National Strategy to Combat Weapons of Mass Destruction" (December 2002). The directive aims to transform our national approach to protecting the health of the American people against all disasters.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995 Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S. C. 804(2)).

Executive Orders 12866 and 13563 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). The total projected cost of this rule would be $225 million in the first year, and the subsequent projected annual cost would be approximately $ 41 million.

Published reports after Hurricane Katrina reported that the Louisiana Attorney General investigated approximately 215 deaths that occurred in hospitals and nursing homes following Katrina. Since nearly all hospitals and nursing homes are certified to participate in the Medicare program, we estimate that at least a small percentage of these lives could be saved as a result of emergency preparedness measures in a single disaster of equal magnitude. Katrina is an extreme example of a natural

disaster, so we also considered other more common disasters. The United States experiences numerous natural disasters annually, including, in particular, tornadoes and flooding. Based on data from the National Oceanic and Atmospheric Administration, the United States experiences an annual average of 56 fatalities as a result of tornadoes (*http://www.spc.noaa.gov/wcm/ustormaps/1981–2010-stateavgfatals.png*). On average, floods kill about 140 people each year (United States Department of the Interior, United States Geological Survey Fact Sheet "Flood Hazards—A National Threat" January, 2006, at *Http://pubs.usgs.gov/fs/2006/3026/2006–3026.pdf*). Floods may be caused by both natural and manmade processes, including hurricanes, severe storms, snowmelt, and dam or levee failure. According to the National Weather Service, in 2010 there were a cumulative 490 deaths and 2,369 injuries and in 2011 there were a cumulative 1,096 deaths and 8,830 injuries as a result of severe weather events such as tornadoes, floods, winter storms, and others. Although we are unable to specifically quantify the number of lives saved as a result of this proposed rule, all of the data we have read regarding emergency preparedness indicate that implementing the requirements in this proposed rule could have a significant impact on protecting the health and safety of individuals served by providers and suppliers that participate in the Medicare and Medicaid programs. We believe it is crucial for all providers and suppliers to have an emergency disaster plan that is integrated with other local, state and federal agencies to effectively address both natural and manmade disasters. Therefore, we believe that it is essential to require providers and suppliers to conduct a risk assessment, to develop an emergency preparedness plan based on the assessment, and to comply with the other requirements we propose to minimize the disruption of services for the community and ensure continuity of care in the event of a disaster.

We believe that this proposed rule would be an economically significant regulatory action under section 3(f)(1) of Executive Order 12866, since it may lead to impacts of greater than $100 million in the first year following the rule's effective date.

This proposed rule would establish a regulatory framework with which Medicare- and Medicaid-participating providers and suppliers would have to comply to ensure that the varied providers and suppliers of healthcare are adequately prepared to respond to natural and man-made disasters.

Several factors influenced our estimates of the economic impact to the providers and suppliers covered by this proposed rule. These factors are discussed under section III. of this proposed rule (Collection of Information Requirements). In addition, we have used the same data source for the RIA that we used to develop the PRA burden estimates, that is, the CMS Online Survey, Certification, and Reporting System (OSCAR).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Act generally defines a "small entity" as: (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity.") HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $35.5 million in any 1 year. For purposes of the RFA, a majority of hospitals are considered small entities due to their non-profit status. Individuals and states are not included in the definition of a small entity. Since the cost associated with this proposed rule is less than $46,000 for hospitals and $4,000 for other entities, the Secretary has determined that this proposed will not have a significant economic impact on a substantial number of small entities."

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Since the cost associated with this proposed rule is less than $46,000 for hospitals, this this proposed will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately $141 million. This omnibus proposed rule contains mandates that would impose a one-time cost of approximately $225 million. Thus, we have assessed the various costs and benefits of this proposed rule. It is clear that a number of providers and suppliers would be affected by the implementation of this proposed rule and that a substantial number of those entities would be required to make changes in their operations. This proposed rule would not mandate any new requirements for state, local or tribal governments. For the private sector facilities, this regulatory impact section constitutes the analysis required under UMRA.

Executive Order 13132 establishes certain requirements that an agency must meet when it develops a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule will not impose substantial direct requirement costs on state or local governments, preempt state law, or otherwise implicate federalism.

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

C. Anticipated Effects on Providers and Suppliers: General Provisions

This proposed rule would require each of the Medicare- and Medicaid-participating providers and suppliers discussed in previous sections to perform a risk analysis; establish an emergency preparedness plan, emergency preparedness policies and procedures, and an emergency preparedness communication plan; train staff in emergency preparedness, and test the emergency plan. The economic impact would differ between hospitals

and the various other providers and suppliers, depending upon a variety of factors, including existing regulatory requirements and accreditation standards.

We discuss the economic impact for each provider and supplier type included in this proposed rule in the order in which they appear in the CFR. Most of the economic impact of this proposed rule would be due to the cost for providers and suppliers to comply with the information collection requirements. Thus, we discuss most of the economic impact under the Collection of Information Requirements section of this proposed rule. We provide a chart at the end of the RIA section of the total regulatory impact for each provider/supplier.

As stated in the ICR section, we obtained all salary information from the May 2011 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at *http://www.bls.gov/oes/current/oes_nat.htm* and calculated the added value of benefits using the estimation that salary accounts for 70 percent of compensation, based on BLS information (Bureau of Labor Statistics News Release, "Employer Cost Index—December 2011, retrieved from *www.bls.gov/news.release/pdf/eci.pdf*).

1. Subsistence Requirement

This proposed rule would require all inpatient providers to meet the subsistence needs of staff and patients, whether they evacuate or shelter in place, including, but not limited to, food, water, and supplies, alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of such provisions.

Based on our experience, we expect inpatient providers to currently have food, water, and supplies, alternate sources of energy to provide electrical power, and the maintenance of temperatures for the safe and sanitary storage of such provisions as a routine measure to ensure against weather related and non-disaster power failures. Thus, we believe that this requirement is a usual and customary business practice for inpatient providers and we have not assigned any impact for this requirement.

Further, we expect that most providers have agreements with their vendors to receive supplies within 24 to 48 hours in the event of an emergency, as well as arrangements with back-up vendors in the event that the disaster affects the primary vendor. We considered proposing a requirement that providers must keep a larger quantity of food and water on hand in the event of a disaster. However, we believe that a provider should have the flexibility to determine what is adequate based on the location and individual characteristics of the facility. While some providers may have the storage capacity to stockpile supplies that would last for a longer duration, other may not. Thus, we believe that to require such stockpiling would create an unnecessary economic impact on some health care providers.

We expect that when inpatient providers determine their supply needs, they would consider the possibility that volunteers, visitors, and individuals from the community may arrive at the facility to offer assistance or seek shelter.

Based on the previous factors, we have not estimated a cost for a stockpile of food and water.

2. Generator Location and Testing

This proposed rule would require hospitals, CAHs, and LTC facilities to test and maintain their emergency and standby power systems in such a way to ensure proper operation in the event they are needed. The 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA) states that the alternate source of power (for example, generator) must be located in an appropriate area to minimize the possible damage resulting from disasters such as storms, floods, earthquakes, tornadoes, hurricanes, vandalism, sabotage and other material and equipment failures. Since hospitals, CAHs and LTC facilities are currently required to comply with the referenced LSC, we have not assigned any additional burden for this requirement.

In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that hospitals test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the hospital anticipates it will require during an emergency. As a result of lessons learned from hurricane Sandy, we believe that this annual 4 hour test will more closely reflect the actual conditions that would be experienced during a disaster of the magnitude of hurricane Sandy. Also, later editions of NFPA 110 require 4 hours of continuous generator testing every 36 months to provide reasonable assurance emergency power systems are capable of running under load during an emergency. In order to provide further assurance that generators will be capable of operating during an emergency, 4 hours of continuous generator testing will be required every 12 months. We have also proposed the same emergency and standby power requirements for CAHs and LTC facilities.

We have estimated the cost in this section for these additional testing requirements. Based on information from the U.S. Bureau of Labor Statistics and the U.S. Energy Information Administration, we have calculated the cost for the generator testing as follows:

- Labor: 6 hours (1-hour preparation, 4 hour run-time, 1 hour restoration) × $25.45 an hour =$152.70
- Fuel: Diesel cost of $3.85 per gallon × 72 gallon per hour × 4 hour of testing=$1,108.80

Therefore, we estimate the total cost to each hospital, CAH and LTC facility to comply with this requirement would be $1,262. However, we request information on this proposal and in particular on how we might better estimate costs in light of the existing LSC and other state and federal requirements.

D. Condition of Participation: Emergency Preparedness for Religious Nonmedical Health Care Institutions (RNHCIs)

1. Training and Testing (§ 403.748(d))

We discuss the majority of the economic impact for this requirement in the ICR section, which is estimated at $18,928.

2. Testing (§ 403.748(d)(2))

Proposed § 403.748(d)(2) would require RHNCIs to conduct a paper-based, tabletop exercise at least annually. RHNCIs must analyze their response and maintain documentation of all tabletop exercises, and emergency events, and revise their emergency plan as needed.

We expect that the cost associated with this requirement would be limited to the staff time needed to participate in the tabletop exercises. We estimate that approximately 4 hours of staff time would be required of the administrator and director of nursing, and 2 hours of staff time for the head of maintenance to coordinate facility evacuations and protocols for transporting residents to alternate sites. We believe that other staff members would be required to spend a minimal amount of time during these exercises and such staff time would be considered a part of regular on-going training for RHNCI staff. We estimate that it would require 10 hours of staff time for each of the 16 RNHCIs to conduct exercises at a cost of $330. Therefore, it would require an estimated

total impact of $5,280 each year after the initial year for all RNHCIs to comply with proposed § 403.748(d)(2). For the initial year, we estimate $24,208 as the total economic impact and cost estimates for all 16 RNHCIs to comply with the requirements in this proposed rule.

E. Condition for Coverage: Emergency Preparedness for Ambulatory Surgical Centers (ASCs)—Testing (§ 416.54(d)(2))

Proposed § 416.54(d)(2) would require ASCs to participate in a community mock disaster drill at least annually. If a community mock disaster drill were not available, the ASC would be required to conduct a facility-based mock disaster drill at least annually and maintain documentation of all mock disaster drills. ASCs also would be required to conduct a paper-based, tabletop exercise at least annually. ASCs also would be required to maintain documentation of the exercise.

State, Tribal, Territorial, and local public health and medical systems comprise a critical infrastructure that is integral to providing the early recognition and response necessary for minimizing the effects of catastrophic public health and medical emergencies. Educating and training these clinical, laboratory, and public health professionals has been, and continues to be, a top priority for the federal Government. There are currently three programs at HHS addressing education and training in the area of public health emergency preparedness and response: the Centers for Public Health Preparedness (CPHP), the Bioterrorism Training and Curriculum Development Program (BTCDP), and National Laboratory Training Network (NLTN).

As discussed earlier in this preamble, ASCs can use these and other resources, such as tools offered by the Department of Homeland Security, to assist them in complying with this proposed requirement. Thus, we believe that the cost associated with this requirement would be limited to the staff time to participate in the community-wide and facility-wide trainings, and tabletop exercises. We believe that appreciable staff time would be required of the administrator and risk assurance nurse. We believe that other staff members would be required to spend a minimal amount of time during these exercises and the training would be considered as part of regular on-going training for ASC staff. We estimate that the administrator and quality assurance nurse would spend about 4 hours each on an annual basis to participate in the disaster drills (3 hours to participate in a community or facility-wide drill and 1 hour to participate in a table-top drill). Thus, we anticipate that complying with this requirement would require 8 hours for an estimated cost of $500 for each of the 5,354 ASCs and a total cost estimate of $2,677,000 for all ASCs ($500 × 5,354 ASCs) each year after the first year. We estimate $15,241,036 ($2,677,000 impact cost + $12,564,036 ICR burden) as the total economic impact and cost estimates for all ASCs to comply with the requirements in this proposed rule.

F. Condition of Participation: Emergency Preparedness for Hospices—Testing (§ 418.113(d)(2))

Proposed § 418.113(d)(2)(i) through (iii) would require hospices to participate in mock drills and tabletop exercises at least annually. In addition, hospices are to conduct a paper-based, tabletop exercise at least annually. We believe that the administrator would be responsible for participating in community-wide disaster drills and would be the primary person to organize a facility-wide drill and tabletop exercise with the assistance of one member of the IDG. We believe that the registered nurse would most likely represent the IDG on the drills and exercises. While we expect that all staff would be involved in the drills and exercises, we would consider their involvement as part of their regular staff training. However, for the purpose of this analysis we assume that the administrator would spend approximately 3 hours annually to participate in a community or facility-wide drill and 1 hour to participate in a tabletop exercise above their regular and ongoing training. We also assume that the registered nurse would spend 3 hours to participate in an annual drill and 1 hour to participate in a tabletop exercise. Thus, we estimate that each hospice would spend $388. The total estimate for all hospices to comply with this requirement after the initial year would total $1,463,924 ($388 × 3,773 hospices). We estimate the total economic impact and cost estimates for all 3,773 hospices to comply with the requirements in this proposed rule for the initial year would be $11,908,072 ($1,463,924 impact cost + $10,444,148 ICR burden).

G. Emergency Preparedness for Psychiatric Residential Treatment Facilities (PRTFs)—Training and Testing (§ 441.184(d))

Proposed § 441.184(d)(2)(i) through (iii) would require PRTFs to participate in a community or facility-based mock disaster drill and a tabletop exercise annually. We propose that if a community drill is not available, the PRTF would be required to conduct a facility-based mock disaster drill. We estimate that the cost associated with this requirement is the time that it would take key personnel to participate in the mock drill and tabletop exercise. We further estimate that the drill and exercise would involve the administrator and registered nurse to spend about 4 hours each on an annual basis to participate (3 hours to participate in a community or facility-wide drill and 1 hour to participate in a table-top drill). Thus, we anticipate that complying with this requirement would require 4 hours for the administrator and 4 hours for the registered nurse at a combined estimated cost of $360 per facility. The total annual cost for all 387 PRTFs would be $139,320. The total cost for the first year to comply with the requirement would be $1,071,990 ($139,320 impact cost + $932,670 ICR burden).

H. Emergency Preparedness for Program for the All-Inclusive Care for the Elderly (PACE) Organizations—Training and Testing (§ 460.84(d))

Proposed § 460.84(d)(2)(i) through (iii) would require PACE organizations to conduct a mock community or facility-wide drill and a paper-based, tabletop exercise annually. Since PACE organizations are currently required to conduct a facility-wide drill annually, we are only estimating economic impact for the annual tabletop drill. We expect that both the home-care coordinator and the quality-improvement nurse would each spend 1 hour to conduct the tabletop exercise. Thus, we estimate the economic impact hours to be 2 hours for each PACE organization (total impact hours = 182) at an estimated cost of $90 for each organization. The total annual cost for all PACE organizations is $8,190 ($90 × 91 providers). The total cost for all PACE organizations to comply with the requirements in the first year would be $342,888 ($8,190 impact cost + $334,698 ICR burden).

I. Condition of Participation: Emergency Preparedness for Hospitals

1. Medical Supplies (§ 482.15(b)(1))

We propose that hospitals must maintain medical supplies. The American Hospital Association (AHA) recommends that individual hospitals have a 24-hour supply of pharmaceuticals and that they develop a list of required medical and surgical equipment and supplies. TJC standards require a hospital to have a 48 to 72 hour stockpile of medication and supplies.

The Department of Homeland Security (DHS) Act of 2002 established the Strategic National Stockpile (SNS) Program to work with governmental and non-governmental partners to upgrade the nation's public health capacity to respond to a national emergency. The SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications and medical supplies.

The SNS, and other federal agencies, *http://emergency.cdc.gov/stockpile/index.asp*, have plans to address the medical needs of an affected population in the event of a disaster. The SNS has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (for example, a terrorist attack, flu outbreak, or earthquake) severe enough to cause local supplies to run out. After federal and local authorities agree that the SNS is needed, medicines can be delivered to any state in the U.S. within 12 hours. Each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible. States have the discretion to decide where to distribute the supplies in the event of multiple events.

However, prudent emergency planning requires that some supplies be maintained in-hospital for immediate needs. The Federal Metropolitan Medical Response System (MMRS) guidelines call for MMRS communities to be self-sufficient for 48 hours. We encourage hospitals to work with stakeholders (state boards of pharmacy, pharmacy organizations, and public health organizations) for guidance and assistance in identifying medications they may need. Based on our experience with hospitals; we believe that they would have on hand a 2 to 3 day supply of medical supplies at the onset of a disaster. After such time, supplies could be replenished from the SNS and other federal agencies. Therefore, based on the previous information, we are not assessing additional burden for medical supplies.

2. Training Program (§ 482.15(d)(1))

Proposed § 482.15(d)(1) would require hospitals to develop and maintain an emergency preparedness training program and review and update it at least annually. Based on our experience with health care facilities, we expect that all health care facilities provide some type of training to all personnel, including those providing services under contract or arrangement and volunteers. Since such training is required for the TJC-accredited hospitals, the proposed requirements for developing an emergency preparedness-training program and the materials they plan to use in providing initial and on-going annual training would constitute a usual and customary business practice for TJC-accredited hospitals.

However, under this proposed rule, non TJC-accredited hospitals would need to review their existing training program and appropriately revise, update, or develop new sections and new material for their training program. The economic impact associated with this requirement is the staff time required for non-TJC accredited hospitals to review, update or develop a training program. We discuss the economic impact for this requirement in the ICR section.

3. Testing (§ 482.15(d)(2)(i) through (iii))

Proposed § 482.15(d)(2)(i) through (iii) would require hospitals to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually.

State, tribal, territorial, and local public health and medical systems comprise a critical infrastructure that is integral in providing early recognition and response necessary for minimizing the effects of catastrophic public health and medical emergencies. Educating and training these clinical, laboratory, and public health professionals has been, and continues to be, a top priority for the federal government. There are currently four programs at HHS addressing education and training in the area of public health emergency preparedness and response. The programs are the Centers for Public Health Preparedness (CPHP), The Bioterrorism Training and Curriculum Development Program (BTCDP), and National Laboratory Training Network (NLTN). As discussed earlier in this preamble, hospitals can use these and other resources, such as tools offered by the DHS, to assist them in complying with this proposed requirement. Thus, for non-TJC accredited hospitals, the costs associated with this requirement would be primarily due to the staff time needed to participate in the community-wide and facility-based disaster drills, and the tabletop exercises. We believe that appreciable staff time would be required of the risk management director, facilities director, safety director, and security manager. We expect that other staff members would be required to spend a minimal amount of time during these exercises, which would be considered a part of regular on-going training for hospital staff. We estimate that the risk management director, facilities director, safety director and security manager would spend about 12 hours each (8 hours for a disaster drill and 4 hours for a tabletop exercise) on an annual basis to meet the proposed requirement.

Thus, we have estimated the economic impact for the 1,518 non-TJC accredited hospitals. We anticipate that complying with this requirement would require 48 hours for an estimate of $3,360 for each non TJC-accredited hospital. Therefore, for all non TJC-accredited hospitals to comply with this requirement would require 72,864 total economic impact hours (48 economic impact hours per non TJC-accredited hospital × 1,518 non TJC-accredited hospitals = 72,864 total economic impact hours) at an estimated total cost of $5,100,480 ($3,360 per non TJC-accredited hospital × 1,518 hospitals = $5,100,480).

Based on TJC's standards, the TJC-accredited hospitals are currently required to test their emergency operations plan twice a year. Therefore, for TJC-accredited hospitals to conduct disaster drills and tabletop exercises would constitute a usual and customary business practice and we will not include this activity in the economic impact analysis.

4. Generator Testing (§ 482.15(e))

Section § 482.15(e) would require hospitals to test each emergency generator and any associated essential electric systems for a minimum of 4 continuous hours at least once every 12 months under a full electrical load anticipated to be required during an emergency. The intent of this requirement is to provide an increased assurance that a generator and associated essential electrical systems will function during an emergency and are capable of running under a full electrical load required during an emergency for an extended period of time. AO's, including TJC, DNV, and HFAP; currently require accredited hospitals to test their generators/emergency power supply system once for 4 continuous hours every 36 months. Therefore, the cost of the existing testing requirement was deducted from the cost calculation for accredited hospitals. However, under this proposed rule, non-accredited hospitals would be required to run their emergency generators an additional 4 hours, with an additional 1 hour for preparation, and an additional 1 hour for restoration.

For non-accredited hospitals, we estimate labor cost to be $132,696 (6 hours × $25.45/hr ($152.70) × 869 non-accredited hospitals). We estimate fuel cost to be $963,547 (72 gallon/hr × $3.85/gallon × 4 hours ($1,108.80) × 869

non-accredited hospitals) for non-accredited hospitals. Thus for non-accredited hospitals, we estimate the total cost to comply with this requirement to be $1,096,243.

For accredited hospitals, we estimate labor cost to be $413,206 (2 (6 hours × $25.45/hr)/3 ($101.80)) × 4,059 accredited hospitals). We estimate fuel cost to be $3,000,413 (2 (72 gallon/hr × $3.85/gallon × 4 hours)/3 ($739.2)) × 4,059 accredited hospitals) for accredited hospitals. Thus for accredited hospitals, we estimate the total cost to comply with this requirement to be $3,413,619.

Therefore, the total economic impact of this rule on hospitals would be $39,265,594 ($5,100,480 disaster drills impact cost + $4,509,862 generator impact cost + $29,655,252 ICR burden).

J. Condition of Participation: Emergency Preparedness for Transplant Centers

There is no additional economic impact to discuss in this section for transplant centers. All transplant centers are located within a hospital and, thus, would not have to stockpile supplies in an emergency or conduct a mock disaster drill or a tabletop exercise.

K. Emergency Preparedness Long Term Care (LTC) Facilities

1. Subsistence (§ 483.73(b)(1))

Section § 483.73(b)(1) would require LTC facilities to provide subsistence needs for staff and residents, whether they evacuate or shelter in place, including, but not limited to, food, water, and medical supplies alternate sources of energy for the provision of electrical power, and maintenance of temperatures for the safe and sanitary storage of such provisions.

As stated earlier in this section, each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible. The federal responsibility ceases at the delivery of the push-packs to state-designated airports. It is then the responsibility of the state to break down and transport the components of the push-pack to the affected community. It is also at the state's discretion where to deliver push-pack material in the event of multiple events.

We expect that a 1- to 2-day supply would be sufficient because various national agencies with stockpiles of medicine, medical supplies, food and water can be mobilized within 12 hours and supplies can be replenished or provided within 48 hours. Thus, for the sake of this impact analysis, we assume that, at a minimum, a LTC facility would have a 2-day supply of food and potable water for the patients and staff at the onset of a disaster and will not assign a cost to this requirement.

We encourage LTC facilities to work with stakeholders (State Boards of Pharmacy, pharmacy organizations, and public health organizations) for guidance and assistance in identifying medications that may be needed and plan to provide access to all healthcare partners during an event.

2. Training and Testing (§ 483.73(d))

Section § 483.73(d)(2)(i) through (iii) would require LTC facilities to participate in or conduct a mock disaster drill and a tabletop exercise at least annually. The current requirements for LTC facilities already mandate that these facilities periodically review their procedures with existing staff, and carry out unannounced staff drills (42 CFR 483.75(m)(2)). Thus, we expect that complying with the requirement for an annual community or facility-wide mock disaster drill and tabletop would constitute a minimal economic impact, if any, after the first year.

3. Generator Testing (§ 483.73(e))

Proposed § 483.73(e) would require LTC facilities to test each emergency generator for a minimum of 4 continuous hours at least once every 12 months. We estimate labor cost to be $2,314,474 (6 hours × $25.45/hr ($152.70) × 15,157 LTC facilities). We estimate fuel cost to be $16,806,082 (72 gallon/hr × $3.85/gallon × 4 hours ($1,108.80) × 15,157 facilities). Therefore, we anticipate that complying with this requirement would cost an estimated $19,120,556.

L. Condition of Participation: Emergency Preparedness for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)

1. Testing (§ 483.475(d)(2))

Proposed § 483.475(d)(2)(i) through (iii) would require ICFs/IID to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. The current ICF/IID CoPs require them to conduct evacuation drills at least quarterly for each shift and under varied conditions to evaluate the effectiveness of emergency and disaster plans and procedures" (42 CFR 483.470(i) and (i)(iii)). In addition, ICFs/IID must evacuate clients during at least one drill each year on each shift, file a report and evaluation on each evacuation drill and investigate all problems with evacuation drills, including accidents, and take corrective action (42 CFR 483.470(i)(2)). Thus, all 6,450 ICFs/IID already conduct quarterly drills. We estimate that any additional economic impact for an ICF/IID to conduct both a drill and an exercise would be minimal, if any. Therefore, the cost of this proposed rule for all ICFs/IID would be limited to the ICR burden of $15,538,104 as discussed in the COI section.

M. § 484.22 Condition of Participation: Emergency Preparedness for Home Health Agencies (HHAs)—Training and Testing (§ 484.22(d))

We discuss the majority of the economic impact for this requirement in the COI section which is estimated to be $48,725,629.

Proposed § 484.22(d)(2)(i) through (iii) would require HHAs to participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, we would require the HHA to conduct an individual, facility-based mock disaster drill at least annually and maintain documentation of all mock disaster drills. We would also require the HHA to maintain documentation of the exercises.

There are currently two programs at HHS addressing education and training in the area of public health emergency preparedness and response: the Centers for Public Health Preparedness (CPHP), and National Laboratory Training Network (NLTN).

As discussed earlier in this preamble, HHAs can use these and other resources, such as tools offered by the Department of Homeland Security, to assist them in complying with this requirement. Thus, we believe that the cost associated with this requirement would be limited to the staff time to participate in the community-wide and facility-wide trainings, and tabletop exercises. We believe that appreciable staff time would be required of the administrator and director of training. We believe that other staff members would be required to spend a minimal amount of time during these exercises and the training would be considered as part of regular on-going training for HHA staff. We estimate that the administrator would spend about 1 hour on the community-wide disaster drill and 1 hour on the tabletop drill (a total of 2 hours to participate in drills). We also estimate that the director of training would spend a total of 3 hours on an annual basis to participate in the disaster drills (2 hours to participate in a community or facility-wide drill and 1 hour to participate in a tabletop drill). All TJC accredited HHAs are required annually to test their emergency

management program by conducting drills and documenting their results. Thus, we anticipate that only non-TJC accredited HHAs would need to comply with this requirement. We anticipate that it would require 5 hours for each of the 10,615 non-JC-accredited HHAs, with an estimated cost of $2,897,895. Therefore, the total economic impact of this rule on HHAs would be $51,623,524 ($2,897,895 impact cost + $48,725,629 ICR burden).

N. Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities (CORFs)—Testing (§ 485.68(d)(2)(i) through (iii))

Proposed § 485.68(d)(2)(i) through (iii) would require CORFs to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually and document the drills and exercises. To comply with this requirement, a CORF would need to develop a specific scenario for each drill and exercise.

The current CoPs require CORFs to provide ongoing drills for all personnel associated with the facility in all aspects of disaster preparedness (42 CFR 485.64(b)(1)). Thus, for the purpose of this analysis, we believe that CORFs would incur minimal or no additional cost to comply with this requirement. Thus, we estimate the cost for all 272 CORFs to comply with this requirement would be limited to the ICR burden of $828,784 discussed in the COI section.

O. Condition of Participation: Emergency Preparedness for Critical Access Hospitals (CAHs)

1. Testing (§ 485.625(d)(2))

Proposed § 485.625(d)(2)(i) through (iii) would require CAHs to conduct annual community or facility-based drills and tabletop exercises. Accredited CAHs are currently required to conduct such drills and exercises. Although we believe that non-accredited CAHs are currently participating in such drills and exercises, we are not convinced that it is at the level that would be required under this proposed rule. Thus, we will analyze the economic impact for these requirements for the 920 non-accredited CAHs. As discussed earlier in this preamble, CAHs would have access to various training resources and emergency preparedness initiatives to use in complying with this requirement. Thus, we believe that the cost associated with this requirement would be limited to staff time to participate in the community-wide and facility-wide trainings, and tabletop exercises. We believe that appreciable staff time would be required of the administrator, facilities director, director of nursing and nursing education coordinator. We believe that other staff members would be required to spend a minimal amount of time during these exercises that would be considered as part of regular on-going training for hospital staff. We estimate that the administrator, facilities director, and the director of nursing would spend approximately a total of 20 hours on an annual basis to participate in the disaster drills. Thus, we anticipate that complying with this requirement would require 20 hours for an estimated cost of $1,132 for each of the 920 non-accredited CAHs. Therefore, for all non-accredited CAHs to comply with this requirement, it would require 18,400 total economic impact hours (20 economic impact hours per non-accredited CAH × 920 non-accredited CAH) at an estimated total cost of $1,041,440 ($1,132 × 920).

2. Generator Testing (§ 485.625(e))

Proposed § 485.625(e) would require CAHs to test each emergency generator for a minimum of 4 continuous hours at least once every 12 months. AO's, including TJC, DNV, and HFAP; currently require accredited CAHs to test their generators/emergency power supply system once for 4 continuous hours every 36 months. Therefore, the cost of the existing testing requirement was deducted from the cost calculation for accredited CAHs. However, under this proposed rule, non-accredited CAHs would be required to run their emergency generators an additional 4 hours, with an additional 1 hour for preparation, and an additional 1 hour for restoration.

For non-accredited CAHs, we estimate labor cost to be $139,721 (6 hours × $25.45/hr ($152.70) × 915 non-accredited CAHs). We estimate fuel cost to be $1,014,552 (72 gallon/hr × $3.85/gallon × 4 hours ($1,108.80) × 915 non-accredited CAHs) for non-accredited CAHs. Thus for non-accredited CAHs, we estimate the total cost to comply with this requirement to be $1,154,273.

For accredited CAHs, we estimate labor cost to be $41,433 (2 (6 hours × $25.45/hr)/3 ($101.80)) × 407 accredited CAHs). We estimate fuel cost to be $300,854 (2 (72 gallon/hr × $3.85/gallon × 4 hours)/3 ($739.2)) × 407 accredited CAHs) for accredited CAHs. Thus for accredited CAHs, we estimate the total cost to comply with this requirement to be $342,287.

Therefore, the total economic impact of this rule on CAHs would be $8,339,742 ($1,041,440 disaster drills impact cost + $1,496,560 generator impact cost + $5,801,742 ICR burden).

P. Condition of Participation: Emergency Preparedness for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology ("Organizations")—Testing (§ 485.727(d)(2)(i) through (iii))

Current CoPs require these organizations to ensure that employees are trained in all aspects of preparedness for any disaster. They are also required to have ongoing drills and exercises to test their disaster plan. Rehabilitation Agencies would need to review their current activities and make minor adjustment to ensure that they comply with the new requirement. Therefore, we expect that the economic impact to comply with this requirement would be minimal, if any. Therefore, the total economic impact of this rule on these organizations would be limited to the estimated ICR burden of $6,939,456.

Q. Condition of Participation: Emergency Preparedness for Community Mental Health Centers (CMHCs)—Training and Testing (§ 485.920(d))

Proposed § 485.920(d)(2) would require CMHCs to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. We estimate that to comply with the requirement to participate in a community mock disaster drill or to conduct an individual facility-based mock drill and a tabletop exercise annually would primarily require the involvement of the administrator and a registered nurse. We estimate that the administrator would spend approximately 4 hours to participate in a community or facility-wide drill and 1 hour to participate in a tabletop drill. We also estimate that a nurse would spend about 3 hours on an annual basis to participate in the disaster drills (2 hours to participate in a community or facility-wide drill and 1 hour to participate in a tabletop drill). Thus, we anticipate that complying with this requirement would require 8 hours for each CMHC at an estimated cost of $415 for each facility. The economic impact for all 207 CMHCs would be 1656 (8 impact hours × 207 CMHCs) total economic impact hours at a total estimated cost of $85,905 ($415 × 207 CMHCs). Therefore, the total economic impact of this rule on CMHCs would be $674,820 ($85,905 impact cost + $588,915 ICR burden).

R. Conditions of Participation: Emergency Preparedness for Organ Procurement Organizations (OPOs)—Training and Testing (§ 486.360(d)(2)(i) through (iii))

The OPO CfCs do not currently contain a requirement for OPOs to conduct mock disaster drills or paper-based, tabletop exercises. We estimate that these tasks would require the quality assessment and performance improvement (QAPI) director and the education coordinator to each spend 1 hour to participate in the tabletop exercise. Thus, the total annual economic impact hours for each OPO would be 2 hours. The total cost would be $107 for a (QAPI coordinator hourly salary and the Education Coordinator to participate in the tabletop exercise. The economic impact for all OPOs would be 116 (2 impact hours × 58 OPOs) total economic impact hours at an estimated cost of $6,206 ($107 × 58 OPOs). Therefore, the total economic impact of this rule on OPOs would be $613,176 ($6,206 impact cost + $606,970 ICR burden).

S. Emergency Preparedness: Conditions for Certification for Rural Health Clinics (RHCs) and Conditions for Coverage for Federally Qualified Health Clinics (FQHCs)

1. Training and Testing (§ 491.12(d))

We expect RHCs and FQHCs to participate in their local and state emergency plans and training drills to identify local and regional disaster centers that could provide shelter during an emergency.

We propose that an RHC/FQHC must review and update its emergency preparedness policies and procedures at least annually. For purposes of determining the economic impact for this requirement, we expect that RHCs/FQHCs would review their emergency preparedness policies and procedures annually. Based on our experience with Medicare providers and suppliers, health care facilities generally have a compliance officer or other staff member who reviews the facility's program periodically to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. We believe that complying with the requirement for an annual review of the emergency preparedness policies and procedures would constitute a minimal economic impact, if any.

2. Testing (§ 491.12(d)(2)(i) through (iii))

Proposed § 491.12(d)(2)(i) through (iii) would require RHCs/FQHCs to participate in a community or facility-wide mock disaster drill and a tabletop exercise at least annually. We have stated previously that FQHCs are currently required to conduct annual drills. We believe that for FQHCs to comply with these requirements would constitute a minimal economic impact, if any. Thus, we are estimating the economic impact for RHCs to comply with these requirements to conduct mock drills and tabletop exercises. We estimate that a RHCs administrator would spend 4 hours annually to participate in the disaster drills. Also, we estimate that a nurse coordinator (registered nurse) would each spend 4 hours on an annual basis to participate in the disaster drills (3 hours to participate in a community or facility-wide drill and 1 hour to participate in a table-top drill). Thus, we anticipate that complying with this requirement would require 8 hours for each RHC for an estimated cost of $452 per facility. The total annual cost for 4,013 RHCs would be $1,813,876. Therefore, the total economic impact of this rule on RHCs/FQHCs would be $33,762,675 ($1,813,876 impact cost + $31,948,799 ICR burden).

T. Condition of Participation: Emergency Preparedness for End-Stage Renal Disease Facilities (Dialysis Facilities)—Testing (§ 494.62(d)(2)(i) through (iv))

Proposed § 494.62(d)(2) would require dialysis facilities to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. The current CfCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (§ 494.60(d)(4)(ii)). Thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency plans. Although the current CfCs do not specify the type of drill or test, we believe that dialysis facilities are currently participating in community or facility-wide drills. Therefore, for the purpose of this impact analysis, we estimate that dialysis facilities would need to add the tabletop exercise to their emergency preparedness activities. We estimate that it would require 1 hour each for the administrator (hourly wage of $74.00) and the nurse manager (hourly wage of $64.00) to conduct the annual tabletop exercise. Thus, for the 5,923 dialysis facilities to comply with the proposed requirements for conducting tabletop exercises, we estimate 11,846 economic impact hours. We estimate the total cost to be $138 for each facility, with a total economic impact of $817,374 ($138 × 5,923 facilities). Therefore, the total economic impact of this rule on ESRD facilities would be $20,398,812 ($817,374 impact cost + $19,581,438 ICR burden).

U. Summary of the Total Costs

The following is a summary of the total providers and the annual cost estimates for all providers to comply with the requirements in this rule.

TABLE 18—TOTAL ANNUAL COST TO PARTICIPATE IN DISASTER DRILLS AND TEST GENERATORS ACROSS THE PROVIDERS

Facility	Number of participants	Total cost (in $)
RNHCI	16	5,280
ASC	5,354	2,677,000
Hospices	3,773	1,463,924
PRTFs	387	139,320
PACE	91	8,190
Hospital	4,928	9,769,771
LTC	15,157	19,128,134
HHAs	12,349	2,897,895
CAHs	1,322	2,541,639
CMHCs	207	85,905
OPOs	58	6,206
RHCs & FQHCs	9,547	1,813,876
ESRD	5,923	817,374
Total	83,802	41,354,514

Based upon the ICR and RIA analyses, it would require all 83,802 providers and suppliers covered by this emergency preparedness proposed rule to comply with all of its requirements an estimated total first-year cost of $225,268,957.

TABLE 19—TOTAL ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS PROPOSED RULE

Facility	Number of participants	Total cost in year 1 (in $)	Total cost in year 2 and thereafter (in $)
RNHCI	16	24,208	5,280
ASC	5,354	15,241,036	2,677,000
Hospices	3,773	10,076,910	1,463,924
PRTFs	387	1,071,990	139,320
PACE	91	342,888	8,190
Hospital	4,928	39,265,594	9,769,771
Transplant Center	770	1,399,104	0
LTC	15,157	19,128,134	19,128,134
ICF/IID	6,442	15,538,104	0
HHAs	12,349	51,623,524	2,897,895
CORFs	272	828,784	0
CAHs	1,322	8,339,742	2,541,639
Organizations	2,256	6,939,456	0
CMHCs	207	674,820	85,905
OPOs	58	613,176	6,206
RHCs & FQHCs	9,547	33,762,675	1,813,876
ESRD Facilities	5,923	20,398,812	817,374
Total	68,852	225,268,957	$41,354,514

The previous summaries include only the upfront and routine costs associated with emergency risk assessment, development and updating of policies and procedures, development and maintenance of communication plans, disaster training and testing, and generator testing (as specified). If these preparations are effective, they will lead to increased amounts of life-saving and morbidity-reducing activities during emergency events. These activities impose cost on society; for example, if complying with this proposed rule's requirements allows an ESRD facility to remain open during and immediately after a natural disaster, there would be associated increases in provision of dialysis services, thus entailing labor, material and other costs. As discussed in the next section ("Benefits of the Proposed Rule"), it is difficult to predict how disaster responses would be different in the presence of this proposed rule than in its absence, so we have been unable to quantify the portion of costs that will be incurred during emergencies. We request comments and data regarding this issue.

Moreover, we have not estimated any costs for generator backup, on the assumption that such backup is already required for virtually all inpatient and many outpatient facilities, either for TJC or other accreditation, or under state or local codes. We request information on this assumption and in particular on any situations or provider types for which this could turn out to be unnecessarily costly.

V. Benefits of the Proposed Rule

The U.S. Department of Health and Human Services, in its Program Guidance for emergency preparedness grants, stated, "as frontline entities in response to mass casualty incidents, hospitals and other healthcare providers such as health centers, rural hospitals and private physicians will be looked to for minimizing the loss of life and permanent disabilities. Hospitals and other healthcare provider organizations must be able to work not only inside their own walls, but also as a team during an emergency to respond efficiently. Hospitals currently, either through experience or empirical evidence, gain knowledge that causes them to become very adept at flexing their systems to respond in an emergency. Because we live under the threat of mass casualties occurring at anytime and anywhere with consequences that may be different than the day-to-day occurrences, the healthcare system must be prepared to respond to these events by working as a team or community system."

This proposed rule is intended to help ensure the safety of individuals by requiring providers and suppliers to adequately plan for and respond to both natural and man-made disasters. The devastation of the Gulf Coast by Hurricane Katrina is one of the most horrific disasters in our nation's history. In those chaotic early days following the disaster in the greater New Orleans area, hundreds of thousands of people were adversely impacted, and health care services were not available for many who needed them. The recent disaster caused by hurricane Sandy has shown that additional safeguards should be in place to secure lifesaving equipment, such as generators. There is no reason to think that future disasters might not be as large or larger, as illustrated by the tsunami that hit Japan in 2011.

In the event of such disasters, vulnerable populations are at greatest risk for negative consequences from healthcare disruptions. According to one study, children and adolescents with chronic conditions are at increased risk of adverse outcomes following a natural disaster (Rath, Barbara, et. al. "Adverse Health Outcomes after Hurricane Katrina among Children and Adolescents with Chronic Conditions" Journal of Health Care for the Poor and Underserved 18:2, May 2007 pp. 405–417). Another study reports that more than 200,000 people with chronic medical conditions were displaced by Hurricane Katrina (Kopp, Jeffrey, et.al. "Kidney Patient Care in Disasters: Lessons from the Hurricanes and Earthquake of 2005" Clin J Am Soc Nephrol 2:814–824, 2007.) Individuals requiring mental health treatments are another at-risk population that can be adversely impacted by health care

disruptions following an emergency or disaster. A 2008 study concluded that many Hurricane Katrina survivors with mental disorders experienced unmet treatment needs, including frequent disruptions of existing care and widespread failure to initiate treatment for new-onset disorders (Wang, P.S., et.al. "Disruption of Existing Mental Health Treatments and Failure to Initiate New Treatment After Hurricane Katrina. American Journal of Psychiatry, 165(1), 34–41)" (2006).

Hospital closures during Sandy resulted in up to a 25 percent increase in emergency department visits at numerous centers in New York and a 70-percent increase in ambulance traffic. A proportion of this increase was due to populations being unable to receive routine care. Not only do vulnerable populations experience disruptions in care, they may also incur increased costs for care, especially when those who require ongoing medical treatment during disasters are required to visit emergency departments for treatment and/or hospitalization. Emergency department visits incur a copay for most beneficiaries. Similar costs are also incurred by patients for hospitalizations. The literature shows that natural catastrophes disproportionately affect ill and socioeconomically disadvantaged populations that are most at risk (Abdel-Kader K, Unrah ML. Disaster and end-stage renal disease: targeting vulnerable patients for improved outcomes. Kidney Int. 2009;75:1131–1133; Zoraster R, Vanholder R, Sever MS. Disaster management of chronic dialysis patients. Am J Disaster Med. 2007;2(2):96–106; and Redlener I, Reilly M. Lessons from Sandy—Preparing Health Systems for Future Disasters. N ENGL J MED. 367;24:2269–2271).

We know that advance planning improves disaster response. In 2007, *Modern Healthcare* reported on a healthcare system's response to encroaching wildfires in California. Staff from a San Diego hospital and adjacent nursing facility transported 202 patients and ensured all patients were out of harm's way. The facilities were ready because of protocols and evacuation drills instituted after a prior event that allowed them to be prepared (Vesely, R. (2007). Wildfires worry hospitals. Modern Healthcare, 37(43), 16).

Therefore, we believe that it is essential to require providers and suppliers to conduct a risk assessment, to develop an emergency preparedness plan based on the assessment, and to comply with the other requirements we propose to minimize the disruption of services for the community and ensure continuity of care in the event of a disaster. As noted previously, we have varied our requirements by provider type and understand that the degree of vulnerability of patients in a disaster will vary according to provider type. For example, patients with scheduled outpatient appointments such as someone coming in for speech therapy or routine clinic services is likely more self-reliant in a disaster than someone in a hospital ICU or someone who is homebound and receiving services from an HHA.

Overall, we believe that rule would reduce the risk of mortality and morbidity associated with disasters. We believe it very likely that some kind of disaster will occur in coming decades in which substantial numbers of lives will be saved by current emergency preparedness as supplemented by the additional measures we propose here. In New Orleans it seems very likely that dozens of lives could have been saved by competent emergency planning and execution. While New Orleans has a unique location below sea level, everywhere in the United States is vulnerable to weather emergencies and other potential natural or manmade disasters. We have not prepared an estimate in either quantitative or dollar terms of the potential life-saving benefits of this proposed rule. There are several reasons for this, most notably the difficulty of estimating how many additional lives would be saved from emergency preparedness contingency planning and training. While we are unable to estimate the number of lives that could be saved by emergency planning and execution, Table 20 provides the number of Medicare FFS beneficiaries receiving services from some of the provider types affected by this proposed rule during the month of July 2013. We are unable to provide volume data for those patients in Medicare Advantage plans or the Medicaid population. However, one could assume the July 2013 summary is representative of an average month during the year. In the event of a disaster, the fee-for-service patients represented in Table 20 could be at risk and therefore, we could assume that they could benefit from the additional emergency preparedness measures proposed in this rule.

TABLE 20—NUMBER OF MEDICARE FFS PATIENTS WHO RECEIVED SERVICES IN JULY 2013

Provider type	Number of FFS patients
Hospitals	6,910,496
Community Mental Health Center	84,959
Comprehensive Outpatient Rehabilitation Facility	4,045
Critical Access Hospital	655,757
HHA	1,033,909
Hospice	312,799
Hospital based chronic renal disease facility	10,239
Non hospital renal disease treatment center	274,638
Religious Nonmedical Health Care Institution	44
Renal disease treatment center	8,261
Rural health clinic (free standing)	261,067
Rural health clinic (provider based)	291,180
Skilled Nursing Facility	538,189

NOTE: In July 2013 there were 8,949,161 distinct patients.

Benefits from effective disaster planning would not only accrue to individuals requiring health care services. Health care facilities themselves may benefit from improved ability to maintain or resume delivering services. After Hurricane Katrina, 94 dialysis facilities closed for at least one week. Almost 2 years later, in June, 2007, 17 dialysis facilities remained closed (Kopp et al, 2007). Following hurricane Sandy, $180 million of the $810 million damages reported by the New York City Health and Hospitals Corporation was due to lost revenue. Lost revenue from Long Beach Medical Center hospital and nursing home was estimated at $1.85 million a week after closing due to damage from hurricane Sandy (*http://www.modernhealthcare.com/article/20121208/MAGAZINE/312089991#ixzz2adUDjFIE?trk=tynt*).

Finally, taxpayers and insurance companies may benefit from effective emergency preparedness. After Hurricane Ike, it was estimated that the cost to Medicare for ESRD patients presenting to the ED for dialysis instead of their usual facility was, on average, $6,997 per visit. Those ESRD patients who did not require dialysis were billed $482 on average (McGinley et al, 2012). The usual cost for these patients as reimbursed through Medicare is in the order of $250 to 300 per visit. Many of these costs or lost revenues may be mitigated by effective emergency preparedness planning. For a non-ESRD individual who cannot receive care from

his or her office-based physician but must instead go to an emergency room, not only are the individual's costs increased, but reimbursement through Medicare, Medicaid or private insurance is also increased. AHRQ's Medical Expenditure Panel Survey from 2008 notes that the average expense for an office based visit was $199 versus $922 for an emergency room visit (Machlin, S., and Chowdhury, S. "Expenses and Characteristics of Physician Visits in Different Ambulatory Care Settings, 2008." Statistical Brief #318. March 2011. Agency for Healthcare Research and Quality, Rockville, MD. *http://www.meps.ahrq.gov/mepsweb/data_files/publications/st318/stat318.pdf*).

With the annualized costs of the rule's emergency preparedness requirements estimated to be approximately $80 million depending on the discount rate used (see the accounting statement table that follows) and the rule generating additional, unquantified costs associated with the life-saving activities that become implementable as a result of the preparedness requirements, this proposed rule would have to result in at least $80 million in average yearly benefits, principally derived from reductions in morbidity and mortality, for the benefits to equal or exceed costs. ASPR and CMS conducted an analysis of the impact of Superstorm Sandy on ESRD patients using Medicare claims. Preliminary results have identified increases in ESRD treatment disruptions, emergency department visits, hospitalizations, and 30-day mortality for ESRD patients living in the areas affected by the storm. This analysis supports other research and experience that clearly demonstrates a relationship between dialysis disruptions and higher rates of adverse events. Adoption of the requirements in this proposed rule would better enable individual facilities to: Anticipate threats; rapidly activate plans, processes and protocols; quickly communicate with their patients, other facilities and state or local officials to ensure continuity of care for these life maintaining services; and reduce healthcare system stress by remaining open or re-opening quickly following closure. This would decrease the rate of interrupted dialysis, thereby reducing preventable ED visits, hospitalizations, and mortality during and following disasters. We welcome comments that may help us quantify potential morbidity reductions, lives saved, and other benefits of the proposed rule.

W. Alternatives Considered

1. No Regulatory Action

As previously discussed, the status quo is not a desirable alternative because the current regulatory requirements for Medicare and Medicaid providers and suppliers addressing emergency and disaster preparedness are insufficient to protect beneficiaries and other patients during a disaster.

2. Defer to Federal, State, and Local Laws

Another alternative we considered would be to propose a regulation that would require Medicare providers and suppliers to comply with local, state and federal laws regarding emergency/disaster planning. Various federal, state and local entities (FEMA, the National Response Plan (NRP), CDC, the Assistant Secretary for Preparedness and Response (ASPR), et al) have disaster management plans that provide an integrated process that involves all local and regional emergency responders. We also considered allowing health care providers to voluntarily implement a comprehensive emergency preparedness program utilizing grant funding from the Office of the Assistant Secretary for Preparedness and Response, (ASPR). Based on a 2010 survey of the American College of Healthcare Executives (ACHE), less than 1 percent of hospital CEOs identified "disaster preparedness" as a top priority. Also, a 2012 survey of 1,202 community hospital CEOs (found at: *http://www.ache.org/Pubs/Releases/2013/Top-Issues-Confronting-Hospitals-2012.cfm*) of ASPR's Hospital Preparedness Program (HPP) showed that disaster preparedness was not identified as a top issue. We believe that absent conditions of participation/certification/coverage, providers and suppliers would not consistently adhere to the various local, state and federal emergency preparedness requirements. Moreover, many such instructions are unclear as to what is mandatory or only strongly recommended, and written in ways that leave compliance difficult or impossible to determine consistently across providers. Such inconsistent application of local, state, and federal requirements could compound the problems faced by governments, health care organizations, and citizens during a disaster. In addition, CMS regulations would enable CMS to survey and enforce the emergency preparedness requirements using standard processes and criteria.

3. Back-Up Power for Outpatient Facilities

A potential regulatory alternative would involve requiring a power backup of some kind for outpatient facilities such as FQHCs and ESRD clinics. Some state codes, for example, require power backup, not generator backup, in such facilities. There are a number of ramifications of such options including, for example, preservation of refrigerated drugs and biologics, and the potential costs of replacing such items if power is not maintained for the duration of the emergency. For example, the current backup power would normally be expected to last for hours, not days.

4. Outpatient Tracking Systems

Under another regulatory alternative, we would require facilities to have systems in place to keep track of outpatients; the benefits of this alternative would depend on whether such systems would have any chance of success in any emergency that led to substantial numbers of refugees before, during, or after the event. As an illustrative example, most southern states have hurricane evacuation systems in place. It is not uncommon for a million people or more to evacuate before a major hurricane arrives. In this or other situations, would it even be possible, and if so using what methods, for a hospital outpatient facility, an ESRD clinic, a Community Mental Health Center, or an FQHC to attempt to track patients? We would appreciate comments that focus on both costs and benefits of such efforts.

5. Request for Comments on Alternative Approaches to Implementation

We request information and comments on the following issues:

- Targeted approaches to emergency preparedness—covering one or a subset of provider classes to learn from implementation prior to extending the rule to all groups.
- A phase in approach—implementing the requirements over a longer time horizon, or differential time horizons for the respective provider classes. We are proposing to implement all of the requirements 1 year after the final rule is published.
- Variations of the primary requirements—for example, we have proposed requiring two annual training exercises—it would be instructive to receive public feedback on whether both should be required annually, semiannually, or if training should be an annual or semiannual requirement.
- Integration with current requirements—we are soliciting

comment on how the proposed requirements will be integrated with/ satisfied by existing policies and procedures which regulated entities may have already adopted.

6. Conclusion

We currently have regulations for Medicare and Medicaid providers and suppliers to protect the health and safety of Medicare beneficiaries and others. We revise these regulations on an as-needed basis to address changes in clinical practice, patient needs, and public health issues. The responses to the various past disasters demonstrated that our current regulations are in need of improvement in order to protect patients, residents, and clients during an emergency and that emergency preparedness for health care providers and suppliers is an urgent public health issue.

Therefore, we are promulgating emergency preparedness requirements that will be consistent and enforceable for all Medicare and Medicaid providers and suppliers. This proposed rule addresses the three key elements needed to ensure that health care is available during emergencies: safeguarding human resources, ensuring business continuity, and protecting physical resources. Current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

X. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circular/a004/a-4.pdf*), we have prepared an accounting statement. As previously explained, achieving the full scope of potential savings will depend on the number of lives affected or saved as a result of this regulation.

TABLE 21—ACCOUNTING STATEMENT

Category	Estimates	Units		
		Year dollar	Discount rate	Period covered
Benefits				
Qualitative	Help ensure the safety of individuals by requiring providers and suppliers to adequately plan for and respond to both natural and man-made disasters.			
Costs *				
Annualized Monetized ($million/year)	86 83	2013 2013	7% 3%	2014–2018 2014–2018
Qualitative	Costs of performing life-saving and morbidity-reducing activities during emergency events.			

* The cost estimation is adjusted from 2011 to 2013 year dollars using the CPI–W published by Bureau of Labor Statistics in June 2013.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 494

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 403.742 [Amended]

■ 2. Amend § 403.742 by:
■ A. Removing paragraphs (a)(1), (4), and (5).
■ B. Redesignating paragraphs (a)(2) and (3) as paragraphs (a)(1) and (2), respectively.
■ C. Redesignating paragraphs (a)(6) through (8) as paragraphs (a)(3) through (5), respectively.
■ 3. Add § 403.748 to subpart G to read as follows:

§ 403.748 Condition of participation: Emergency preparedness.

The Religious Nonmedical Health Care Institution (RNHCI) must comply with all applicable Federal and State emergency preparedness requirements. The RNHCI must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the RNHCI has the ability to provide in an emergency; and, continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the RNHCI's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The RNHCI must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the RNHCI's care both during and after the emergency.

(3) Safe evacuation from the RNHCI, which includes the following:

(i) Consideration of care needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of care documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Ensures records are secure and readily available.

(6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.

(7) The development of arrangements with other RNHCIs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of nonmedical services to RNHCI patients.

(8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The RNHCI must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under agreement.

(iii) Next of kin, guardian or custodian.

(iv) Other RNHCIs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) RNHCI's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to ensure continuity of care, based on the written election statement made by the patient or his or her legal representative.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the RNHCI's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The RNHCI must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The RNHCI must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.

PART 416—AMBULATORY SURGICAL SERVICES

■ 4. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 416.41 [Amended]

■ 5. Amend § 416.41 by removing paragraph (c).

■ 6. Add § 416.54 to subpart C to read as follows:

§ 416.54 Condition for coverage: Emergency preparedness.

The Ambulatory Surgical Center (ASC) must comply with all applicable Federal and State emergency preparedness requirements. The ASC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The ASC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the ASC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the ASC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and patients in the ASC's care both during and after the emergency.

(2) Safe evacuation from the ASC, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the ASC.

(4) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Ensures records are secure and readily available.

(5) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other ASCs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to ASC patients.

(7) The role of the ASC under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The ASC must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other ASCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) ASC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the ASC's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ASC's needs, and its ability to provide assistance, to the authority having jurisdiction the Incident Command Center, or designee.

(d) *Training and testing.* The ASC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The ASC must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The ASC must conduct exercises to test the emergency plan. The ASC must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed.

PART 418—HOSPICE CARE

■ 7. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

§ 418.110 [Amended]

■ 8. Amend § 418.110 by removing paragraph (c)(1)(ii) and by removing the paragraph designation (i) from paragraph (c)(1)(i).

■ 9. Add § 418.113 to subpart D to read as follows:

§ 418.113 Condition of participation: Emergency preparedness.

The hospice must comply with all applicable Federal and State emergency preparedness requirements. The hospice must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care.

(3) Address patient population, including, but not limited to, the type of services the hospice has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospice's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of hospice employees and patients in the hospice's care both during and after the emergency.

(2) Procedures to inform State and local officials about hospice patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of hospice employees in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(5) The development of arrangements with other hospices and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospice patients.

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(i) A means to shelter in place for patients, hospice employees who remain in the hospice.

(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s). and primary and alternate means of communication with external sources of assistance.

(iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(A) Food, water, and medical supplies.

(B) Alternate sources of energy to maintain the following:

(*1*) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(*2*) Emergency lighting.

(*3*) Fire detection, extinguishing, and alarm systems.

(C) Sewage and waste disposal.

(iv) The role of the hospice under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The hospice must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Hospice employees.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians,

(iv) Other hospices.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Hospice's employees.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the hospice's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The hospice must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The hospice must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.

(ii) Ensure that hospice employees can demonstrate knowledge of emergency procedures.

(iii) Provide emergency preparedness training at least annually.

(iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special

emphasis placed on carrying out the procedures necessary to protect patients and others.

(v) Maintain documentation of all emergency preparedness training.

(2) *Testing.* The hospice must conduct exercises to test the emergency plan. The hospice must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospice's emergency plan, as needed.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 10. The authority citation for Part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 11. Add § 441.184 to subpart D to read as follows:

§ 441.184 Emergency preparedness.

The Psychiatric Residential Treatment Facility (PRTF) must comply with all applicable Federal and State emergency preparedness requirements. The PRTF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The PRTF must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the PRTF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the PRTF's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The PRTF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the PRTF's care both during and after the emergency.

(3) Safe evacuation from the PRTF, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other PRTFs and other providers to receive residents in the event of limitations or cessation of operations to ensure the continuity of services to PRTF residents.

(8) The role of the PRTF under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The PRTF must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other PRTFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the PRTF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the PRTF's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PRTF's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The PRTF must develop and maintain an emergency preparedness training program that must be reviewed and updated at least annually.

(1) *Training program.* The PRTF must do all of the following:

(i) Provide initial training in emergency preparedness policies and

procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) After initial training, provide emergency preparedness training at least annually.

(iii) Ensure that staff can demonstrate knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(2) *Testing.* The PRTF must conduct exercises to test the emergency plan. The PRTF must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv)(A) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events.

(B) Revise the PRTF's emergency plan, as needed.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 12. The authority citation for part 460 continues to read as follows:

Authority: Secs: 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

§ 460.72 [Amended]

■ 13. Amend § 460.72 by removing paragraph (c).

■ 14. Add § 460.84 to subpart E to read as follows:

§ 460.84 Emergency preparedness.

The Program for the All-Inclusive Care for the Elderly (PACE) organization must comply with all applicable Federal and State emergency preparedness requirements. The PACE organization must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The PACE organization must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address participant population, including, but not limited to, the type of services the PACE organization has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the PACE's efforts to contact such officials and, when applicable, of its participation in organization's collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and participants under the PACE center(s) care both during and after the emergency.

(2) Safe evacuation from the PACE center, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(3) The procedures to inform State and local emergency preparedness officials about PACE participants in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric conditions and home environment.

(4) A means to shelter in place for participants, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves participant information, protects confidentiality of patient information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other PACE organizations, PACE centers, or other providers to receive participants in the event of limitations or cessation of operations to ensure the continuity of services to PACE participants.

(8) The role of the PACE organization under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(9)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.

(ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.

(iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

(c) *Communication plan.* The PACE organization must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for staff; entities providing services under arrangement; participants' physicians; other PACE organizations; and volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) PACE organization's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for participants under the organization's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release participant information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of participants under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PACE organization's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The PACE organization must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The PACE organization must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Ensure that staff demonstrate a knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

(2) *Testing.* The PACE organization must conduct exercises to test the emergency plan. The PACE organization must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the PACE organization experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE organization is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 15. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 16. Add § 482.15 to subpart B to read as follows:

§ 482.15 Condition of participation: Emergency preparedness.

The hospital must comply with all applicable Federal and State emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the hospital's care both during and after the emergency.

(3) Safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients.

(8) The role of the hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The hospital must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.
(iii) Patients' physicians.
(iv) Other hospitals
(v) Volunteers.
(2) Contact information for the following:
(i) Federal, State, tribal, regional, and local emergency preparedness staff.
(ii) Other sources of assistance.
(3) Primary and alternate means for communicating with the following:
(i) Hospital's staff.
(ii) Federal, State, tribal, regional, and local emergency management agencies.
(4) A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to ensure continuity of care.
(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.
(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).
(7) A means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.
(d) *Training and testing.* The hospital must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.
(1) *Training program.* The hospital must do all of the following:
(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.
(ii) Provide emergency preparedness training at least annually.
(iii) Maintain documentation of the training.
(iv) Ensure that staff can demonstrate knowledge of emergency procedures.
(2) *Testing.* The hospital must conduct drills and exercises to test the emergency plan. The hospital must do all of the following:
(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.
(ii) If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.
(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
(iv) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.
(e) *Emergency and standby power systems.* The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(2)(i) and (ii) of this section.
(1) *Emergency generator location.* (i) The generator must be located in accordance with the location requirements found in NFPA 99, NFPA 101, and NFPA 110.
(2) *Emergency generator inspection and testing.* In addition to the emergency power system inspection and testing requirements found in NFPA 99—Health Care Facilities and NFPA 110—Standard for Emergency and Standby Power systems, as referenced by NFPA 101—Life Safety Code (as required by 42 CFR 482.41(b)), the hospital must:
(i) At least once every 12 months, test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the hospital anticipates it will require during an emergency.
(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation and repairs.
(3) *Emergency generator fuel.* Hospitals that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

■ 17. Add § 482.78 to subpart E to read as follows:

§ 482.78 Condition of participation: Emergency preparedness for transplant centers.

A transplant center must have policies and procedures that address emergency preparedness.
(a) *Standard:* Agreement with at least one Medicare approved transplant center. A transplant center or the hospital in which it operates must have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and related care for its patients during an emergency. The agreement must address the following, at a minimum:
(1) Circumstances under which the agreement will be activated.
(2) Types of services that will be provided during an emergency.
(b) *Standard:* Agreement with the Organ Procurement Organization (OPO) designated by the Secretary. The transplant center must ensure that the written agreement required under § 482.100 addresses the duties and responsibilities of the hospital and the OPO during an emergency.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 18. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 19. Add § 483.73 to subpart B to read as follows:

§ 483.73 Emergency preparedness.

The LTC facility must comply with all applicable Federal and State emergency preparedness requirements. The LTC facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:
(a) *Emergency plan.* The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must:
(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents;
(2) Include strategies for addressing emergency events identified by the risk assessment;
(3) Address resident population, including, but not limited to, persons at-risk; the type of services the LTC facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the LTC facility's efforts to contact such officials and, when applicable, of its

participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to:

(i) Food, water, and medical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems, and;

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the LTC facility's care both during and after the emergency.

(3) Safe evacuation from the LTC facility, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the LTC facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other LTC facilities and other providers to receive residents in the event of limitations or cessation of operations to ensure the continuity of services to LTC residents.

(8) The role of the LTC facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The LTC facility must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other LTC facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) The State Licensing and Certification Agency.

(iii) The Office of the State Long-Term Care Ombudsman.

(iv) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) LTC facility's staff.

(ii) Federal, State, tribal, regional, or local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the LTC facility's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the LTC facility's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives.

(d) *Training and testing.* The LTC facility must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The LTC facility must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The LTC facility must conduct drills and exercises to test the emergency plan, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

(e) *Emergency and standby power systems.* The LTC facility must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* (i) The generator must be located in accordance with the location requirements found in NFPA 99 and NFPA 100.

(2) *Emergency generator inspection and testing.* In addition to the emergency power system inspection and testing requirements found in NFPA 99—Health Care Facilities and NFPA 110—Standard for Emergency and Standby Power Systems, as referenced by NFPA 101—Life Safety Code as required under paragraph (a) of this section, the LTC facility must do the following:

(i) At least once every 12 months test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the LTC facility anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator

inspections, tests, exercising, operation and repairs.

(3) *Emergency generator fuel.* LTC facilities that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

§ 483.75 [Amended]

■ 20. Amend § 483.75 by removing and reserving paragraph (m).

§ 483.470 [Amended]

■ 21. Amend § 483.470 by—

■ A. Removing paragraph (h).

■ B. Redesignating paragraphs (i) through (l) as paragraphs (h) through (k), respectively.

■ C. Newly redesginated paragraph (h)(3) is amended by removing the reference "paragraphs (i)(1) and (2)" and adding in its place the reference "paragraphs (h)(1) and (2)".

■ 22. Add § 483.475 to subpart I to read as follows:

§ 483.475 Condition of participation: Emergency preparedness.

The Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) must comply with all applicable Federal and State emergency preparedness requirements. The ICF/IID must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address the special needs of its client population, including, but not limited to, persons at-risk; the type of services the ICF/IID has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the ICF/IID efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The ICF/IID must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the ICF/IID's care both during and after the emergency.

(3) Safe evacuation from the ICF/IID, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves client information, protects confidentiality of client information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other ICF/IIDs or other providers to receive clients in the event of limitations or cessation of operations to ensure the continuity of services to ICF/IID clients.

(8) The role of the ICF/IID under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other ICF/IIDs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(iii) The State Licensing and Certification Agency.

(iv) The State Protection and Advocacy Agency.

(3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the ICF/IID's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ICF/IID's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives.

(d) *Training and testing.* The ICF/IID must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. The ICF/IID must meet the requirements for evacuation drills and training at § 483.470(h).

(1) *Training program.* The ICF/IID must do all the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The ICF/IID must conduct exercises to test the emergency plan. The ICF/IID must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

PART 484—HOME HEALTH SERVICES

■ 23. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 24. Add § 484.22 to subpart B to read as follows:

§ 484.22 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal and State emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the HHA has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the HHA's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at § 484.55.

(2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system to track the location of staff and patients in the HHA's care both during and after the emergency.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other HHAs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to HHA patients.

(c) *Communication plan.* The HHA must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other HHAs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The HHA must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The HHA must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(ii) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The HHA must conduct drills and exercises to test the emergency plan. The HHA must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency

plan, the HHA is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 25. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

§ 485.64 [Removed]

■ 26. Remove § 485.64.

■ 27. Add § 485.68 to subpart B to read as follows:

§ 485.68 Condition of participation: Emergency preparedness.

The Comprehensive Outpatient Rehabilitation Facility (CORF) must comply with all applicable Federal and State emergency preparedness requirements. The CORF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CORF must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the CORF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CORF's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts;

(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) *Policies and procedures.* The CORF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the CORF, which includes staff responsibilities, and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The CORF must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CORFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the CORF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CORF's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the CORF's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The CORF must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The CORF must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The CORF must ensure that staff can demonstrate knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within two weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and fire fighting equipment.

(2) *Testing.* The CORF must conduct drills and exercises to test the emergency plan. The CORF must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CORF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CORF is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the CORF's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CORF's emergency plan, as needed.

§ 485.623 [Amended]

■ 28. Amend § 485.623 by removing paragraph (c) and redesignating paragraph (d) as paragraph (c).

■ 29. Add § 485.625 to subpart F to read as follows:

§ 485.625 Condition of participation: Emergency preparedness.

The Critical Access Hospital (CAH) must comply with all applicable Federal and State emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CAH's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to:

(i) Food, water, and medical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the CAH's care both during and after the emergency.

(3) Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to CAH patients.

(8) The role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The CAH must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CAHs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CAH's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The CAH must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The CAH must do all of the following:

(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with fire fighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The CAH must conduct exercises to test the emergency plan. The CAH must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions

designed to challenge an emergency plan.

(iv) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

(e) *Emergency and standby power systems.* The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* (i) The generator must be located in accordance with the location requirements found in NFPA 99 and NFPA 100.

(2) *Emergency generator inspection and testing.* In addition to the emergency power system inspection and testing requirements found in NFPA 99—Health Care Facilities and NFPA 110—Standard for Emergency and Standby Power Systems, as referenced by NFPA 101—Life Safety Code (as required by 42 CFR 485.623(d)), the CAH must do all of the following:

(i) At least once every 12 months test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the CAH anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation, and repairs.

(3) *Emergency generator fuel.* Hospitals that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

■ 30. Revise § 485.727 to read as follows:

§ 485.727 Condition of participation: Emergency preparedness.

The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services ("Organizations") must comply with all applicable Federal and State emergency preparedness requirements. The Organizations must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The Organizations must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the Organizations have the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Address the location and use of alarm systems and signals; and methods of containing fire.

(5) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation.

(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) *Policies and procedures.* The Organizations must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the Organizations, which includes staff responsibilities, and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The Organizations must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other Organizations.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, state, tribal, regional and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Organizations' staff.

(ii) Federal, state, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the Organizations' care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the Organizations' needs, and their ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The Organizations must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The Organizations must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The Organizations must ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The Organizations must conduct drills and exercises to test the emergency plan. The Organizations must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the Organizations experience an actual natural or man-made emergency that requires activation of the emergency plan, they are exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop

exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the Organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed.

■ 31. Section 485.920 is added to subpart J (as added on October 29, 2013, at 78 FR 64630 and effective on October 29, 2014) to read as follows::

§ 485.920 Condition of participation: Emergency preparedness.

The Community Mental Health Center (CMHC) must comply with all applicable federal and state emergency preparedness requirements. The CMHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CMHC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address client population, including, but not limited to, the type of services the CMHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CMHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The CMHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and clients in the CMHC's care both during and after the emergency.

(2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(4) A system of medical documentation that preserves client information, protects confidentiality of client information, and ensures records are secure and readily available.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other CMHCs or other providers to receive clients in the event of limitations or cessation of operations to ensure the continuity of services to CMHC clients.

(7) The role of the CMHC under a waiver declared by the Secretary of Health and Human Services, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The CMHC must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other CMHCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CMHC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the CMHC's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CMHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The CMHC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training.* The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must ensure that staff can demonstrate knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least annually.

(2) *Testing.* The CMHC must conduct drills and exercises to test the emergency plan. The CMHC must:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CMHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CMHC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the CMHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CMHC's emergency plan, as needed.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 32. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

■ 33. Add § 486.360 to subpart G to read as follows:

§ 486.360 Condition of participation: Emergency preparedness.

The Organ Procurement Organization (OPO) must comply with all applicable Federal and State emergency preparedness requirements. The OPO must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the OPO's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The OPO must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and, the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff during and after an emergency.

(2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and ensures records are secure and readily available.

(c) *Communication plan.* The OPO must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Volunteers.

(iv) Other OPOs.

(v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) OPO's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(d) *Training and testing.* The OPO must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training.* The OPO must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The OPO must ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The OPO must conduct exercises to test the emergency plan. The OPO must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the OPO's emergency plan, as needed.

(e) *Agreements with other OPOs and hospitals.* Each OPO must have an agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's Donation Service Area in the event that the OPO cannot provide such services due to an emergency. Each OPO must include within the hospital agreements required under § 486.322(a) and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 34. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 491.6 [Amended]

■ 35. Amend § 491.6 by removing paragraph (c).

■ 36. Add § 491.12 to read as follows:

§ 491.12 Condition of participation: Emergency preparedness.

The Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) must comply with all applicable Federal and State emergency preparedness requirements. The RHC/FQHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The RHC/FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response

during a disaster or emergency situation, including documentation of the RHC/FQHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The RHC/FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The RHC/FQHC must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other RHCs/FQHCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) RHC/FQHC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(5) A means of providing information about the RHC/FQHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The RHC/FQHC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The RHC/FQHC must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles,

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The RHC/FQHC must conduct exercises to test the emergency plan. The RHC/FQHC must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 37. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 494.60 [Amended]

■ 38. Amend § 494.60 by—

■ A. Removing paragraph (d).

■ B. Redesignating paragraph (e) is as paragraph (d).

■ 39. Add § 494.62 to subpart B to read as follows:

§ 494.62 Condition of participation: Emergency preparedness.

The dialysis facility must comply with all applicable Federal and State emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The dialysis facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the dialysis facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to ensure that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) *Policies and procedures.* The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. These

emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and patients in the dialysis facility's care both during and after the emergency.

(2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to dialysis facility patients.

(7) The role of the dialysis facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(8) A process to ensure that emergency medical system assistance can be obtained when needed.

(9) A process ensuring that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

(c) *Communication plan.* The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other dialysis facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Dialysis facility's staff.

(ii) Federal, State, tribal, regional, or local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the dialysis facility's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the dialysis facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training, testing, and orientation.* The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that must be evaluated and updated at least annually.

(1) *Training program.* The dialysis facility must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually. Staff training must:

(A) Ensure that staff can demonstrate knowledge of emergency procedures, including informing patients of—

(*1*) What to do;

(*2*) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(*3*) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(*4*) How to disconnect themselves from the dialysis machine if an emergency occurs.

(B) Ensure that, at a minimum, patient care staff maintain current CPR certification; and

(C) Ensure that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

(D) Maintain documentation of the training.

(2) *Testing.* The dialysis facility must conduct drills and exercises to test the emergency plan. The dialysis facility must:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the dialysis facility is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

(3) *Patient orientation.* Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 28, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 12, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Editorial Note: This document was received in the Office of the Federal Register on December 19, 2013.

Note: The following appendix will not appear in the Code of Federal Regulations

Appendix—Emergency Preparedness Resource Documents and Sites

Presidential Directives

- *Hameland Security Presidential Directive (HSPD–5): "Management of Damestic Incidents"* authorized the Department of Homeland Security to develop and administer the National Incident Management System (NIMS). NIMS consists of federal, state, local, tribal governments, private-sector and nongovernmental organizations to work together to prevent, respond to and recover from domestic incidents. The directive can be found at *http://www.gpa.gav/fdsys/pkg/PPP-2003-book1/pdf/PPP-2003-book1-doc-pg229.pdf.*
- The elements of NIMS can be found at *http://www.fema.gov/emergency/nims/index.shtin.*
- The National Response Framework (NRF) is a guide to how the nation should conduct all-hazards responses. Further information can be found at *http://www.fema.gov/NRF.*
- The National Strategy for Pandemic Influenza and Implementation Plan is a comprehensive approach to addressing the threat of pandemic influenza and can be found at *http://www.flu.gav/prafessianal/federal/pandemic-influenza.pdf.*
- The World Health Organization (WHO) maintains a relatively up-to-date human case count of reported cases and death related to pandemic influenzas. The document can be found at *http://www.wha.int/csr/disease/avian_influenza/cauntry/en/index.html.*
- The National Strategy for Pandemic Influenza Implementation Plan was established to ensure that the Federal government's efforts and resources would occur in a coordinated manner, the Federal government's response, international efforts, transportation and borders, protecting human and animal health, law enforcement, public safety, and security, protection of personnel and insurance of continuity of operations. This document can be found at *http://www.fao.org/docs/eims/upload/221561/national_plan_ai_usa_en.pdf.*
- *Homeland Security Presidential Directive (HSPD–21)* addresses public health and medical preparedness. It establishes a National Strategy for Public Health and Medical Preparedness. The key principles are: preparedness for all potential catastrophic health events, vertical and horizontal coordination across levels of government, regional approach to health preparedness, engagement of the private sector, academia and other non-governmental entities, and the roles of individual families and communities. It discusses integrated biosurveillance capability, countermeasure stockpiling and rapid distribution of medical countermeasures, mass casualty care in coordinating existing resources, and community resilience with oversight of this effort led by ASPR. The directive can be found at *http://www.dhs.gav/xabout/laws/gc_1219263961449.shtm.*
- "National Preparedness Guidelines" adopt an all-hazards and risk-based approach to preparedness. It provides a set of national planning scenarios that represent a range of threats that warrant national attention. For further information, this document can be found at *http://www.dhs.gav/xlibrary/assets/Natianal_Preparedness_Guidelines.pdf.*
- *Presidential Directive (PPD–8): National Preparedness.* It is aimed at facilitating an integrated, all-of-nation, flexible, capabilities-based approach to preparedness. It requires the development of a National Preparedness Goal, a national system description, a national planning system that features the 5 integrated national planning frameworks for prevention, protection, response, recovery and mitigation and federal interagency operational plans (FIOPS). This directive can be found at *http://www.dhs.gov/presidential-policy-directive-8-national-preparedness* and at *http://www.phe.gav/Preparedness/legal/policies/Pages/ppd8.aspx.*

Office of Inspector General (OIG), Government Accountability Office (GAO) and Additional Reports and Their Recommendations

- OIG study entitled, "Nursing Home Emergency Preparedness and Responses During Recent Hurricanes" (OEI–06–06–00020) conducted in response to a request from the U. S. Senate Special Committee on Aging asking for an examination of nursing home emergency preparedness. Based on the study, the OIG had two recommendations for CMS: (1) strengthen federal certification standards for nursing home emergency plans; and (2) encourage communication and collaboration between State and local emergency entities and nursing homes. As a result of the OIG's recommendations, the Secretary initiated an emergency preparedness improvement effort coordinated across all HHS agencies. This study can be found at *http://oig.hhs.gov/oei/reports/oei-06-06-00020.pdf.*
- The National Hurricane Center report entitled, "Tropical Cyclone Report, Hurricane Katrina, 23–30 August 2005" provided data on the effect that the 2005 hurricanes had on the community. This report can be found at *http://www.nhc.naaa.gov/pdf/TCR-AL122005_Katrina.pdf.*
- GAO report entitled, "Disaster Preparedness: Preliminary Observations on the Evacuation of Hospitals and Nursing Homes Due to Hurricanes" (GAO–06–443R) discusses the GAO's findings regarding (1) responsibility for the decision to evacuate hospitals and nursing homes; (2) issues administrators consider when deciding to evacuate hospitals and nursing homes; and (3) the federal response capabilities that support evacuation of hospitals and nursing homes. This can be found at *http://www.gao.gov/new.items/d06443r.pdf.*
- GAO report entitled, "Disaster Preparedness: Limitations in Federal Evacuation Assistance for Health Facilities Should be Addressed" (GAO–06–826) supports the findings noted in the first GAO report. In addition, the GAO noted that the evacuation issues that facilities faced during and after the hurricanes occurred due to their inability to secure transportation when needed. This report can be found at *www.gaa.gav/cgi-bin/getrpt?GAO-06-826.*
- GAO report, an after-event analysis, entitled, "Hurricane Katrina: Status of Hospital Inpatient and Emergency Departments in the Greater New Orleans Area" (GAO–06–1003) revealed that: (1) Emergency departments were experiencing overcrowding and (2) the number of staffed inpatient beds per 1,000 population was greater than that of the national average and expected to increase further and the number of staffed inpatient beds was not available in psychiatric care settings. While this study focused specifically on patient care issues in the New Orleans area, the same issues are common to hospitals in any major metropolitan area. This report can be found at *http://www.gao.gav/dacdblite/details.php?rptna=GAO-06-1003.*
- GAO report, an after-event analysis entitled, "Disaster Recovery: Past Experiences Offer Recovery Lessons for Hurricane Ike and Gustav and Future Disasters" (GAO–09–437T) concluded that recovery from major disasters involves the combined efforts of federal, state and local governments. This report can be found at *http://www.gaa.gav/products/GAO-09-437T.*
- OIG study entitled, "Gaps Continue to Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007–2010, OEI–06–09–00270. The report noted 6 areas of concern that nursing homes did not include in their plans but could affect residents during an emergency which are: Staffing, resident care, resident identification, information and tracking, sheltering in place, evacuation and communication and collaboration.

GAO Recommendations for Response to Influenza Pandemics

- GAO report entitled, "Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed" (GAO–09–909T July 29,2009 expressed concern that many gaps in pandemic planning and preparedness still existed in the presence of a potential pandemic influenza outbreak. This report can be located at *http://www.gao.gov/new.items/d09909t.pdf.*
- GAO report entitled, "Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement" (GAO–10–73). The GAO assessed the progress of the responsible federal agencies in implementing the plans 342 action items set forth in the "National Strategy for Pandemic Influenza: Implementation Plan. These reports can be found at *http://www.gao.gav/new.items/d1073.pdf* and *http://geargewbush-whitehause.archives.gav/hameland/pandemic-influenza-implementatian.htm.* Resources for Healthcare Providers and Suppliers for Responding to Pandemic Influenza:
- "One-step access to U. S. Government h1N1, Avian, and Pandemic Flu Information" Web site provides links to influenza guidance and information from federal agencies. This can be found at *www.flu.gav* More information can be found at *http://www.flu.gov/prafessianal/index.html* that provides information for hospitals, long term care facilities, outpatient facilities, home health agencies, other health care providers and clinicians.
- "HHS Pandemic Influenza Plan Supplement 3: Healthcare Planning"

provides planning guidance for the provision of care in hospitals. This can be located at *http://www.hhs.gov/pandemicflu/plan/sup3.html.*

• "Best Practices in Preparing for Pandemic Influenza: A Primer for Governors and Senior State Officials (2006) written by the National Governors Association (NGA) provides both current and historical perspective on potential disease outbreaks in communities. This report can be found at *http://www.nga.org/Files/pdf/0607PANDEMICPRIMER.PDF.*

• The Public Readiness and Preparedness Act of 2005 establishes liability protections for program planners and qualified persons who prescribe, administer, or dispense covered counter measures in the event of a credible risk of a future public health emergency. Additional information can be found at: *https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx.*

Public Health Emergency Preparedness

• HRSA Policy Information notice entitled, "Health Center Emergency Management Program Expectations" (Document No. 2007–15 dated August 22, 2007, can be found at *http://www.hsdl.org/?view&did=478559* describes the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a governor, the Secretary of the Department of Health and Human Services or the President of the United States.

• CDC report describes natural disasters and man-made disasters. To access this list, go to *http://emergency.cdc.gov/disasters/* under "emergency preparedness and response" and click on "specific hazards".

• RAND Corporation 2006 report stated that since 2001, the challenge has been the need to define public health emergency preparedness and the key elements that characterize a well-prepared community. This report can be found at *http://www.rand.org/publications/randreview/issues/summer2006/pubhealth.html.* The RAND Corporation convened a diverse panel of experts to propose a public health emergency preparedness definition. According to this expert panel, in an article by Nelson, Lurie, Wasserman and Zakowski, titled "Conceptualizing and Defining Public Health Emergency Preparedness", published in the American Journal of Public Health, Supplement 1, 2007, Volume 97, No S9–S11 defined public health emergency preparedness as the capability of the public health and health care systems, communities, and individuals to prevent, protect against, quickly respond to and recover from health emergencies. This report can be found at *http://ajph.aphapublications.org/doi/full/10.2105/AJPH.2007.114496*

• Trust for America's Health (TFAH) report published in December 2012 entitled, "Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism". This report can be found at *http://www.healthyamericans.org/report/101/.*

• The HHS, 2011 Hospital Preparedness Program (HPP) report, entitled "From Hospitals to Healthcare Coalitions: Transforming Health Preparedness and Response in Our Communities", describes how the HPP has become a critical component of community resilience and enhancing the healthcare system's response capabilities, preparedness measures, and best practices across the country. The report can be found at: *http://www.phe.gov/Preparedness/planning/hpp/Documents/hpp-healthcare-coalitions.pdf.*

• A 2008 ASPR published document entitled, "Pandemic and All-Hazards Preparedness Act: Progress Report on the Implementation of Provisions Addressing At Risk Individuals," describes the activities undertaken since the passage of the PAPHA to address needs of at-risk populations and describes some of the activities planned to work toward preparedness for at-risk populations. The report can be found at: *http://www.phe.gov/Preparedness/legal/pahpa/Documents/pahpa-at-risk-report0901.pdf.*

• An August 30, 2005 article in the *Health Affairs* publication by Dausey, D., Lurie, N., and Diamond, A, entitled, "Public Health Response to Urgent Case Reports," evaluated the ability of local public health agencies (LPHAs) to adequately meet "a preparedness standard" set by the CDC. The standard was for the LPHAs to receive and respond to urgent case reports of communicable diseases 24 hours a day, 7 days a week. The goal of the test was to contact an "action officer" (that is, physician, nurse, epidemiologist, bioterrorism coordinator, or infection control practitioner) responsible for responding to urgent case reports.

• A June 2004 article published by Lurie, N., Wasserman, J., Stoto, M., Myers, S., Namkung, P., Fielding, J., and Valdez, R. B., entitled, "Local Variations in Public Health Preparedness: Lessons from California", provides information on performance measures that were developed based on identified essential public health services. The article can be found at: *http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.341/DC1.*

Development of Plans and Responses

• Distributed nationally in FY 2012, ASPR's publication (distributed nationally in FY 2012), "Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness", takes an innovative capability approach to assist state and territory grant awardee planning that focuses on a jurisdiction's capacity to take a course of action. Additional information can be found at: *http://www.phe.gov/preparedness/responders/ndms/Pages/default.aspx.*

A different ASFR guidance provides information, guidance and resources to support planners in preparing for mass casualty incidents and medical surges. The document includes a total of (8) healthcare preparedness capabilities that are: (1) Healthcare system preparedness (for example. information regarding healthcare coalitions); (2) healthcare system recovery; (3) emergency operations coordination, (4) fatality management; (5) information sharing; (6) medical surge; (7) responder safety and health; and (8) volunteer management. This information can be found at: *http://www.phe.gov/Preparedness/planning/hpp/reports/Documents/capabilities.pdf.*

• Center for Health Policy, Columbia University School of Nursing, policy paper, March 2008 entitled, "Adapting Standards of Care Under Extreme Conditions: Guidance for Professionals During Disasters, Pandemics, and Other Extreme Emergencies". This paper, aimed at the nursing population, discusses the challenges to meeting the usual standards of care during natural or man-made disasters and makes recommendations for effectively providing care during emergency events. The paper can be found at: *http://www.nursingworld.org/MainMenuCategories/HealthcareandPolicyIssues/DPR/TheLawEthicsofDisasterResponse/AdaptingStandardsofCare.aspx.*

• Institute of Medicine (IOM) September 2009 report to the HHS entitled, "Guidelines for Establishing Crisis Standards of Care for Use in Disaster Situations. The report provides guidance for State and local health agencies and health care facilities regarding the standards of care that should apply during disaster situations. This report covers guidance on conserving, substituting, adapting, and doing without resources. Further information on this report can be found at *http://www.nap.edu/catalog.php?record_id=12749#.*

• CMS published two guidance documents dated September 30, 2007 and October 24, 2007. The first document entitled, "Provider Survey and Certification Frequently Asked Questions: Declared Public Health Emergencies—All Hazards, Health Standards and Quality Issues", answers questions for all providers and suppliers regarding the lessons that were learned during and after the 2005 hurricanes and can be found at: *http://www.cms.hhs.gov/SurveyCertEmergPrep/Downloads/AllHazardsFAQs.pdf.* The second document entitled, "Survey and Certification Emergency Preparedness Initiative: Provider Survey & Certification Declared Public Health Emergency FAQs—All Hazards," provides web address for emergency preparedness information. It provides links to various resources and to other federal emergency preparedness Web sites and can be found at: (*http://www.nhha.org/WhatsNewFiles/S&C-08-01.01.AllHazardsFAQsmemo.pdf*). In addition, the Web site entitled, "Emergency Preparedness for Every Emergency," can be found at *http://www.cms.HHS.gov/SurveyCertEmergPrep/.*

Emergency Preparedness Related to People With Disabilities

The National Council on Disability's Web site has a page entitled, "Emergency Management," that can be found at *http://www.ncd.gov/policy/emergency_management.* There are various reports/papers that contain specific information on emergency planning for people with disabilities and on how important it is to include people with disabilities in emergency planning, such as:

- Effective Emergency Management: Making Improvements for Communities and People with Disabilities (2009)
- The Impact of Hurricanes Katrina and Rita on People with Disabilities: A Look Back and Remaining Challenges (2006)

- Saving Lives: Including People with Disabilities in Emergency Planning (2005)

[FR Doc. 2013–30724 Filed 12–20–13; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 249 December 27, 2013

Part III

Department of Health and Human Services

Office of Inspector General

42 CFR Part 1001

Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991–AB33

Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: In this final rule, the Office of Inspector General (OIG) amends the safe harbor regulation concerning electronic health records items and services, which defines certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act). Amendments include updating the provision under which electronic health records software is deemed interoperable; removing the electronic prescribing capability requirement; extending the sunset provision until December 31, 2021; limiting the scope of protected donors to exclude laboratory companies; and clarifying the condition that prohibits a donor from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services.

DATES: *Effective Date:* With the exception of the revision of 42 CFR 1001.952(y)(13), this regulation is effective on March 27, 2014. The revision of 42 CFR 1001.952(y)(13) is effective on December 31, 2013.

FOR FURTHER INFORMATION CONTACT: James A. Cannatti III, Heather L. Westphal, or Andrew VanLandingham, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Social security act citation	United States code citation
1128B	42 U.S.C. 1320a–7b

Executive Summary

A. Purpose of the Regulatory Action

Pursuant to section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 and its legislative history, Congress required the Secretary of Health and Human Services (the Secretary) to promulgate regulations setting forth various "safe harbors" to the anti-kickback statute, which would be evolving rules that would be periodically updated to reflect changing business practices and technologies in the health care industry. In accordance with this authority, OIG published a safe harbor to protect certain arrangements involving the provision of interoperable electronic health records software or information technology and training services. The final rule for this safe harbor was published on August 8, 2006 (71 FR 45110) and is scheduled to sunset on December 31, 2013 (42 CFR 1001.952(y)(13)). OIG published a notice of proposed rulemaking on April 10, 2013 (78 FR 21314), proposing to update certain aspects of the electronic health records safe harbor and to extend the sunset date. The purpose of this final rule is to address comments received on the proposed rule and to finalize certain aspects of the proposed rule.

B. Summary of the Final Rule

In this final rule, we amend the current safe harbor in several ways. First, we update the provision under which electronic health records software is deemed interoperable. Second, we remove the requirement related to electronic prescribing capability from the safe harbor. Third, we extend the sunset date of the safe harbor to December 31, 2021. Fourth, we limit the scope of protected donors to exclude laboratory companies. And fifth, we revise the text to clarify the condition that prohibits a donor from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services.

C. Costs and Benefits

This final rule modifies an existing safe harbor to the anti-kickback statute. This safe harbor permits certain entities to provide certain items and services in the form of software and information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records to certain parties. Parties may voluntarily seek to comply with safe harbors so that they have assurance that their conduct will not subject them to any enforcement actions under the anti-kickback statute, the civil monetary penalty (CMP) provision for anti-kickback statute violations, or the program exclusion authority related to kickbacks, but safe harbors do not impose new requirements on any party.

This is not a major rule, as defined at 5 U.S.C. 804(2). It is also not economically significant, because it will not have a significant effect on program expenditures, and there are no additional substantive costs to implement the resulting provisions. We expect the safe harbor, as modified by this final rule, to continue to facilitate the adoption of electronic health records technology.

I. Background

A. Anti-Kickback Statute and Safe Harbors

Section 1128B(b) of the Act (42 U.S.C. 1320a–7b(b), the anti-kickback statute) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the anti-kickback statute may also result in the imposition of CMPs under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients, but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 (section 1128B(b)(3)(E) of the Act; 42 U.S.C. 1320a–7b(B)(3)(E)), which specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, that would specify various payment and business practices that would not be subject to sanctions under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under the Federal health care programs. Since July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing "safe harbors"

in various areas. These OIG safe harbor provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements." 56 FR 35952, 35958 (July 29, 1991).

Health care providers, suppliers, and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks. In giving the Department of Health and Human Services (Department or HHS) the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.

B. The Electronic Health Records Safe Harbor

Using our authority at section 1128B(b)(3)(E) of the Act, we published a notice of proposed rulemaking (the 2005 Proposed Rule) that would promulgate two safe harbors to address donations of certain electronic health records software and directly related training services. 70 FR 59015, 59021 (Oct. 11, 2005). One proposed safe harbor would have protected certain arrangements involving donations of electronic health records items and services made before the adoption of certification criteria. The other proposed safe harbor would have protected certain arrangements involving nonmonetary remuneration in the form of interoperable electronic health records software certified in accordance with criteria adopted by the Secretary and directly related training services. In the same issue of the **Federal Register**, the Centers for Medicare & Medicaid Services (CMS) proposed similar exceptions to the physician self-referral law. 70 FR 59182 (Oct. 11, 2005).

On August 8, 2006 (71 FR 45110), we published a final rule (the 2006 Final Rule) that, among other things, finalized a safe harbor at 42 CFR 1001.952(y) (the electronic health records safe harbor) for protecting certain arrangements involving interoperable electronic health records software or information technology and training services. In the same issue of the **Federal Register**, CMS published similar final regulations pertaining to the physician self-referral law at 42 CFR 411.357(w). 71 FR 45140 (Aug. 8, 2006). The electronic health records safe harbor is scheduled to sunset on December 31, 2013. 42 CFR 1001.952(y)(13).

C. Summary of the 2013 Proposed Rulemaking

On April 10, 2013 (78 FR 21314), we published a proposed rule (the 2013 Proposed Rule) setting forth certain proposed changes to the electronic health records safe harbor. In the 2013 Proposed Rule, we proposed to amend the current safe harbor in several ways. First, we proposed to update the provision under which electronic health records software is deemed interoperable. Second, we proposed to remove the requirement related to electronic prescribing capability from the safe harbor. Third, we proposed to extend the sunset date of the safe harbor. In addition to these proposals, we solicited public comment on other proposals and possible amendments to the safe harbor, including limiting the scope of protected donors and adding or modifying conditions to limit the risk of data and referral lock-in. CMS proposed almost identical changes to the physician self-referral law electronic health records exception elsewhere in the same issue of the **Federal Register**. 78 FR 21308 (Apr. 10, 2013). We attempted to ensure as much consistency as possible between our proposed safe harbor changes and CMS's proposed exception changes, within the limitations imposed by the differences in the underlying statutes. We noted in the 2013 Proposed Rule that, due to the close nexus between the 2013 Proposed Rule and CMS's proposed rule, we may consider comments submitted in response to CMS's proposed rule when crafting our final rule. Similarly, CMS stated that it may consider comments submitted in response to the 2013 Proposed Rule in crafting its final rule.

D. Summary of the Final Rulemaking

In this final rulemaking, we amend the electronic health records safe harbor at 42 CFR 1001.952(y) in several ways. First, we update the provision under which electronic health records software is deemed interoperable. Second, we remove the requirement related to electronic prescribing capability from the safe harbor. Third, we extend the sunset date of the safe harbor to December 31, 2021. Fourth, we limit the scope of protected donors to exclude laboratory companies. And fifth, we revise the text to clarify the condition that prohibits a donor from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services.

As we observed in the 2006 Final Rule,

> OIG has a longstanding concern about the provision of free or reduced price goods or services to an existing or potential referral source. There is a substantial risk that free or reduced-price goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business. Financial incentives offered, paid, solicited, or received to induce or in exchange for generating Federal health care business increase the risks of, among other problems: (i) [o]verutilization of health care items or services; (ii) increased Federal program costs; (iii) corruption of medical decision making; and (iv) unfair competition.

71 FR 45110, 45111 (Aug. 8, 2006). We further stated that,

> consistent with the structure and purpose of the anti-kickback statute and the regulatory authority at section 1128B(b)(3)(E) of the Act, we believe any safe harbor for electronic health records arrangements should protect beneficial arrangements that would eliminate perceived barriers to the adoption of electronic health records without creating undue risk that the arrangements might be used to induce or reward the generation of Federal health care program business.

Id.

We believe that the safe harbor, as amended by this final rule, achieves this goal.

Elsewhere in this issue of the **Federal Register**, CMS is finalizing almost identical changes to the electronic health records exception [1] under the physician self-referral law. We attempted to ensure as much consistency as possible between our changes to the electronic health records safe harbor and CMS's exception changes, within the limitations imposed by the differences in the underlying statutes. As indicated in the 2013 Proposed Rule, we have considered and responded to the timely comments we received as well as those CMS received. Similarly, CMS considered comments submitted in response to our 2013 Proposed Rule in crafting its final rule. For purposes of this final rule, we treat comments that were made with respect to the physician self-referral law as if they had been made with respect to the anti-kickback statute, except where they relate to differences in the underlying statutes.

II. Summary of Public Comments and OIG Responses

OIG received approximately 109 timely filed comments from a variety of entities and individuals. CMS received a similar number of timely filed comments. Overall, the commenters (including in comments submitted to

[1] 42 CFR 411.357(w).

CMS) supported the proposed amendments to the electronic health records safe harbor. However, we received many specific comments about various aspects of the proposed amendments. We have divided the summaries of the public comments and our responses into five parts: A. The Deeming Provision, B. The Electronic Prescribing Provision, C. The Sunset Provision, D. Additional Proposals and Considerations, and E. Comments Outside the Scope of Rulemaking.

A. The Deeming Provision

Our current electronic health records safe harbor requires at 42 CFR 1001.952(y)(2) that the donated software must be "interoperable" (as defined at Note to Paragraph (y) in 42 CFR 1001.952(y)). This condition further provides that software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient. We proposed two modifications to this provision in 1001.952(y)(2), which is known as the "deeming provision." Both modifications to the deeming provision were proposed to reflect recent developments in the Office of the National Coordinator for Health Information Technology (ONC) certification program.

The first proposed modification would reflect ONC's responsibility for authorizing certifying bodies. The second proposal would modify the time frame during which donated software must be certified. Currently, to meet the deeming provision, the safe harbor requires software to be certified within no more than 12 months prior to the date of donation.

Subsequent to the issuance of the 2006 Final Rule, ONC developed a regulatory process for adopting certification criteria and standards, which is anticipated to occur on a cyclical basis. (For more information, see ONC's September 4, 2012 Final Rule entitled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" (77 FR 54163).) Our proposal would modify the deeming provision to track ONC's anticipated regulatory cycle. As a result, software would be eligible for deeming if, on the date it is provided to the recipient, it has been certified to any edition of the electronic health record certification criteria that is identified in the then-applicable definition of Certified EHR Technology in 45 CFR part 170. For example, for 2013, the applicable definition of Certified EHR Technology includes both the 2011 and the 2014 editions of the electronic health record certification criteria. Therefore, in 2013, software certified to meet either the 2011 edition or the 2014 edition could satisfy the safe harbor provision as we proposed.

Additionally, we solicited comments on whether removing the current 12-month certification requirement would impact donations and whether to retain the 12-month certification period as an additional means of determining eligibility under the deeming provision.

After consideration of the public comments, we are finalizing the proposed revisions to subparagraph (y)(2) with one clarification to our proposed regulatory text to ensure the deeming provision closely tracks ONC's certification program. We are revising 42 CFR 1001.952(y)(2) to state that software is deemed to be interoperable if, on the date it is provided to the recipient, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. As we stated in the 2006 Final Rule, we understand that

> the ability of software to be interoperable is evolving as technology develops. In assessing whether software is interoperable, we believe the appropriate inquiry is whether the software is as interoperable as feasible given the prevailing state of technology at the time the items or services are provided to the recipient.
>
> 71 FR 45110, 45126 (Aug. 8, 2006).

We believe our final rule with respect to this condition is consistent with that understanding and our objective of ensuring that software is certified to the current required standard of interoperability when it is donated.

ONC as Agency To Recognize Certifying Bodies

Comment: All commenters addressing the subject supported the proposed modification that would amend the safe harbor to recognize ONC as the agency responsible for authorizing certifying bodies on behalf of the Secretary, with one commenter requesting that we clarify that software need not be certified to ONC standards to be eligible for donation.

Response: We appreciate the commenters' support for this modification. With respect to the request for clarification, the commenter is correct that 42 CFR 1001.952(y)(2) does not require software to be certified to ONC standards in order to be eligible for donation. As we discussed in the 2006 Final Rule (71 FR 45110, 45127 (Aug. 8, 2006)), the deeming provision offers parties one way to be certain that the interoperability condition of subparagraph (y)(2) is met at the time of donation. Even if donated software is not deemed to be interoperable, the donation would satisfy the interoperability condition of subparagraph (y)(2) if it meets the definition of "interoperable" in the Note to Paragraph (y) in 42 CFR 1001.952(y).

Comment: One commenter expressed concerns about linking the interoperability requirement of the safe harbor to ONC's certification criteria and standards because they do not, in the commenter's assessment, reflect contemporary views of interoperability. The commenter suggested that we instead implement a broad definition of interoperability adopted by the International Organization for Standardization or, alternatively, that we adopt interoperability functional definitions developed by the American National Standards Institute.

Response: While we are mindful that other non-governmental organizations may be developing their own standards to encourage the adoption of interoperable electronic health records technology, the ONC certification criteria and standards are the core policies the Department is utilizing to accelerate and advance interoperability and health information exchange. ONC and CMS jointly published a Request for Information (78 FR 14793 (Mar. 7, 2013)) to solicit public feedback on a set of possible policies "that would encourage providers to routinely exchange health information through interoperable systems in support of care coordination across health care settings." 78 FR 14793, 14794 (Mar. 7, 2013). The process by which ONC considers the implementation of new certification criteria and standards is a public, transparent effort that allows the Department's electronic health records technology experts to appropriately consider the comments submitted in light of the goal "to accelerate the existing progress and enhance a market environment that will accelerate [health information exchange] across providers. . . ." 78 FR 14793, 14795 (Mar. 7, 2013).

We believe it is reasonable and appropriate to link the deeming provision to the ONC certification criteria and standards because of ONC's expertise and its public process for considering and implementing the criteria and standards. ONC is the

Department agency with expertise in determining the relevant criteria and standards to ensure that software is as interoperable as feasible given the prevailing state of technology. ONC expects to revise and expand such criteria and standards incrementally over time to support greater electronic health record technology interoperability. *See* 77 FR 54163, 54269 (Sept. 4, 2012). Additionally, utilizing the ONC certification criteria and standards that are implemented through a public process affords the best opportunity for interested parties to comment on, understand, and ultimately implement those criteria and standards. Therefore, we are not adopting the commenter's suggestion.

Comment: One commenter stated that many electronic health records systems lack the capabilities to function within a patient-centered medical home. The commenter suggested that we finalize policies that further strengthen the use of core electronic health records features.

Response: As discussed, ONC is the Department agency with expertise in determining the relevant criteria and standards for electronic health records technology, including those related to the use of core features. ONC certification criteria and standards that are implemented through a public process afford the best opportunity for interested parties to comment on, understand, and ultimately implement those criteria and standards. Therefore, we are not adopting the commenter's suggestion.

Time Frame for Certification

Comment: Of the commenters that addressed the issue, most supported our proposal to modify the time frame within which donated software must have been certified to more closely track the current ONC certification program. Commenters asserted that aligning with ONC's certification program will provide donors and recipients more certainty about the deemed status of donated software because the software must be certified to meet only one set of standards on the same certification cycle to comply with both the ONC certification criteria and the deeming provision of the safe harbor. One commenter supported the modification, but suggested that the 12-month certification time frame also be retained or, alternatively, that we allow software to be deemed to be interoperable if it has been certified to any edition of the ONC electronic health record certification criteria.

Response: We appreciate the commenters' support for our proposal to modify the safe harbor certification time frame to align with ONC's certification program. We believe, as the commenters suggest, that such a modification will support our dual goals of the deeming provision: (1) To ensure that donated software is as interoperable as feasible given the prevailing state of technology at the time it is provided to the recipient and (2) to provide donors and recipients a means to have certainty that donated software satisfies the interoperability condition of the safe harbor.

We are not persuaded to adopt the commenter's suggestion to retain the 12-month certification time frame; this would not ensure that software is certified to the current required standard of interoperability. In the course of evaluating the commenter's alternative proposal, however, we realized that our proposed regulatory text may be too narrow to satisfy the dual goals of the deeming provision. Under our proposed regulatory text from the 2013 Proposed Rule, software would be deemed interoperable if it was certified to an edition [2] of certification criteria referenced in the then-applicable definition of "Certified EHR Technology" at 45 CFR 170.102. That definition applies only to the Medicare and Medicaid Electronic Health Record Incentive Programs (the EHR Incentive Programs). *See generally* 42 CFR part 495. However, ONC also has the authority to adopt certification criteria for health information technology, including electronic health records, into other regulations at 45 CFR part 170 that may not be referenced in the definition of "Certified EHR Technology" because they are not related to the EHR Incentive Programs. If we retained our proposed regulatory text, software certified to criteria in editions not included in the definition "Certified EHR Technology" would not be eligible for deeming under the safe harbor, which was not our intent. The safe harbor described in this rule is not limited to donations to individuals and entities eligible to participate in the EHR Incentive Programs. Individuals and entities such as long-term/post-acute care providers and non-physician behavioral health practitioners, while not eligible to participate in the EHR Incentive Programs, may receive donations that are protected by this safe harbor, if the donations meet the conditions of the safe harbor. Further, we have recently learned that ONC intends to retire outdated editions of certification criteria by removing them from the regulatory text at 45 CFR part 170. Accordingly, software certified to an edition identified in the regulations in effect on the date of the donation would be certified to a then-applicable edition, regardless of whether the particular edition was also referenced in the then-applicable definition of Certified EHR Technology.

Thus, we are finalizing our policy to more closely track ONC's certification program in the deeming provision. We are adopting modified regulatory text to provide that software is deemed to be interoperable if, on the date it is provided to the recipient, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We believe that this modified regulatory text is consistent with the intent we articulated in the 2013 Proposed Rule to modify the deeming provision by removing the 12-month timeframe and substituting a provision that more closely tracks ONC's certification program. Further, we believe that the regulatory text, as modified, will support our dual goals of the deeming provision, which we discussed above.

New Certification/Deeming Requirements

Comment: One commenter suggested that, for deeming purposes, we should require that software be certified to the *latest* edition of electronic health record certification criteria rather than any edition then-applicable. This commenter also suggested that the electronic directory of service (e-DOS) standard should be a certification requirement for donated software, and asserted that both recommendations would help ensure electronic health records software is interoperable.

Response: We decline to adopt the commenter's suggested requirements for the safe harbor at 42 CFR 1001.952(y). We believe that requiring that donated software be certified to editions that are adopted and not yet retired by ONC through its certification program ensures that the software is certified to interoperability standards updated regularly by the Department agency with the relevant expertise. Further, adding requirements to the ONC certification criteria and standards is outside the scope of this rule. Therefore, we are not implementing the commenter's suggestions.

B. The Electronic Prescribing Provision

At 42 CFR 1001.952(y)(10), our current electronic health records safe harbor specifies that the donated

[2] ONC has recently begun characterizing sets of adopted certification criteria as "editions."

software must "contain[ ] electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided." In the preamble to the 2006 Final Rule (71 FR 45110, 45125 (Aug. 8, 2006)), we stated that we included "this requirement, in part, because of the critical importance of electronic prescribing in producing the overall benefits of health information technology, as evidenced by section 101 of the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173]." We also noted that it was "our understanding that most electronic health records systems already include an electronic prescribing component." *Id.*

We understand the critical importance of electronic prescribing. However, in light of developments since the 2006 Final Rule, we proposed to delete from the safe harbor the condition at 42 CFR 1001.952(y)(10). Based on our review of the public comments and for the reasons stated in the 2013 Proposed Rule, we are finalizing our proposal to eliminate the requirement that electronic health records software contain electronic prescribing capability in order to qualify for protection under the safe harbor at 42 CFR 1001.952(y).

Comment: Two commenters disagreed that it is no longer necessary to require the inclusion of electronic prescribing capability in donated electronic health records software. One of the commenters stated that it was encouraged by the growth in the number of physicians using electronic prescribing between 2008 and 2012, but believed that the requirement should remain for patient safety reasons because electronic prescribing is critical to lowering the incidences of preventable medication errors.

Response: Like the commenters, and as we stated in the 2013 Proposed Rule (78 FR 21314, 21317 (Apr. 10, 2013)), we believe in the importance of electronic prescribing. However, as discussed in the 2013 Proposed Rule, we are persuaded that other existing policy drivers, many of which did not exist in August 2006 when the safe harbor was promulgated, sufficiently support the adoption of electronic prescribing capabilities. We do not want to undermine important public policy goals by requiring redundant and sometimes expensive software capabilities that may not contribute to the interoperability of a given system. As we discussed in the 2013 Proposed Rule, electronic prescribing technology would remain eligible for donation under the electronic health records or under the electronic prescribing safe harbor at 42 CFR 1001.952(x). We do not believe that removing this condition would increase the risk of fraud or abuse posed by donations made pursuant to the safe harbor.

Comment: Many commenters supported our proposal to eliminate the requirement that donated software include electronic prescribing capability at the time it is provided to the recipient, agreeing that developments since the promulgation of the safe harbor make it unnecessary to retain this requirement. One of the commenters asserted that the goal of the requirement for the inclusion of electronic prescribing technology in donated electronic health records software—that is, increasing the use of electronic prescribing—had been achieved through the electronic prescribing incentive program authorized by the Medicare Improvements for Patients and Providers Act of 2008.

Response: We appreciate the commenters' support and, for reasons explained in more detail previously in this final rule, we are eliminating the requirement in 42 CFR 1001.952(y)(10) that donated electronic health records software contain electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system that meets the applicable standards under Medicare Part D, at the time the items and services are provided.

C. The Sunset Provision

Protected donations under the current electronic health records safe harbor must be made on or before December 31, 2013. In adopting this condition of the electronic health records safe harbor, we stated that "the need for a safe harbor for donations of electronic health records technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice." 71 FR 45110, 45133 (Aug. 8, 2006).

As we discussed in the 2013 Proposed Rule, although the industry has made great progress in the adoption and meaningful use of electronic health records technology, the use of such technology has not yet been adopted nationwide. Continued use and further adoption of electronic health records technology remains an important goal of the Department. We continue to believe that as progress on this goal is achieved, the need for a safe harbor for donations should continue to diminish over time. Accordingly, we proposed to extend the sunset date of the safe harbor to December 31, 2016, selecting this date for the reasons described in the 2013 Proposed Rule. We also specifically sought comment on whether we should, as an alternative, select a later sunset date and what that date should be. For example, we stated that we were considering establishing a sunset date of December 31, 2021. 78 FR 21314, 21318 (Apr. 10, 2013). In response to comments, we are extending the sunset date of the safe harbor to December 31, 2021.

Comment: Numerous commenters urged us to make permanent the safe harbor at 42 CFR 1001.952(y). According to these commenters, a permanent safe harbor could (1) provide certainty with respect to the cost of electronic health records items and services for recipients, (2) encourage adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an electronic health records system, (3) encourage adoption by providers and suppliers that are not eligible for incentive payments through the Medicare and Medicaid programs, and (4) preserve the gains already made in the adoption of interoperable electronic health records technology, especially where hospitals have invested in health information technology infrastructure through protected donations of such technology. According to some commenters, although the safe harbor was implemented to encourage the adoption of health information technology, it is now a necessity for the creation of new health care delivery and payment models. Some commenters also stated their support for a permanent safe harbor because electronic health record technology adoption has been slower than expected and allowing the safe harbor to expire in 2016 would adversely affect the rate of adoption. Some of these commenters requested that if we are not inclined to make the safe harbor permanent, we extend the availability of the safe harbor through the latest date noted in the 2013 Proposed Rule—December 31, 2021.

Response: We agree with the commenters that the continued availability of the safe harbor plays a part in achieving the Department's goal of promoting electronic health record technology adoption. However, we do not believe that making the safe harbor permanent is required or appropriate at this time. The permanent availability of

the safe harbor could serve as a disincentive to adopting interoperable electronic health record technology in the near-term. Moreover, as described in the 2013 Proposed Rule and elsewhere in this final rule, we are concerned about inappropriate donations of electronic health records items and services that lock in data and referrals between a donor and recipient, among other risks. A permanent safe harbor might exacerbate these risks over the longer term without significantly improving adoption rates. Instead, we believe that a reasonable extension of the safe harbor strikes an appropriate balance between furthering the Department's electronic health record adoption goals and safeguarding against undue risks of abuse. In light of other modifications we are making in this final rule to mitigate ongoing risks, including removing laboratory companies from the scope of protected donors, we are persuaded to permit the use of the safe harbor for more than the additional 3-year period that we proposed.

The adoption of interoperable electronic health records technology remains a challenge for some providers and suppliers, despite progress in its implementation and meaningful use since the August 2006 promulgation of the safe harbor. *See ONC's Report to Congress on Health IT Adoption*, (June 2013) at *http://www.healthit.gov/sites/default/files/rtc_adoption_of_healthit_and_relatedefforts.pdf* and the *U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation's EHR Payment Incentives for Providers Ineligible for Payment Incentives and Other Funding Study*, (June 2013) at *http://aspe.hhs.gov/daltcp/reports/2013/ehrpi.shtml*. Although we believe that the protection afforded by the safe harbor encourages the adoption of such technology, its permanence is not essential to the achievement of widespread adoption. It is only one of a number of ways that providers and suppliers are incented to adopt electronic health records technology, including the incentives offered by the EHR Incentive Programs and the movement in the health care industry toward the electronic exchange of patient health information as a means to improve patient care quality and outcomes. Balancing the desire to encourage further adoption of interoperable electronic health records technology against concerns about potential disincentives to adoption and the misuse of the safe harbor to lock in referral streams, we are establishing a December 31, 2021 sunset date for the safe harbor. We believe this sunset date will support adoption, provide a timeframe that aligns with the financial incentives for electronic health records adoption currently offered by the Federal government, and safeguard against foreseeable future fraud risks.

Comment: Two commenters suggested that the sunset date should be extended, but not beyond December 31, 2016. One asserted that a shorter extension of the sunset date for the safe harbor would allow a wider range of people to obtain access to health information technology services while not diminishing the incentive for providers and suppliers to acquire, implement, and standardize the necessary electronic health records systems. Another commenter supported our proposal to extend the availability of the safe harbor through December 31, 2016, and encouraged us to consider an additional extension as that date approaches. One commenter suggested that we extend the availability of the safe harbor for at least 6 years, although a shorter or longer time period could be established after review of adoption rates across the range of providers and suppliers who may or may not be eligible for incentives under the EHR Incentive Programs. Other commenters supported our alternative proposal to extend the availability of the safe harbor through December 31, 2021, which corresponds to the statutory end of the Medicaid EHR Incentive Program. These commenters noted that more remains to be done to promote electronic health records technology adoption, and suggested that maintaining the safe harbor through this date will help maximize the incentives for eligible physicians to adopt electronic health records technology and thereby increase greater use of electronic health records. Two other commenters suggested tying the sunset of the safe harbor to the corresponding date for assessing "penalties" under the Medicare EHR Incentive Program in order to align Federal regulation of electronic health records technology adoption and use.

Response: After considering all of the comments on this issue, we believe that an extension of the safe harbor to December 31, 2021 (which corresponds to the end of incentive payments under the Medicaid Incentive Program), would (1) support adoption, (2) provide a timeframe that aligns with the financial incentives for electronic health records adoption currently offered by the Federal government, and (3) safeguard against foreseeable future fraud risks. We note that the two commenters that suggested tying the sunset date to the corresponding date for assessing "penalties" under the Medicare EHR Incentive Program appear to misunderstand the duration of the downward payment adjustment under the EHR Incentive Programs, which will continue until an eligible participant adopts and meaningfully uses appropriate electronic health record technology. For additional information, see the July 28, 2010 final rule entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program (75 FR 44448). The practical effect of the commenters' suggestion would be to extend permanently the electronic health records safe harbor. For the reasons stated elsewhere in this final rule, we do not believe that making the safe harbor permanent is required or appropriate at this time and we are not adopting the commenters' suggestion. We believe the date we selected better serves the goals of the safe harbor. Therefore, we are extending the availability of the safe harbor at 42 CFR 1001.952(y) through December 31, 2021. We also note that there are several types of Medicare and Medicaid providers and suppliers that are not eligible for incentives under the EHR Incentive Programs (*e.g.*, long-term/post-acute care providers and non-physician behavioral health practitioners). This rule applies to donations to any individual or entity engaged in the delivery of health care, regardless of whether the recipient of the donation is eligible for incentives under the EHR Incentive Programs.

Comment: A few commenters expressed general support for extending the sunset date, but did not specify whether the extension should be for 3 years, 8 years, or some other length of time. Commenters noted that failure to extend the sunset of the safe harbor would negatively impact the adoption of electronic health records technology, as well as its continued use.

Response: As described previously, we are finalizing our alternative proposal to extend the availability of the safe harbor through December 31, 2021.

Comment: A number of commenters urged us to let the safe harbor expire on December 31, 2013. Some asserted that the safe harbor permits the exact behavior the law was intended to stop. Other commenters asserted that the safe harbor permits "legalized extortion" or provides "legal sanction to trample the competition." Another commenter asserted that the inclusion of "non-market factors" (that is, the influence of donors, rather than end users) in the decision to adopt electronic health record technology may result in lower quality products or services and higher costs, often with an adverse impact on

technology adoption and innovation. Still others asserted that, given the financial incentives that the Federal government itself has provided, it is no longer necessary to spur the adoption of electronic health record technology through the underwriting of the cost of electronic health record technology by outside entities.

Response: Although we appreciate the commenters' concerns, on balance we continue to believe that the safe harbor serves to advance the adoption and use of interoperable electronic health records. However, we caution that a donation arrangement is not protected under the anti-kickback statute unless it satisfies each condition of the safe harbor at 42 CFR 1001.952(y). Arrangements that disguise the "purchase" or lock-in of referrals and donations that are solicited by the recipient in exchange for referrals would fail to satisfy the conditions of the safe harbor.

Comment: Numerous commenters suggested that the safe harbor sunset as scheduled on December 31, 2013, but only with respect to laboratories and pathology practices, "ancillary service providers," entities not listed in section 101 of the MMA (directing the creation of a safe harbor for certain donations of electronic prescribing items and services), or entities that are not part of an accountable care organization or not integrated in a meaningful manner.

Response: We consider these comments to be related to "protected donors" and address them later in section II.D.1.

D. Additional Proposals and Considerations

1. Protected Donors

As we discussed in the 2013 Proposed Rule, while broad safe harbor protection may significantly further the important public policy goal of promoting electronic health records, we continue to have concerns, which we originally articulated in the 2006 Final Rule, about the potential for fraud and abuse by certain donors. 78 FR 21314, 21318 (Apr. 10, 2013). We also noted that we had received comments suggesting that abusive donations are being made under the electronic health records safe harbor. *Id.*

In order to address these concerns, we proposed to limit the scope of protected donors under the electronic health records safe harbor. In the 2013 Proposed Rule, we stated that we were considering revising the safe harbor to cover only the MMA-mandated donors we originally proposed when the safe harbor was first established: hospitals, group practices, prescription drug plan (PDP) sponsors, and Medicare Advantage (MA) organizations. We stated that we were also considering whether other individuals or entities with front-line patient care responsibilities across health care settings, such as safety net providers, should be included, and, if so, which ones. Alternatively, we stated that we were considering retaining the current broad scope of protected donors, but excluding specific types of donors—providers and suppliers of ancillary services associated with a high risk of fraud and abuse—because donations by such providers and suppliers may be more likely to be motivated by a purpose of securing future business than by a purpose of better coordinating care for beneficiaries across health care settings. In particular, we discussed excluding laboratory companies from the scope of protected donors as their donations have been the subject of complaints of abuse. We also discussed excluding other high-risk categories, such as durable medical equipment (DME) suppliers and independent home health agencies. We sought comment on the alternatives under consideration, including comments (with supporting reasons) regarding particular types of providers or suppliers that should or should not be protected donors, given the goals of the safe harbor.

Many commenters raised concerns about donations of electronic health records items and services by laboratory companies and strongly urged us to adopt our proposal to eliminate from the safe harbor protection for such donations, either by excluding laboratory companies from the scope of protected donors (if we extend the availability of the safe harbor), or by letting the safe harbor sunset altogether (for more detailed discussion of comments concerning the sunset provision, please see section II.C. of this final rule). Other commenters raised similar concerns, but did not suggest a particular approach to address them. We summarize the relevant comments and provide our responses below. We have carefully considered the comments that we received on this proposal and, based on the concerns articulated by commenters and the wide-ranging support from the entire spectrum of the laboratory industry (from small, pathologist-owned laboratory companies to a national laboratory trade association that represents the industry's largest laboratory companies), we are finalizing our proposal to remove laboratory companies from the scope of protected donors under the safe harbor. We believe this decision is consistent with and furthers the goal of promoting the adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that the safe harbor will be misused by donors to secure referrals. We also believe that our decision will address potential abuse identified by some of the commenters involving potential recipients conditioning referrals for laboratory services on the receipt of, or redirecting referrals for laboratory services following, donations from laboratory companies.

Protected Donors: Comments and Suggestions Regarding Laboratory Companies

Comment: Many commenters raised concerns that, notwithstanding a clear prohibition in the safe harbor, laboratory companies are, explicitly or implicitly, conditioning donations of electronic health records items and services on the receipt of referrals from the recipients of those donations or establishing referral quotas and threatening to require the recipient to repay the cost of the donated items or services if the quotas are not reached. Some commenters suggested that such *quid pro quo* donations, and donations by laboratory companies generally, are having a negative effect on competition within the laboratory services industry (including increased prices for laboratory services) and impacting patient care as referral decisions are being made based on whether a laboratory company donated electronic health records items or services, not whether that company offers the best quality services or turnaround time. A few commenters also raised concerns that laboratory companies were targeting possible recipients based on the volume or value of their potential referrals.

Response: The current safe harbor provision at 42 CFR 1001.952(y)(5) prohibits determining the eligibility of a recipient or the amount or nature of the items or services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Accordingly, the *quid pro quo* arrangements and targeted donations described by the commenters would not qualify for safe harbor protection. Such arrangements are not consistent with the purpose of the safe harbor and can result in the precise types of harm the anti-kickback statute is designed to prevent, such as corruption of medical decision making. We urge those with information about such arrangements to contact our fraud hotline at 1–800–

HHS–TIPS or visit *https://forms.oig.hhs.gov/hotlineoperations/* to report fraud.

We appreciate the commenters sharing their concerns about arrangements involving laboratory company donations. As previously discussed, we have decided to exclude laboratory companies from the scope of protected donors. We believe that our decision will continue to support the Department's electronic health record adoption policies, while addressing the risk of fraud and abuse. By excluding laboratory companies from the scope of protected donors, parties to such donations will not be able to assert safe harbor protection for such arrangements. The effect will be a reduction in the risk that parties will enter into arrangements like the *quid pro quo* and targeted donation arrangements described by the commenters.

Comment: Several commenters raised concerns about laboratory company arrangements with electronic health record technology vendors. The commenters described arrangements involving laboratory companies and vendors that result in the vendor charging other laboratory companies high fees to interface with the donated technology or prohibiting other laboratory companies from purchasing the technology for donation to their own clients. One of the commenters also raised the concern that volume discount arrangements between laboratory companies and vendors of electronic health record technology are resulting in donations of electronic health record technology that may not best suit the needs of the recipient. The commenter asserted that donor laboratory companies are pushing a particular vendor's specific electronic health record system onto recipients because of a donor's close business relationship with the vendor.

Response: Excluding potential competitors of the donors from interfacing with the donated items or services described by the commenters can result in data and referral lock-in. We discuss the issue of lock-in elsewhere in this final rule in more detail. We believe that our determination to exclude laboratory companies from the scope of protected donors will help address the data and referral lock-in risks posed by arrangements such as those described by the commenters. We also believe that the changes we are finalizing to the scope of protected donors will help address the commenter's concern about the negative impact of relationships between laboratory companies and vendors on the selection of electronic health records technology by providers and suppliers. We stated in the 2006 Final Rule that, although physicians and other recipients remain free to choose any electronic health record technology that suits their needs, we do not require donors to facilitate that choice for purposes of the safe harbor. However, donors must offer interoperable products and must not impede the interoperability of any electronic health record software they decide to offer. 71 FR 45110, 45128–9 (Aug. 8, 2006). Agreements between a donor and a vendor that preclude or limit the ability of competitors to interface with the donated software would cause the donation to fail to meet the condition at 42 CFR 1001.952(y)(3), and thus preclude protection under the electronic health records safe harbor.

Comment: Many commenters noted that several States—including Missouri, New Jersey, New York, Pennsylvania, Tennessee, Washington, and West Virginia—have prohibited or restricted donations of electronic health record technology by laboratory companies to address fraud and abuse concerns. Some of the commenters urged us to effectuate a similar prohibition or restriction by removing safe harbor protection from laboratory company donations. One of these commenters, referencing an earlier discussion of "the need for [electronic health record technology] subsidies to compete for business," went on to state that "[laboratory companies] that are licensed in states that strictly prohibit [laboratory companies] from donating all or part of the costs of [electronic health record technology] to referring physicians are put at a considerable disadvantage in the marketplace."

Response: We appreciate the commenters providing this information and we believe that our determination to exclude laboratory companies from the scope of protected donors will address the fraud and abuse concerns the commenters referenced. With respect to the commenter's concern about being disadvantaged, we note that our decision to remove laboratory companies from the scope of protected donors under the electronic health records safe harbor applies equally to all laboratory companies, regardless of their location.

Comment: Several commenters, including a national laboratory trade association that represents the industry's largest laboratory companies, took exception to what it perceived as a characterization that laboratory companies are solely responsible for problematic donations. Some of these commenters asserted that electronic health record vendors are encouraging physicians to seek or demand donations from laboratory companies, and that physicians are threatening to withhold referrals or send laboratory business elsewhere if donations are not made. According to one commenter, because physicians are not paying for a significant portion of the cost of these items and services, electronic health record technology vendors are able to charge high prices and the size of donations (in dollars) in recent years has increased exponentially. The commenter also suggested that vendors may be manipulating pricing to maximize the amount a laboratory company pays for donated items and services while minimizing or eliminating any physician responsibility. Another commenter raised a related concern that electronic health records technology vendors have increased the costs of their products because they know that laboratory companies are paying for them. Generally, commenters raising concerns about the conduct of electronic health record technology vendors and physicians recommended that we remove safe harbor protection for laboratory company donations.

One commenter asserted that electronic health records items and services are no longer being chosen by physicians based on which system is most appropriate, but rather based on which will produce the largest donation. Another commenter claimed that many physicians will change laboratory companies and seek a new donation once an existing donor laboratory company ceases to subsidize the physicians' electronic health records items and services costs. This commenter stated that such conversions are not only inefficient, but undermine the spirit of the regulatory requirement that recipients do not possess the same or equivalent items or services as those being donated.

Response: Our proposed modification related to the scope of protected donors and, thus, the focus of our discussion in the 2013 Proposed Rule was on donor conduct. Some of the comments we describe in this final rule also raise concerns about the conduct of recipients. We are clarifying that we do not believe that problematic donations involving laboratory companies are solely the result of questionable conduct by laboratory companies. Our decision to exclude laboratory companies from the scope of protected donors is the best way to reduce the risk of misuse of donations by both donors and recipients and address the concerns identified by the commenters.

The safe harbor at 42 CFR 1001.952(y)(4) contains a condition that prohibits the donation recipient, the recipient's practice, or any affiliated individual or entity, from making the receipt, amount or nature of the donated items or services a condition of doing business with the donor. This condition recognizes the risk of fraud and abuse posed by a potential recipient demanding a donation in exchange for referrals. This type of *quid pro quo* arrangement is no less troubling than *quid pro quo* arrangements that originate with the donor and would not be subject to safe harbor protection. Whether a *quid pro quo* donation is for an initial installation of a donated item or service or a conversion to a different donated item or service would not change our analysis. Additionally, we caution those engaging in conversion arrangements to be mindful of the limitations in the safe harbor at 42 CFR 1001.952(y)(7) concerning the donation of equivalent items or services.

Comment: Several commenters suggested that laboratory companies should be prohibited from making donations to physicians or that physicians should pay for their own electronic health records technology. Other commenters asserted that laboratory companies do not share an essential interest in their referring clients having electronic health records technology. Still other commenters stated simply that laboratory companies represent a high risk of fraud and abuse.

Response: We are excluding laboratories from the scope of protected donors.

Comment: A few commenters noted that laboratory companies typically use a laboratory information system (LIS), anatomic pathologist information system and/or blood banking system to store and share patients' laboratory results, and that these systems should not be confused with an electronic health record that includes a patient's full medical record composed of information from many medical specialties, including pathology. One of these commenters asserted that laboratories already bear the cost of establishing LIS interfaces that they provide in order to exchange laboratory services data electronically, and that clinical and anatomic laboratories could continue to do so legally even if they were no longer protected donors under the safe harbor. One commenter expressed concern about the costs associated with interfaces, other commenters asked us to clarify our position on the donation of interfaces by laboratory companies, and one commenter stated that interfaces were not closely analogous to facsimile machines.

Response: We appreciate the information provided by the commenters. We take this opportunity to note that our decision to exclude laboratory companies from the scope of protected donors under the safe harbor does not affect our position concerning the provision of free access to certain limited-use interfaces. We have long distinguished between free items and services that are integrally related to the offering provider's or supplier's services and those that are not. For instance, we have stated that a free computer provided to a physician by a laboratory company would have no independent value to the physician if the computer could be used only, for example, to print out test results produced by the laboratory company. In contrast, a free personal computer that the physician could use for a variety of purposes would have independent value and could constitute an illegal inducement. 56 FR 35952, 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulations). The donation of free access to an interface used only to transmit orders for the donor's services to the donor and to receive the results of those services from the donor would be integrally related to the donor's services. As such, the free access would have no independent value to the recipient apart from the services the donor provides and, therefore, would not implicate the anti-kickback statute. *See, e.g.*, OIG Ad. Op. 12–20 (2012). Accordingly, safe harbor protection for such donations would not be necessary.

We disagree with the commenter that asserted that interfaces are not sufficiently analogous to facsimile machines. We believe that a limited-use interface (as described in the preceding paragraph) is the contemporary analog to the limited-use computer described in the example from the 1991 preamble to the safe harbor regulations. A similarly limited-use facsimile machine would not materially differ from the limited-use computer and, thus, would be analogous to the access to the limited-use interface. It is the lack of independent value to the recipient that takes the donation outside the scope of the anti-kickback statute's prohibition, not the mode of technology. Finally, in the circumstances presented above, the free access to a limited-use interface would not require safe harbor protection, and thus the costs of the interface are outside the scope of this rulemaking.

Comment: Several commenters inquired whether our proposal to remove laboratory companies from the scope of protected donors applied to suppliers of both anatomic and clinical pathology services, and suggested that our proposal should apply to both. Commenters also inquired about the application of this proposal to hospitals that operate laboratory companies for non-hospital affiliated customers. Raising concerns about an uneven playing field, some of these commenters urged us to exclude such hospitals from the scope of protected donors if we determined to exclude laboratory companies. One commenter suggested that we effectuate this limitation by restricting protected hospital donations to those made to the hospital's employed physicians and the hospital's wholly-owned physician practices.

Response: Our proposal applied to "laboratory companies" and did not distinguish between those that provide anatomic pathology services and those that provide clinical pathology services. We intend that references to "laboratory company" or "laboratory companies" include entities that furnish either type of service. With respect to the commenters' suggestion to limit or prohibit hospital donations, we appreciate the commenters' concerns, but are not adopting their suggestion at this time. We continue to believe that hospitals have a substantial and central stake in patients' electronic health records. Further, the types and prevalence of the concerns that have been brought to our attention and discussed elsewhere in this final rule in the context of laboratory company donations have not arisen, to our knowledge, in the hospital-donation context.

We are clarifying that if a hospital furnishes laboratory services through a laboratory that is a department of the hospital for Medicare purposes (including cost reporting) and that bills for the services through the hospital's provider number, then the hospital would not be considered a "laboratory company" for purposes of this safe harbor and would continue to qualify as a protected donor under the modified safe harbor. However, if a hospital-affiliated or hospital-owned company with its own supplier number furnishes laboratory services that are billed using a billing number assigned to the company and not the hospital, the company would be considered a "laboratory company" for purposes of this safe harbor and would no longer qualify as a protected donor. The ability of the affiliated hospital to avail itself of the safe harbor would be unaffected. We remind readers that it is the substance, not the form, of an arrangement that governs under the anti-kickback statute.

A donation purported to be by an affiliate of a laboratory company could, depending on the facts and circumstances, be attributed to the affiliated laboratory company, and thus not be subject to safe harbor protection.

Comment: One commenter requested that, if we finalize our proposal to exclude laboratory companies from the scope of protected donors, we specifically clarify that "[laboratory companies] are prohibited from providing [] software to physicians unless they comply with another one of the existing safe harbors." The commenter went on to cite examples of software leases and sales at fair market value.

Response: We cannot make the statement requested. Safe harbors set forth specific conditions that, if met, assure the parties involved of not being subject to any enforcement actions under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The failure of an arrangement to fit in a safe harbor does not mean that the arrangement is illegal. That an arrangement does not meet a safe harbor only means that the arrangement must be evaluated on a case-by-case basis. Arrangements regarding the lease or sale of software are outside the scope of this rulemaking.

Comment: One commenter shared its concerns about a practice that it described as "post donation in-sourcing." The commenter stated that it is aware of situations in which laboratory companies are donating to ordering physicians only to have those physicians in-source their laboratory services shortly after the donation. The commenter suggested that "[t]he donation enables [] ordering physicians to avoid bearing the full cost of the [electronic health records items and services] when they discontinue use of an outside laboratory and bring the specimen testing into their own in-house self-referral arrangement just after receiving the donation."

Response: The safe harbor does not require the donation recipient to make referrals to the donor. To the contrary, subparagraph (y)(4) prohibits the donation recipient, the recipient's practice, or any affiliated individual or entity, from making the receipt, amount or nature of the donated items or services a condition of doing business with the donor. Moreover, subparagraph (y)(5) prohibits determining the eligibility of a recipient or the amount or nature of the items or services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Whether safe harbor protection is afforded to the types of arrangements described by the commenter will depend on whether all conditions of the safe harbor are satisfied.

Comment: Two commenters raised issues regarding the type of remuneration permissible under the safe harbor at 42 CFR 1001.952(y). One commenter characterized the safe harbor in terms of allowing laboratory companies to donate funds to recipients to help them implement electronic health records technology. Another commenter noted that some donations from laboratory companies have included hardware.

Response: We remind stakeholders that the electronic health records safe harbor applies only to the donation of nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records. As stated in the preamble to the 2006 Final Rule, reimbursement for previously incurred expenses is not protected, as it poses a substantial risk of fraud and abuse. 71 FR 45110, 45134 (Aug. 8, 2006). We also remind stakeholders that the safe harbor does not protect the donation of hardware.

Scope of Protected Donors: Other Comments and Suggestions

Although the majority of commenters recommended removing safe harbor protection for donations by laboratory companies, including by excluding laboratory companies from the scope of protected donors, some commenters had alternate or additional recommendations.

Comment: A number of commenters recommended that we maintain our current scope of protected donors. Some of these commenters stated that limiting the scope of protected donors could have an impact on specialists, who, according to the commenters, still have relatively low rates of electronic health records adoption. Along the same lines, one commenter stated that limiting the categories of donors that may seek protection under the safe harbor will negatively impact recipients by preventing certain entities from helping move the entire healthcare system towards more interoperable electronic health records systems. Others cautioned that restricting the scope of protected donors will stymie innovation and restrict learning from the technology. Finally, some commenters contended that laboratory companies and other ancillary service providers and suppliers have a legitimate clinical interest in donating electronic health record items and services, and that many physician practices depend on it.

Some commenters, while acknowledging our concerns regarding abusive donation practices, suggested alternative means to address the concerns we articulated in the 2013 Proposed Rule. These commenters variously recommended that we strengthen interoperation requirements, provide education materials, or adopt enforcement policies to prevent abuses rather than limiting the scope of potential donors.

Response: We agree with many of the reasons articulated by the commenters that support maintaining our current broad scope of protected donors. We recognize that limiting the scope of potential donors could constrain the ability of many providers and suppliers to adopt electronic health record technology. Other than with respect to laboratory companies, the scope of protected donors will remain the same. We will continue to monitor and may, prior to 2021, reconsider in a future rulemaking the risk of fraud or abuse relating to the use of the safe harbor by other donors or categories of donors.

We appreciate the suggestions from commenters regarding alternative means of addressing abusive donation practices. The purpose of safe harbors is to permit certain non-abusive arrangements that, in the absence of the safe harbor, potentially would be prohibited by the anti-kickback statute. Compliance with safe harbors is voluntary, and safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Thus, any individual or entity engaging in an arrangement that does not meet all conditions of the safe harbor could be subject to an enforcement action unless the arrangement otherwise complies with the law. In response to the suggestion that we provide additional education materials, we would like to highlight our efforts to educate the industry about compliance with the anti-kickback statute and other fraud and abuse laws generally. Our Web site (*www.oig.hhs.gov*) has a "Compliance" tab with many compliance-related materials. These include Compliance Education for Physicians, Compliance Program Guidance documents for various segments of the industry (including hospitals, nursing facilities,

and others), Special Fraud Alerts, advisory opinions, and more. We believe that the information we include in this final rule sufficiently sets forth donors' and recipients' requirements under the safe harbor with respect to donations. If an individual or entity desires guidance about a specific arrangement involving the donation of electronic health records items or services under the safe harbor, our advisory opinion process remains available. Finally, we address the issue of interoperation requirements elsewhere in this final rule.

Comment: We received a number of comments requesting that we retain certain categories of providers and suppliers within the scope of protected donors under the safe harbor at 42 CFR 1001.952(y). For example, commenters that provide dialysis services specifically requested that they remain protected donors. One of the dialysis provider commenters noted that excluding this specialty would have a chilling effect on the development and availability of the specialized electronic health records systems used by nephrologists. A few commenters requested that we continue to include hospitals and health systems as protected donors in order for them to retain the ability to assist physicians in adopting electronic health records technology. Other commenters requested that we explicitly retain home health agencies as protected donors. In support of retaining home health agencies, one commenter stated that the depth, breadth, and frequency of communications between home health agencies and other direct care providers makes the use of interoperable electronic health record technology essential to improving clinical outcomes and financial efficiencies. We also received comments in support of retaining safety-net providers and pharmacies as protected donors.

Response: We agree generally with the thrust of these comments. We recognize the value of permitting individuals and entities that participate directly in the provision of health care to patients and that have a need to coordinate with care providers and suppliers to donate electronic health record items or services to facilitate those interactions. Based on the information we have available at this time, we intend to continue to protect donors, other than laboratory companies, that provide patients with health care items or services covered by a Federal health care program and submit claims or requests for payment to those programs directly or through reassignment. Thus, whether a particular donation is eligible for safe harbor protection will hinge, in part, on whether the particular individual or entity making the donation meets this standard. For example, a hospital (whether stand-alone or within a health system) is an entity that typically provides health care services and submits claims or requests for payment to Federal health care programs and, therefore, could be a protected donor under this safe harbor.

Comment: Some commenters agreed with the option we presented in the 2013 Proposed Rule to retain the current scope of protected donors but exclude providers and suppliers of ancillary services associated with a high risk of fraud and abuse. A few of these commenters suggested that taking a targeted approach minimizes the risk of unintended consequences. One of these commenters asserted that we should exclude the particular individuals or entities that have been the subject of complaints. Another of these commenters specifically recommended that we target categories of providers and suppliers with a history or pattern of abusive behavior. Other commenters variously recommended excluding laboratory companies, DME suppliers, home health agencies, or safety-net providers from the scope of protected donors. One commenter asserted that entities like laboratory companies and DME suppliers do not have an overarching and essential interest in having physicians use electronic health records, nor do they coordinate a patient's care. In contrast, one commenter objected to singling out a provider or supplier type to exclude from the scope of protected donors. This commenter stated that such an action unjustly (1) penalizes a whole category of providers or suppliers when most, in the commenter's assessment, are law-abiding, and (2) supports other providers or suppliers that may have similar motivations.

Response: We respond earlier to the commenters who recommended removing only laboratory companies from the scope of protected donors. With respect to the other comments, we note that, in the 2013 Proposed Rule, we specifically requested comments with supporting reasons regarding whether particular provider or supplier types should not be protected. 78 FR 21314, 21318 (Apr. 10, 2013). Some commenters generally suggested that we remove additional provider or supplier types from the scope of protected donors, but their comments did not provide specific examples of abusive practices with respect to donations by other donors, nor did the comments contain indicia of problems comparable to those that are arising in the laboratory context. We have not heard the same concerns or received similar complaints about other categories of donors or types of donation arrangements, and therefore believe it is premature to exclude potential donors (other than laboratory companies). We also decline to identify particular individuals or organizations in the regulation.

Comment: A few commenters recommended restricting the scope of protected donors under the safe harbor to those types listed in the MMA. These commenters also made suggestions regarding how to restrict donations from these limited categories of donors. For example, one commenter recommended limiting the protected donors to hospitals and providers and suppliers operating in an integrated setting and to MA plans and providers and suppliers under contract with them. Another commenter suggested limiting the application of the safe harbor to a similar integrated model, and to hospitals that donate to their employed physicians and the physician groups that they own. In contrast, one commenter suggested that limiting the protected donor types to the original MMA list is too restrictive because some provider and supplier types not listed in the MMA (*e.g.*, ambulatory surgical centers that now perform many procedures previously performed only in hospitals) should have the opportunity to make donations.

Response: We agree that providers and suppliers operating in an integrated environment need interoperable electronic health records. However, we do not believe that the need for this technology is limited to individuals and entities in an integrated care setting. Patients may receive care from providers and suppliers that are not in the same integrated system, and the patient's medical records need to be shared with those providers and suppliers who care for a patient. The Department's goal continues to be fostering broad adoption of interoperable electronic health records technology. At this time, we believe that excluding laboratory companies from the scope of protected donors, rather than limiting the scope to the original MMA list of donors (or some other subset of protected donors) strikes the right balance between furthering that goal and preventing fraud and abuse.

2. Data Lock-In and Exchange

We solicited comments on what new or modified conditions could be added to the electronic health records safe harbor to achieve the two goals of (1) preventing misuse of the safe harbor

that results in data and referral lock-in and (2) encouraging the free exchange of data (in accordance with protections for privacy). Additionally, we requested comments on whether those conditions, if any, should be in addition to, or in lieu of, our proposal to limit the scope of protected donors. We also solicited comments on possible modifications to 42 CFR 1001.952(y)(3), which is a condition of the safe harbor requiring that "[t]he donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems."

Data Lock-In: Comments on Current Conditions

Comment: Many commenters asserted that the current conditions of the safe harbor provide adequate safeguards to prevent donations that result in data or referral lock-in between the donor and recipient. These commenters expressed general support for enforcement when arrangements do not comply with the conditions of the safe harbor. Several of these commenters were also concerned that adding or modifying conditions of the safe harbor may increase the burden of compliance and, therefore, lead to fewer entities willing to make appropriate donations.

Response: We are not persuaded to adopt significant new requirements or modifications to the safe harbor to address the issue of data and referral lock-in at this time. However, as described below, we are making limited clarifications to current conditions to reflect our intended meaning.

We remain committed to investigating potentially abusive arrangements that purport to meet the conditions of the safe harbor, but, in fact, do not. Donations that do not meet the conditions of the safe harbor—because they are used to lock in referrals—are suspect under the law.

Comment: Several commenters expressed concerns about donations that lead to data lock-in. As described elsewhere in this final rule, some commenters suggested that, although some donated items or services have the ability to be interoperable, vendors may charge providers and suppliers who do not use the same donated software high fees to interface with it. The commenters contended that these business practices result in electronic health records software that is not practically interoperable because non-donor providers and suppliers cannot afford to connect to it. Other commenters expressed general concerns that donated items or services are capable of interoperation, but that recipients implicitly agree to send referrals only to the donor. These commenters did not provide specific recommendations to modify the data lock-in conditions of the safe harbor, but generally supported our efforts to prevent data lock-in.

Two commenters representing laboratory companies expressed specific concerns about a feature of donated software that may lead to data lock-in. They explained that some software is designed to limit the accessibility of data that is received from an electronic health records system that is different than the donated software. Most often, data sent from the non-donated electronic health records system cannot populate automatically in a patient's electronic health record or other limits are placed on the portability of data sent from the non-donated electronic health records system. According to these commenters, the limited accessibility of the data makes it harder for the recipient to access and use it for clinical purposes. As a result, a physician or other recipient is more likely to use only the donor's services to make sure that necessary data is easily accessible. These commenters asserted that there are no technical solutions to reducing the possibility of data lock-in; rather, the only solution is to remove laboratory companies from the scope of protected donors.

Several other commenters endorsed generally our efforts to prevent referral and data lock-in. These commenters evidenced strong support of the free exchange of health information across different provider and supplier types to better coordinate care for patients. However, apart from supporting our efforts to ensure that electronic health records systems are interoperable, the commenters made no specific recommendations regarding modifications to the exception.

Response: We share the commenters' concerns about the interoperability of donated software. While any definitive conclusion regarding the existence of an anti-kickback violation requires a case-by-case determination of the parties' intent, we note that donations of items or services that have limited or restricted interoperability due to action taken by the donor or by any person on the donor's behalf (which could include the recipient acting on the donor's behalf) would fail to meet the condition at 42 CFR 1001.952(y)(3) and is inconsistent with the intent of the safe harbor to promote the use of technology that is able to communicate with products from other vendors. Resulting donations would be suspect under the law as they would appear to be motivated, at least in part, by a purpose of securing Federal health care program business. For example, arrangements in which a donor takes an action to limit the use, communication, or interoperability of donated items or services by entering into an agreement with a recipient to preclude or inhibit any competitor from interfacing with the donated items or services would not satisfy the requirement of 42 CFR 1001.952(y)(3). Other donation arrangements described by the commenters in which electronic health records technology vendors agree with donors to charge high interface fees to non-recipient providers or suppliers or to competitors may also fail to satisfy the conditions of 42 CFR 1001.952(y)(3). We believe that any action taken by a donor (or any person on behalf of the donor, including the electronic health record vendor or the recipient) to limit the use of the donated items or services by charging fees to deter non-recipient providers and suppliers and the donor's competitors from interfacing with the donated items or services would pose legitimate concerns that parties were improperly locking-in data and referrals and that the arrangement in question would not qualify for safe harbor protection.

However, whether a donation actually satisfies the conditions of the safe harbor depends on the specific facts of each donation arrangement. We encourage the reporting of instances of data lock-in, as we believe that investigation may establish that where such lock-in has occurred, existing conditions of the safe harbor have not been met. Moreover, any action taken to achieve such a result could be evidence of intent to violate the anti-kickback statute. In regard to the specific recommendation to remove laboratories from the scope of protected donors, we note that we are excluding laboratory companies from the scope of protected donors as discussed earlier in this final rule.

Data Lock-In: Recommendations Outside the Scope of the Rulemaking

Comment: One commenter expressed concern regarding data lock-in and supported ensuring that donations are transparent and free of any attempts to steer future business. Although the commenter denied knowledge of any specific abuse of the safe harbor, the commenter requested that we allow individuals or entities to remedy a donation that may not be protected by the safe harbor. The commenter suggested that the remedy for failure to

satisfy the conditions of the safe harbor as modified by this final rule should be to make recipients pay the fair market value of any costs for ongoing support of the donated items or services and provide 3 years for the recipient to either pay full value for the donation or make a transition to a new system.

Response: We appreciate the commenter's concern and recommendation; however we decline to make the suggested modification. Even if we were inclined to do so, implementing the commenter's suggestions would be outside the scope of this rulemaking.

Data Lock-in: Recommendations for Additions or Modifications to the Safe Harbor Conditions

Comment: A few commenters urged us to amend the safe harbor to require that the recipient or the donor participate in actual health information exchange with an electronic health records system that is different from the donated item. One commenter specifically suggested that the recipient should have to demonstrate exchange with at least one other electronic health record system within a certain time frame after receipt of the donation. Another commenter suggested that the donor should have to—upon request—enable the donation recipients to engage in bi-directional exchange of data with competitors not using the same electronic health record system.

Response: We appreciate the commenters' recommendations; however, we are not modifying the conditions of the safe harbor that require the parties to a donation arrangement to demonstrate interoperation. We question whether adequate demonstration of interoperation could occur only after the donation has been made, which would create uncertainty about whether the donation meets the conditions for protection under the safe harbor at the time of the donation. This uncertainty would undermine the Department's goal to support widespread adoption of interoperable electronic health record technology. It is our intent and expectation that interoperation will, in fact, occur, and we believe the safe harbor conditions, in their entirety, promote such interoperation. Moreover, routine interoperation with systems other than those of the donor may be evidence that neither the donor nor any person on the donor's behalf has taken any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems. *See* 42 CFR 1001.952(y)(3).

Further, we note that the Department is considering a number of policies to accelerate and advance interoperability and health information exchange. As part of this process, ONC and CMS requested input from the public on possible policies and programmatic changes to accelerate electronic health information exchange among individuals and entities that furnish health care items and services, as well as new ideas that would be both effective and feasible to implement. 78 FR 14793, 14794 (Mar. 7, 2013). We believe that the process initiated by ONC and CMS is better suited than this anti-kickback statute safe harbor to consider and respond to evolving functionality related to the interoperability of electronic health record technology.[3]

Comment: In response to our solicitation of comments, some commenters provided suggestions as to how we could broaden the current safe harbor conditions related to data lock-in. Two commenters suggested broadening 42 CFR 1001.952(y)(3), which imposes the condition that the donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems. Specifically, one of the commenters suggested that we replace the reference to "electronic prescribing or electronic health records systems" with "health information technology platforms or other health care providers." The commenters asserted that this proposed change reflects the development of health information technology that may not be classified as an electronic health record system, but supports the free exchange of health information. These two commenters also suggested that we modify the condition at 42 CFR 1001.952(y)(3) to state that neither the donor nor the recipient may take any action to limit the interoperability of donated items or services and require that the modified condition be included as part of the written agreement condition at 42 CFR 1001.952(y)(6).

Another commenter suggested amending 42 CFR 1001.952(y)(3) by providing a non-exhaustive list of actions that would cause a donation not to satisfy this condition and by establishing a process for entities to provide the Department with information about potential abuses of the safe harbor. A representative of several health plans suggested modifying the safe harbor conditions to ensure that, in the context of health information exchange, the interoperability condition requires that all key stakeholders, including health insurance plans, have access to the health information exchange. The commenter suggested that we modify the interoperability condition at 42 CFR 1001.952(y)(2) to prohibit restrictions on the communication and exchange of data with any "covered entity" as defined 45 CFR 160.103.

Response: The current language in the regulatory text prohibits donors (or persons on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of donated items or services with other "electronic prescribing or electronic health records systems." The term "electronic prescribing or electronic health records systems" was intended to be broad in order to account for developments in the health information technology industry. Based on the commenters' suggestions it appears, however, that some have read this term more narrowly. This narrow reading is inconsistent with our intended meaning. We have always believed and continue to believe that an action taken by a donor (or on behalf of the donor) that limits the use, compatibility, or interoperability of donated items or services with any other health information technology may impede the free exchange of data and limit the ability of providers and suppliers to coordinate care, which is inconsistent with one of the goals of the safe harbor. Therefore, we are clarifying 42 CFR 1001.952(y)(3) by adding a parenthetical that includes a non-exhaustive list of some of the forms of technologies we believe are included within the meaning of the current regulatory language. We are not adopting the commenters' suggested edit as we do not believe that it is necessary in light of the clarification we have made. We also decline to modify 42 CFR 1001.952(y)(2) to prohibit restrictions on the communication and exchange of data with any covered entity as defined at 45 CFR 160.103. We believe that the existing condition at 42 CFR 1001.952(y)(3), which we have clarified in this final rule as including health information technology applications, products, or services, promotes interoperability with a variety of providers and suppliers, as well as other health care entities that may play a role in the coordination of care, including health plans that operate health

[3] ONC and CMS have subsequently published a "Strategy and Principles to Accelerate HIE" document. *http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie.*

information technology applications, products, or services.

We are not adopting the commenters' suggestion to modify the safe harbor to state that neither the donor nor the recipient may take any actions to limit the interoperability of the donated item or service. The condition at 42 CFR 1001.952(y)(3) requires the donor (or any person on behalf of the donor) to refrain from taking any action that limits or restricts the use, compatibility, or interoperability of the donated items or services. To the extent that a recipient takes an action on the donor's behalf to limit the use, compatibility, or interoperability of donated items or services, that donation would fail to qualify for protection under the safe harbor. Because we see no obvious reason for a recipient to take action to limit the use, compatibility, or interoperability of donated items or services other than at a donor's behest or as a condition of the donation, we believe that any action of this type by a recipient would be suspect. We are not making the suggested modification because the concern articulated by the commenters is already addressed by the existing regulatory language and the policies we are adopting in this final rule. Because we are not adopting the commenters' suggestion, we are not making any corresponding revisions to require that the recommended provision be incorporated into the written agreement condition at 42 CFR 1001.952(y)(6).

We are not implementing the suggestion that we provide in regulation text examples of actions that may cause a donation not to meet the condition of 42 CFR 1001.952(y)(3). Whether a donation meets the precise conditions of the safe harbor requires a case-by-case analysis and depends on the specific facts of the donation. We encourage the reporting of instances when the donor (or any other person on behalf of the donor) takes action to limit the interoperability of donated items or services, as we believe that investigation may establish that, when such lock-in has occurred, existing conditions of the safe harbor not have been met. Moreover, any action taken to achieve such a result could be evidence of intent to violate the anti-kickback statute.

Data Lock-in: Other Comments and Suggestions

Comment: One commenter objected to the use of the safe harbor to address the issue of data lock-in. The commenter contended that data lock-in may arise in response to legitimate concerns, such as Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security rules, liability issues, licensing requirements, and anti-trust issues. Further, according to the commenter, data lock-in conditions may cause uncertainty for donors because parties may not be able to determine whether a donation met these conditions until after donation.

Response: Nothing in this final rule is intended to prohibit legitimate actions taken to ensure that donated items and services appropriately protect data, including measures to ensure the privacy and security of health information data. We recognize that there may be appropriate security, privacy, and other business reasons to protect data. This final rule addresses only actions that inappropriately lock in data, for example locking in data to secure future referrals.

Comment: One commenter expressed support for preventing electronic health records data lock-in and the free exchange of data. However, the commenter did not agree that additional conditions designed to promote these goals would be effective. Instead, the commenter suggested that CMS adopt payment models that continue to foster care coordination activities.

Response: We appreciate the commenter's suggestion; however, changes to CMS payment models are outside the scope of this OIG rulemaking. We note that ONC and CMS in their Request for Information solicited input on options for improving several different CMS payment models to support better the adoption of interoperable electronic health record technology. 78 FR 14793, 14797 (Mar. 7, 2013).

Comment: Two commenters suggested data lock-in could be limited by requiring electronic health record software to be open or "open source." Both commenters asserted that open source software would limit data lock-in due to the transparent nature of open source software. In addition, it would lead to greater interoperability of electronic health record systems. One commenter also suggested that we require mandatory advance disclosure of the operational and business policies and practices associated with the electronic health record technologies. One commenter suggested that we adopt the e-DOS standard as certification criteria for electronic health records.

Response: We generally share the commenters' support for free exchange of health information, provided that there are appropriate protections for privacy and security. However, we are not adopting the commenters' recommendations because software certification criteria and standards are determined by ONC and are, therefore, outside the scope of this rulemaking.

3. Covered Technology

In the 2013 Proposed Rule, we noted that "we received questions concerning whether certain items or services . . . fall within the scope of covered technology under the electronic health records safe harbor." 78 FR 21314, 21319 (Apr. 10, 2013). There, we stated that "[t]he answer to such questions depends on the exact items or services that are being donated." *Id.* We referenced the discussion of our interpretation of the term "software, information technology and training services necessary and used predominantly" in the 2006 Final Rule. *Id.* We stated that "[w]e believe that the current regulatory text, when read in light of the preamble discussion, is sufficiently clear concerning the scope of covered technology . . . ." *Id.* Nonetheless, because we have received suggestions from stakeholders to modify the regulatory text of the electronic health records safe harbor to reflect explicitly this interpretation, we sought comments from the public regarding this issue. After considering the public comments with respect to this issue, we determined not to make any changes to the regulation text to address the scope of covered technology.

Comment: Several commenters stated that the regulatory text describing the scope of technology covered by the safe harbor, when read in light of the 2006 Final Rule preamble, is sufficiently clear. One of these commenters urged us not to revise the regulation in any way that might limit the scope of covered technology, limit the ability of donors and recipients in the design and selection of items and services, or create barriers to achieving interoperability. Other commenters agreed that the current definition of covered technology is appropriate, with two of these commenters suggesting that we revisit the definition in the future as health information technology evolves. Still other commenters asserted that the existing regulatory language can be interpreted to include "services that enable the interoperable exchange of electronic health records data;" thus, no revisions to the regulatory text are required. In contrast, one commenter suggested that we incorporate into the regulatory text the preamble language from the 2006 Final Rule where we discussed examples of items and services that would qualify for coverage under the safe harbor. Another commenter suggested that we revise the regulatory text to include as many examples of covered "software,"

information technology and training services" as possible while emphasizing that the list is not exhaustive.

Response: We agree that maintaining flexibility is important, particularly as health information technology evolves. We endeavor to avoid revisions to the regulation text that could inadvertently narrow the safe harbor, which is intended to promote the adoption of interoperable electronic health record technology. Moreover, our interpretation of what is covered by the safe harbor has not changed. As we stated in the 2013 Proposed Rule, whether specific items or services fall within the scope of covered technology under the safe harbor depends on the exact items or services that are being donated. 78 FR 21314, 21319 (Apr. 10, 2013). If the "services that enable the interoperable exchange of electronic health records data" are of the type that do not meet the requirements for covered technology (for example, because they include hardware, storage devices, or have core functionality other than electronic health records), they would not be eligible for protection under the safe harbor at 42 CFR 1001.952(y).

For these reasons, we are not revising the regulation text at 42 CFR 1001.952(y) to identify any specific types of items or services that may be donated if the other conditions of the safe harbor are satisfied. We are also not modifying the examples identified in the preamble discussion in the 2006 Final Rule. 71 FR 45110, 45151–2 (Aug. 8, 2006). The safe harbor continues to protect nonmonetary remuneration in the form of software, information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

Comment: A few commenters requested clarification regarding whether third-party fees related to the exchange of health information, such as health information exchange (HIE) service charges for interconnectivity, are "covered technologies" under the safe harbor.

Response: The safe harbor protects only nonmonetary remuneration. Whether particular items or services, like interconnectivity services, can be donated under the safe harbor depends on the exact item or service that is being donated and whether the item or service is: (1) In the form of software, information technology and training services; and (2) necessary and used predominantly to create, maintain, transmit, or receive electronic health records. We caution, however, that the donation of items or services, including interconnectivity services that are eligible for donation, would not be protected if the recipient, the recipient's practice, or any affiliated individual or entity makes the receipt, amount or nature of the donated items or services a condition of doing business with the donor or if the donor determines the eligibility of a recipient or the amount or nature of the items or services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. *See* 42 CFR 1001.952(y)(4) and (5).

Comment: One commenter suggested that, in addition to maintaining as much flexibility as possible, we broaden the scope of the technology covered by the safe harbor to include software and services used for care coordination, quality measurement, improving population health, or improving the quality or efficiency of health care delivery among parties. The commenter noted that some of these items may be covered by the waivers issued in connection with the Medicare Shared Savings Program (MSSP); however, because those waivers extend only to parties participating in that program, protection for the donation of items or services that advance the Department's goal of encouraging the adoption of health information technology that supports public policy objectives is not available to other health care industry stakeholders. To advance these goals in a broader way, the commenter suggested that the safe harbor be expanded to include items potentially covered by the MSSP pre-participation waiver, such as electronic health information exchanges that allow for electronic data exchange across multiple platforms, data reporting systems (including all-payer claims data reporting systems), and data analytics (including staff and systems, such as software tools, to perform analytic functions). Another commenter suggested that we broaden the scope of technology covered by the safe harbor to include software separate from the certified electronic health record software as long as it is interoperable with the electronic health record software. The commenter gave as examples of such electronic health-records-associated components "patient portals that support patient engagement, direct and other standards-compliant means for secure patient information exchange between providers, solutions to support transition care, and tools that may assist in inter- and intra-patient matching." A third commenter urged us to consider a broader array of covered technologies, provided that they support policy goals such as reducing hospital readmissions and coordinated care across settings outside of traditional office settings, including telemonitoring and telemedicine. Another commenter suggested that we expand the protection of the safe harbor to cover "any additional items or services that will be required or helpful in meeting Stage 2 or Stage 3 requirements for [the EHR Incentive Programs]."

Response: As stated previously, whether specific items or services fall within the scope of covered technology under the safe harbor depends on the exact items or services that are being donated. Some of the particular items and services that may be included within the broad categories identified by the commenters may be eligible for donation. For example, if a particular software product related to transitions of care was necessary and used predominantly to create, maintain, transmit, or receive electronic health records, then it would be eligible for donation, provided that the donation met all of the other safe harbor conditions. As noted previously in this final rule, software is not required to be certified to ONC certification criteria in order to be donated under the electronic health records safe harbor. Thus, software that is separate from certified software may still be eligible for donation if it satisfies the definition of "interoperable" in the Note to paragraph (y) in 42 CFR 1001.952(y). To the extent that the commenters suggest that we expand the scope of the safe harbor to protect items or services that are not already eligible for donation, we note that revision of the safe harbor to include such items or services would be outside the scope of this rulemaking. In the 2013 Proposed Rule, with respect to the scope of technology potentially covered by the safe harbor, we sought input from the public regarding the singular issue of "whether the current regulatory text, when read in light of the preamble discussion, is sufficiently clear concerning the scope of covered technology." 78 FR 21314, 21319 (Apr. 10, 2013). With regard to whether the scope of the covered technology should be broadened, as opposed to clarified, we are mindful of the important issues raised by the commenters and may consider them in the future. We further note that, depending on the circumstances, some of the arrangements described by the commenters may fit in other safe harbors or may not implicate the anti-kickback statute.

Comment: One commenter suggested that we define "equivalent technology" for purposes of the condition in the safe

harbor that the donor of electronic health record technology may not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those being donated. This commenter also suggested that we prohibit a provider or supplier from seeking or accepting a donation before a certain period of time has elapsed since the receipt of a previous donation. Another commenter urged us to eliminate maintenance and service agreements from the scope of potentially protected donations under the safe harbor. In the alternative, the commenter suggested that we impose a restriction on the time period that donations of such services would be permitted. The commenter noted concerns that donors may use ongoing donations of maintenance and service agreements to lock in referrals from recipients. A commenter that urged us not to extend the availability of the safe harbor suggested that we prohibit the donation of all technology except interfaces for reporting of laboratory results.

Response: Although we appreciate the commenters' suggestions, we are not making the requested changes. We believe that the modifications to and clarifications of 42 CFR 1001.952(y) adopted in this final rule and the clarifications offered in this preamble address the concerns raised by these commenters.

Comment: One commenter asserted that the prohibition on donating equivalent technology currently included in the safe harbor locks physician practices into a vendor, even if they are dissatisfied with the technology, because the recipient must choose between paying the full amount for a new system and continuing to pay 15 percent of the cost of the substandard system. The commenter asserts that the cost difference between these two options is too high and effectively locks physician practices into electronic health record technology vendors.

Response: Although we appreciate the commenter's concern, we continue to believe that items and services are not "necessary" if the recipient already possesses the equivalent items or services. 71 FR 45110, 45123 (Aug. 8, 2006). As stated in the 2006 Final Rule, "the provision of equivalent items and services poses a heightened risk of abuse, [because] such arrangements potentially confer independent value on the recipient (*i.e.*, the value of the existing items and services that might be put to other uses) unrelated to the need for electronic health records technology." *Id.* Thus, we retain our policy to preclude safe harbor protection in instances when the donor has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained equivalent items or services. We expect physicians would not select or continue to use a substandard system if it posed a threat to patient safety.

Comment: One commenter referenced the 2013 Proposed Rule's statement that "software or information technology and training services necessary and used predominantly for electronic health records purposes" included "information services related to patient care (but not separate research or marketing support services." 78 FR 21314, 21319 (Apr. 10, 2013). The commenter requested that we retract that statement and clarify that it is appropriate for health researchers to use data in electronic health records for research that is related to, for example, evidence-based medicine, population management, or other research, provided that the use complies with applicable Federal, State, and institutional requirements.

Response: We decline to retract our statement in the 2013 Proposed Rule. To promote adoption of electronic health records while minimizing the risk of abuse, the scope of items and services permitted to be donated under the safe harbor is limited to items and services in the form of software and information technology and training services that are "necessary and used predominantly to create, maintain, transmit, or receive electronic health records." Donations of software for research that is separate from clinical support and information services related to patient care are not consistent with the primary goals of the safe harbor.

The electronic health records safe harbor addresses only the donation of electronic health records items and services, not the use of data. Thus, the portion of the comment related to data use is outside the scope of this rulemaking. We note, however, that nothing in the safe harbor prohibits the use of data in electronic health record systems for research purposes (assuming the parties comply with all other applicable laws, including HIPAA privacy and security rules).

Comment: One commenter asked us to confirm that patient portals are within the scope of the technology potentially protected by the safe harbor.

Response: We are not certain what the commenter precisely means by "patient portals." Patient portals come in a variety of forms; the key to the safe harbor analysis is whether the specific item or service donated is: (1) In the form of software, information technology and training services; and (2) necessary and used predominantly to create, maintain, transmit, or receive electronic health records. As we stated in the 2006 Final Rule in response to a commenter's recommendation that the safe harbor specifically protect the provision of patient portal software that enables patients to maintain online personal medical records, including scheduling functions (71 FR 45110, 45125 (Aug. 8, 2006)), nothing in the safe harbor precludes protection for patient portal software if it satisfies all of the safe harbor conditions.

E. Comments Outside the Scope of Rulemaking

In addition to some of the comments noted above, we received several comments from stakeholders, including suggestions on policy changes, that are outside the scope of this rulemaking. For example, one commenter raised concerns about a private insurer's proposed fee schedule for laboratory services. Another commenter expressed a concern about "outrageous bills" the commenter received from a laboratory company. While we appreciate the commenters taking time to raise these concerns, we will not be addressing them as they are outside the scope of this rulemaking.

III. Provisions of the Final Regulations

For the most part, this final rule incorporates the proposed revisions from the 2013 Proposed Rule. Specifically, we update the provision under which electronic health records software is deemed interoperable by revising 42 CFR 1001.952(y)(2) to remove the phrase "recognized by the Secretary" and replace it with the phrase "authorized by the National Coordinator for Health Information Technology" and to replace the 12-month time frame for certification of electronic health records software with a requirement that the software be certified to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170 (ONC's certification program). Second, we remove from the safe harbor the requirement at 42 CFR 1001.952(y)(10) related to electronic prescribing capability. Third, we extend the sunset date of the safe harbor to December 31, 2021 by modifying 42 CFR 1001.952(y)(13). Fourth, we limit the scope of protected donors to exclude laboratory companies. We are modifying 42 CFR 1001.952(y)(1)(i) to effectuate this change. And fifth, we are clarifying the condition at 42 CFR 1001.952(y)(3)

that prohibits a donor from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services.

IV. Waiver of the Delay in the Effective Date

Ordinarily we provide a delay of at least 30 days in the effective date of a final rule after the date that the rule is issued. However, the 30-day delay in effective date can be waived if the rule grants or recognizes an exemption or relieves a restriction. We believe that it is appropriate to waive the 30-day delay in effective date for 42 CFR 1001.952(y)(13), which relieves a restriction on donations of electronic health records items and services. Specifically, this final rule amends 42 CFR 1001.952(y)(13) to extend the sunset date of the existing safe harbor from December 31, 2013 to December 31, 2021. Without a waiver of the requirement for a delayed effective date, the entire safe harbor will expire on December 31, 2013 and will not be available to protect any ongoing donation arrangements or new donations of electronic health records items and services made after December 31, 2013. By waiving the 30-day delay in effective date, the safe harbor will not expire, thereby allowing parties to continue utilizing the safe harbor to protect donations of electronic health records items and services. We stress, however, that donations of electronic health records items and services that occur between January 1, 2014 and the effective date of the remaining provisions of this final rule (March 27, 2014) will need to comply with all the conditions of the existing safe harbor. The waiver of the 30-day delay in effective date simply serves to maintain the status quo until the rest of this final rule becomes effective.

The 30-day delay in effective date can also be waived if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and reasons in the rule issued. We find that it is unnecessary to provide a 30-day delay in effective date for 42 CFR 1001.952(y)(13) because an earlier effective date simply allows parties to continue making donations under the existing electronic health records safe harbor; it does not impose any new requirements or restrictions on potentially affected parties. Moreover, we find that a 30-day delayed effective date for 42 CFR 1001.952(y)(13) is impracticable because it would cause the entire safe harbor to expire, thereby nullifying this final rule.

V. Regulatory Impact Statement

We have examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (Sept. 30, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review (Jan. 18, 2011); the Regulatory Flexibility Act (RFA) (Sept. 19, 1980, Pub. L. 96–354, codified at 5 U.S.C. 601 et seq.); section 1102(b) of the Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Mar. 22, 1995; Pub. L. 104–4); Executive Order 13132 on Federalism (August 4, 1999); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We believe this final rule does not reach the economic threshold for being considered economically significant and thus is not considered a major rule. It is not economically significant because it will not have a significant effect on program expenditures, and there are no additional substantive costs to implement the resulting provisions. The rule modifies an existing safe harbor, and the modifications would not impose significant additional costs on those seeking to use the safe harbor. Further, the donation of electronic health records items or services and the use of the safe harbor to protect such donations are entirely voluntary. In section II, we provide a detailed discussion and analysis of the alternatives considered in this final rule, including those considered for extending the sunset date of the electronic health records safe harbor, limiting the scope of protected donors, and tying the timeframe for the deeming provision to ONC's certification program. Finally, we received no public comments specific to the RIA set forth in the 2013 Proposed Rule.

This final rule updates (1) the provision under which electronic health records software is deemed interoperable; (2) removes the requirement related to electronic prescribing capability; (3) extends the safe harbor's sunset date to December 31, 2021; (4) limits the scope of protected donors to exclude laboratory companies; and (5) clarifies the condition that prohibits a donor from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services. Neither this final rule nor the regulations it amends requires any entity to donate electronic health records items and services, but we expect these changes to continue to facilitate the adoption of electronic health record technology by eliminating perceived barriers rather than by creating the primary means by which this technology will be adopted.

The summation of the economic impact analysis regarding the effects of electronic health records in the ambulatory setting that is presented in the 2006 Final Rule still pertains to this final rule. 71 FR 45110 (Aug. 8, 2006). However, since the 2006 Final Rule, several developments have occurred to make us conclude that it is no longer necessary to retain a requirement related to electronic prescribing capability in the electronic health records safe harbor. These developments include the passage of two laws encouraging adoption of electronic prescribing and electronic health-records technology: (1) In 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Public Law 110–275; (2) in 2009, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111–5. In addition, there has been an increase over the past few years in the rate of electronic health record-based electronic prescribing capabilities. *See, e.g.,* State Variation in E-Prescribing Trends in the United States—available at: *http://www.healthit.gov/sites/default/files/us_e-prescribingtrends_onc_brief_4_nov2012.pdf.*

As discussed in more detail in the preamble to the 2013 Proposed Rule, section 132 of MIPPA authorized an electronic prescribing incentive program (starting in 2009) for certain types of eligible professionals. The HITECH Act authorized CMS to establish the EHR Incentive Programs for certain eligible professionals, eligible hospitals, and critical access hospitals. Also, the HITECH Act required that eligible professionals under the EHR Incentive Programs demonstrate meaningful use of certified electronic health record technology, including the use of electronic prescribing. Specifically, the final rule for Stage 2 EHR Incentive Programs (77 FR 53968 (Sept. 4, 2012)) includes more demanding requirements for electronic prescribing and identifies

electronic prescribing as a required core measure. As a result, beginning in calendar year 2015, an eligible professional risks a reduction in the Medicare Physician Fee Schedule payment amount that will otherwise apply for covered professional services if they are not a meaningful electronic health record technology user for a reporting period during that year. Our intent is to withhold safe harbor protection from the donation of items or services that a potential recipient already owns, while protecting donation of items and services that advance the adoption and use of electronic health records. Lastly, according to ONC, electronic prescribing by physicians using electronic health record technology has increased from 7 percent in December 2008 to approximately 48 percent in June 2012. Furthermore, the rules recently published to implement Stage 2 of the EHR Incentive Programs continue to encourage physicians' use of electronic prescribing technology. *See* 77 FR 53968, 53989 (Sept. 4, 2012); 77 FR 54163, 54198 (Sept. 4, 2012). However, due to data limitations, we are unable to accurately estimate how much the electronic health records safe harbor has contributed to the increase in electronic prescribing. We believe, as a result of these legislative and regulatory developments advancing in parallel, the increase in the adoption of electronic prescribing using electronic health record technology will continue without making it necessary to retain the electronic prescribing capability requirement in the electronic health records safe harbor.

The RFA generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, certain non-profit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues below specific limits that range from $7.0 million to $35.5 million (depending on the type of entity in question) in any 1 year. Individuals and States are not included in the definition of a small entity. The Secretary has determined that this final rule would not have a significant economic impact on a substantial number of small entities. Therefore, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The Secretary has determined that this final rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (codified at 2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under UMRA, agencies must assess a rule's anticipated costs and benefits before issuing any rule that may result in aggregate costs to State, local, or tribal governments, or the private sector, of greater than $100 million in 1995 dollars (currently adjusted to $141 million). This final rule imposes no mandates and, as a result, will have no consequential effect on State, local, or tribal government or on the private sector of $141 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. For the reasons stated earlier, this final rule will not have a substantial effect on State or local governments, nor does it preempt State law or have Federalism implications.

In accordance with Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

VI. Paperwork Reduction Act

The provisions in this final rule will not impose any new or revised information collection, recordkeeping, or disclosure requirements. Consequently, this rule does not need additional Office of Management and Budget review under the authority of the Paperwork Reduction Act of 1995.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

Accordingly, 42 CFR part 1001 is amended as set forth below:

PART 1001—[AMENDED]

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395w–104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

■ 2. Section 1001.952 is amended by revising paragraphs (y)(1)(i), (y)(2), (y)(3), and (y)(13), and removing and reserving paragraph (y)(10), to read as follows:

§ 1001.952 Exceptions.

* * * * *

(y) * * *

(1) * * *

(i) An individual or entity, other than a laboratory company, that provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment, to the Federal health care program; or

* * * * *

(2) The software is interoperable at the time it is provided to the recipient. For purposes of this subparagraph, software is deemed to be interoperable if, on the date it is provided to the recipient, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services).

* * * * *

(10) [Reserved]

* * * * *

(13) The transfer of the items and services occurs, and all conditions in this paragraph (y) have been satisfied, on or before December 31, 2021.

* * * * *

Dated: September 10, 2013.

Daniel R. Levinson,

Inspector General.

Approved: November 14, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–30924 Filed 12–23–13; 4:15 pm]

BILLING CODE 4152–01–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 249 December 27, 2013

Part IV

Department of Education

34 CFR Part 200
Title I—Improving the Academic Achievement of the Disadvantaged; Migrant Education Program; Proposed Rule

DEPARTMENT OF EDUCATION

34 CFR Part 200

RIN 1810–AA99

[Docket ID ED–2013–OESE–0119]

Title I—Improving the Academic Achievement of the Disadvantaged; Migrant Education Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes regulations to implement the Migrant Student Information Exchange (MSIX), a nationwide, electronic records exchange mechanism mandated under title I, part C, of the Elementary and Secondary Education Act of 1965, as amended (ESEA). As a condition of receiving a grant of funds under the Migrant Education Program (MEP), each State educational agency (SEA) would be required to collect, maintain, and submit minimum health and educational information to MSIX within established time frames. The proposed regulations would facilitate timely school enrollment, placement, and accrual of secondary course credits for migratory children and help the Department determine accurate migratory child counts and meet other MEP reporting requirements.

DATES: We must receive your comments on or before February 25, 2014.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under "Are you new to the site?"
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed regulations, address them to Lisa C. Gillette, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E313, Washington, DC 20202–6135.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov*. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Lisa C. Gillette, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E313, Washington, DC 20202–6135. Telephone: (202) 260–1426 or by email: *lisa.gillette@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding these proposed regulations. To ensure that your comments have maximum effect in developing the final regulations, we urge you to identify clearly the specific section or sections of the proposed regulations that each of your comments addresses and to arrange your comments in the same order as the proposed regulations. We specifically request public comment on issues raised in our discussion of records of secondary school-aged migratory children in proposed section 200.85(b)(3)(i)(B) and procedures for MSIX data correction in proposed section 200.85(e).

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from these proposed regulations. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the Department's programs and activities.

During and after the comment period, you may inspect all public comments about these proposed regulations by accessing Regulations.gov. You may also inspect the comments in person in Room 3E315, 400 Maryland Avenue SW., Washington, DC, between 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed regulations. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Background

The educational needs of children of migratory agricultural workers and migratory fishers present unique challenges for educators and our Nation's schools. Migratory workers travel from community to community in search of temporary and seasonal work. Given the nature of their employment, migratory workers and their families often settle in a single community for a short period of time. One consequence of this lifestyle and mobility is that the children of migratory workers frequently enroll in new schools and school districts without adequate, and in many cases any, documentation of their educational and health history.

In section 1308(b)(2) of the ESEA, Congress directed the Secretary, in consultation with the States, to "ensure the linkage of migrant student record systems for the purpose of electronically exchanging, among the States, health and educational information regarding all migratory students." The statute specifies that the linkage of migrant student records shall occur in a cost-effective manner, utilizing those systems that States used before or developed after enactment of the latest reauthorization of the ESEA in the No Child Left Behind Act in January 2002. Congress further directed the Secretary, in section 1308(b)(2) of the ESEA, to seek public comment on (1) the "minimum data elements" (MDEs) that each State receiving MEP funds would be required to collect for purposes of the electronic transfer of migratory student information, and (2) the requirements that States must meet for immediate electronic access to this information.

In addition to these specific directives, section 1304(b)(3) of the ESEA requires each State that applies for a grant of MEP funds to include in its application a description of how it will use MEP funds to promote interstate and intrastate coordination of services for migratory children. The description must include how the State will provide for educational continuity through the timely transfer of pertinent school records when children move from one school to another either during or outside of the regular school year. All States that receive MEP funds do so on the basis of consolidated State applications authorized in section 9302 of the ESEA. However, the Department requires all SEAs to implement the statutory provisions governing program design and operation that otherwise

would be required of their individual program applications. See 67 FR 35967, 35970–71 (May 22, 2002).

In early 2000, the Department began consulting extensively with migrant education stakeholders to identify what information is essential to the continuity of services for migratory children. These consultations included State officials, migrant program administrators and educators, guidance counselors, registrars, and other school district officials, migrant health officials, and other users of student data.

On May 28, 2002, the Department published for public comment in the **Federal Register** (67 FR 36862–69) a notice of proposed requirements and minimum data elements for the electronic transfer of this information. Since then, we have spent considerable time and attention consulting with migrant education stakeholders and addressing their suggestions and concerns about the proposed MDEs and how MSIX would operate. (Summaries of the Department's consultative activities are contained in question and answer number 8 of the supporting statements for the 2007 and 2011 MDE Paperwork Reduction Act submissions.)

The Department has learned through this extensive consultative process that the lack of health and educational information for migratory children may cause delays in student enrollment, lead to inappropriate classroom and course placements, complicate or hinder the accrual of course credits needed for high school graduation, and result in duplicate services, such as multiple assessments and immunizations. As such, we determined that the primary purpose of MSIX should be to provide migrant education and other school personnel with the data essential to facilitate—

(1) The timely enrollment of all school-aged migrant children;

(2) The placement of migratory students in the appropriate grade level and courses of instruction; and

(3) For secondary students, the accrual of course credits needed to graduate from high school.

Further background on the Department's early consultation with migrant education stakeholders may be found in the Office of Migrant Education's full report to Congress in 2003, *Education of Migratory Children: Maintenance and Transfer of Health and Educational Information for Migrant Students by the States*, which is available at *www2.ed.gov/admins/lead/account/reporttocongress.pdf*.

School staff at all levels need basic enrollment data, and typically need proof of immunizations, to place students in the correct grade or course in a timely manner. Migrant educators have stressed, however, that students in secondary grades have the greatest need for the timely exchange of records because they have much less time to make up for mistakes made when school officials lack information needed for proper grade placement, course selection, and accrual of course credits required for high school graduation. As such, educators suggested that the migrant record-linking mechanism have a "special focus" on exchanging information needed for full and partial credit accrual for mobile secondary students.

We also learned through consultations that gaining access to student records in a timely manner generally is more of a concern for students who make interstate, rather than intrastate, moves. This is because the new school district in another State is much less likely than a new school district in the same State to have ready access to information in the former district's records, and thus the new district in another State is far less able to avoid critical delays in the transfer of necessary information. In many cases, however, the same problem exists when students make an intrastate move because district officials do not always have ready access to student-level data from another district within the State. In both cases, the problem is exacerbated for students who move during the summer, when many migrant education programs are conducted, because many of the schools that those students last attended, and from which student records would need to be gathered and transmitted, are closed.

Through our continued consultations with migrant education stakeholders, we have also identified MDEs that would facilitate enrollment, grade and course placement, and accrual of secondary school course credits for migratory students. We published a notice of proposed information collection requests relating to the MDEs in the **Federal Register** on May 30, 2007 (72 FR 29994), and the Office of Management and Budget (OMB) approved the collection of 66 MDEs on November 27, 2007, under OMB Approval Number 1810–0683.

On August 20, 2010, we published in the **Federal Register** (75 FR 51449) a second notice of proposed information collection requests to add five new data elements to the set of MDEs collected and exchanged through MSIX. On January 30, 2011, OMB approved the revision and extended the expiration date of this information collection to January 31, 2014. After additional public comments, on March 30, 2011, OMB approved minor, non-substantive modifications to the collection, which now contains 71 MDEs. As discussed elsewhere in the Paperwork Reduction Act section of this notice, we are publishing a third notice of proposed information collection requests for MSIX with these proposed regulations.

MSIX is a system in which SEAs upload the required MDEs from their own State student record systems into a single data repository where information on each migrant student is maintained, organized, and compiled. MSIX uses a Web-based application that allows stakeholders with the appropriate security clearance to access the system via a Web browser. Using the required MDEs, MSIX generates a "Consolidated Migrant Student Record." It is used to promote proper enrollment, grade and course placement, and accrual of secondary school course credits for any identified migratory child by SEAs, their local operating agencies—that is, local educational agencies (LEAs) and other public or nonprofit private agencies that receive a subgrant of MEP funds—and those LEAs, sometimes known as "non-project LEAs," that do not receive subgrants of MEP funds.

The Department started collecting data from participating SEAs on September 28, 2007, and MSIX is now fully operational. At present, State use of MSIX is voluntary. As of April 2013, 46 of the 47 States participating in the MEP, as well as the contractor that operates the program through a bypass arrangement under section 1307 of the ESEA for eligible migratory children in the three States that do not participate in the MEP, have voluntarily executed both the MSIX Interconnection Agreement and MSIX Interconnection Security Agreement, which is a precondition for using MSIX under the Computer Security Act of 1987 (Pub. L. 100–235), the Information Technology Management Reform Act of 1996 (Pub. L. 104–106), OMB Circular A–130 Appendix III, and National Institute of Standards and Technology Special Publication 800–47. These States are now using MSIX to electronically transfer and receive migrant student data that apply to 99 percent of the Nation's migrant children found eligible for the MEP.

Under these proposed regulations, and consistent with sections 1304(b)(3) and 1308(b)(2) of the ESEA, as a condition of receiving a grant of MEP funds, an SEA would be required to collect, maintain, and submit to MSIX the MDEs approved by the Secretary within the timeframes established in final regulations. In addition, each SEA

receiving MEP funds would be required to obtain the MDEs both from their MEP local operating agencies and from their non-project LEAs.

We note finally that, in addition to its role in exchanging information among States and creating Consolidated Migrant Student Records for enrollment, placement, and credit accrual purposes, MSIX may also be used to produce national data on the migrant population. For further information, see the description of MSIX objectives at *www2.ed.gov/admins/lead/account/recordstransfer.html*. In particular, the Department plans to use MSIX to provide stakeholders with census data and statistics on the national migrant population and to generate accurate child counts under section 1303(e)(1) of the ESEA. After all phases of MSIX data submission have been completed, we also plan to use statistical data from MSIX to help meet reporting requirements related to the national migrant child population.

Summary of Proposed Changes

These proposed regulations would help ensure that health and educational records of migratory children are available promptly for school enrollment, grade and course placement, and credit accrual purposes, and for producing national statistical data on the migrant population, by requiring each SEA that receives a grant of MEP funds to—

- Collect, maintain, and submit current and updated MDEs for eligible migratory children to MSIX within established timeframes;
- Ensure that all data submitted to MSIX are accurate and complete and that appropriate safeguards are in place to protect the integrity, security, and confidentiality of Consolidated Migrant Student Records in MSIX;
- Establish procedures for using, and requiring each of its subgrantees to use, Consolidated Migrant Student Records in MSIX; and
- Establish procedures for MSIX data correction by parents, guardians, and migratory children.

Significant Proposed Regulations

We discuss substantive issues under the sections of the proposed regulations to which they pertain. Generally, we do not address proposed regulatory changes that are technical or otherwise minor in effect.

Section 200.81 Program definitions

Statute: The statute does not define "Consolidated Migrant Student Record," "Migrant Student Information Exchange (MSIX)," "Minimum Data Elements (MDEs)," "MSIX Interconnection Agreement," or "MSIX Interconnection Security Agreement."

Current Regulations: The current regulations do not define "Consolidated Migrant Student Record," "Migrant Student Information Exchange (MSIX)," "Minimum Data Elements (MDEs)," "MSIX Interconnection Agreement," or "MSIX Interconnection Security Agreement."

Proposed Regulations: The proposed regulations would define "Consolidated Migrant Student Record" as the MDEs for a migratory child that have been submitted by one or more SEAs and consolidated into a single, uniquely identified record available through MSIX. The proposed regulations would define "Migrant Student Information Exchange (MSIX)" as the nationwide system for linking and exchanging specified health and educational information for all migratory children in accordance with section 1308(b)(2) of the ESEA. The proposed regulations would define "Minimum Data Elements (MDEs)" to mean the health and educational information for migratory children that the Secretary requires each SEA that receives an MEP grant to collect, maintain, submit to MSIX, and use. The proposed regulations would define "MSIX Interconnection Agreement" to mean the agreement between the Department and an SEA that governs the interconnection between the State student records system and MSIX. The proposed regulations would define "MSIX Interconnection Security Agreement" to mean the agreement between the Department and an SEA that specifies the technical and security requirements for establishing, maintaining, and operating the interconnection between the State student records system and MSIX.

Reasons: These definitions are needed to clarify the meanings of basic terms used in these proposed regulations for implementing the nationwide system for the linkage and exchange of migrant student records established under section 1308(b)(2) of the ESEA.

Section 200.84 Responsibilities for Evaluating the Effectiveness of the MEP and Using Evaluations To Improve Services to Migratory Children

Statute: Section 1304 of the ESEA requires each grantee to evaluate the effectiveness of MEP projects using measurable program goals and outcomes.

Current Regulations: Current § 200.84 specifies the responsibilities of SEAs for evaluating the effectiveness of the MEP. Current § 200.85 identifies the responsibilities of SEAs and local operating agencies for improving services to migratory children.

Proposed Regulations: The proposed regulations would revise the heading for § 200.84 as set forth above and make technical changes to this proposed section. We would designate the current text of § 200.84 (concerning the responsibilities of SEAs for evaluating the effectiveness of the MEP) as § 200.84(a) and redesignate the current text of § 200.85 (concerning the responsibilities of SEAs and local operating agencies for improving services to migratory children) as new § 200.84(b). We would not make any substantive changes to the text of current § 200.84 and § 200.85; we would make technical changes to the text of current § 200.85 by deleting the introductory phrase and clarifying in proposed § 200.84(b) that the evaluation under paragraph (a) is carried out by the SEA. The redesignation of current §§ 200.84 and 200.85 is needed to create space for the proposed MSIX regulations in 34 CFR part 200, subpart C.

Section 200.85 Responsibilities of SEAs for the Electronic Exchange Through MSIX of Specified Health and Educational Information of Migratory Children

Statute: Section 1308(b)(2) of the ESEA requires the Secretary, in consultation with the States, to ensure the linkage of migrant student records systems for the purpose of States exchanging health and educational information about all migratory students and to determine the MDEs that each State receiving MEP funds shall collect and maintain for this purpose.

Current Regulations: Current § 200.85 clarifies the statutory responsibilities of an SEA receiving MEP funds to use evaluation results to improve services provided to migratory children.

Proposed Regulations: As described in our discussion of proposed § 200.84, we would move the text of current § 200.85 ("Responsibilities of SEAs and operating agencies for improving services to migratory children") to new § 200.84(b). We would replace current § 200.85 with a new § 200.85, "Responsibilities of SEAs for the electronic exchange through MSIX of specified health and educational information of migratory children," and the new regulations would address the following:

MSIX State record system and data exchange requirements. Proposed § 200.85(a) provides that as a condition of receiving a grant of MEP funds, an SEA would be required to collect, maintain, and submit to MSIX the

MDEs, and otherwise exchange and use information on, migratory children in accordance with all of the data submission and other requirements in proposed § 200.85. Failure of an SEA to do so would constitute a failure under section 454 of the General Education Provisions Act, 20 U.S.C. 1234c, to comply substantially with a requirement of law applicable to the funds made available under the MEP.

Reasons: We recognize that at this time the various State student-information systems do not uniformly contain all the information that the Department has determined is needed to support the purposes and goals of MSIX. Likewise, although MSIX has been operational since 2007 and nearly all States currently participate, SEAs still do not uniformly submit and use MSIX data in a manner that would most benefit migratory children. Proposed § 200.85(a) would ensure that SEAs participate fully in MSIX so that it can fulfill its principal statutory purpose—to enable school personnel throughout the Nation to quickly access data needed to make proper educational decisions about any migratory child who enrolls in school. It would also clarify that the Secretary may take appropriate enforcement action if an SEA fails to comply with any of these proposed requirements.

We note that under the proposed regulations, a State would not be required to maintain a separate migrant student records system and could use any statewide or local system that contains the necessary information on migratory children. While the proposed regulations would require an SEA to collect, maintain, and submit to MSIX the MDEs required by the Secretary and use Consolidated Migrant Student Records, they would not otherwise require any change in an SEA's approach to student data systems.

MSIX data submission requirements. Proposed § 200.85(b) sets forth requirements for the content and timing of an SEA's start-up and subsequent data submissions to MSIX.

General. Under proposed § 200.85(b)(1), an SEA that receives a grant of MEP funds would be required to submit to MSIX, within the timelines for start-up and subsequent data submissions contained in proposed § 200.85(b)(2) and (b)(3), the MDEs applicable to a migratory child's age and grade level that the Secretary has determined are needed to implement MSIX. We note that these proposed data submission requirements would apply to any migratory child whom the SEA considered eligible for MEP services in accordance with § 200.89(c). This would include not only pre-school and K–12 migratory children enrolled in public schools, but also those who are home-schooled or enrolled in non-public schools because, as they migrate, these home-schooled or non-public school children may move into and out of public schools, where their private school or home-school records would be needed for enrollment and placement purposes. The proposed data submission requirements would apply also to secondary school-aged children who are not enrolled in school at all, known as out-of-school youth or "OSY," whom the SEA had determined to be eligible for MEP services. Applying these proposed requirements to all of these migratory children will ensure that demographic, educational, health, and other information will be available promptly upon initial or subsequent school enrollments.

Reasons: Proposed § 200.85(b)(1) would establish a requirement that SEAs must submit electronically to MSIX those MDEs that the Secretary designates. For the convenience of the reader, we have appended to this notice a list of the 71 MDEs currently collected by the Secretary under OMB Control Nos. 1875–0240, 1810–0662, and 1810–0683, as well as one new MDE identified in the Paperwork Reduction Act section of this notice. As discussed in the Background and Paperwork Reduction Act sections of this notice, we have consulted extensively with MEP stakeholders and believe that these MDEs reflect the minimal information needed to ensure the proper enrollment, grade and course placement, and accrual of secondary course credits (including credit for any courses taken for college credit) for migratory children. The Secretary would continue to consult with MEP stakeholders in connection with any future changes to the MDEs collected for submission to MSIX.

While the majority of MDEs, such as name, date of birth, qualifying arrival date, etc., apply to all migratory children, some of the required MDEs apply only after a child reaches a certain age or grade level. For example, depending on their grade level, primary and middle school children may not have certain assessments, nor will the course title and type of information that is required for secondary school students apply to them. Because State policies vary regarding the ages and grade levels at which these requirements come into play, we are not proposing to regulate precisely which MDEs an SEA must submit to MSIX for a migratory child. Rather, under the proposed regulations, SEAs would need to determine which MDEs are applicable to the child's age and grade level in accordance with State policy and submit those MDEs to MSIX as required under this section. The Department would issue non-regulatory guidance on this issue as needed.

Start-up data submissions. Under proposed § 200.85(b)(2), no later than 90 calendar days after the effective date of the final regulations, an SEA would be required to collect and submit to MSIX each of the MDEs required by the Secretary, as described in paragraph (b)(1) of this section, applicable to the child's age and grade level. An SEA would do so for every migratory child whom the SEA considered eligible for the MEP under § 200.89(c) within one year preceding the effective date of the final regulations. An SEA would have to collect and submit MDEs for a migratory child whether or not the child has a current Certificate of Eligibility under § 200.89(c) at the time the SEA makes its start-up data submission.

Reasons: Proposed § 200.85(b)(2) would ensure that by a specified date MSIX is fully populated with MDEs for migratory children whom SEAs have already determined are eligible for the MEP. The section would specify the group of migratory children covered under an SEA's start-up data submission as well as the content and timeframe of those submissions. We believe that 90 days is a reasonable period of time for SEAs to locate and submit the required MDEs to MSIX given that the proposed requirement applies only to those children considered eligible for the MEP within the preceding year, and that many SEAs would have already submitted some or all of the required MDEs by the time the final regulations would take effect. With regard to the administrative effort required for this proposed requirement, we note that the SEA would not have to ascertain whether the child is still resident in the State or otherwise eligible for the program at the time of this data submission.

As noted in the Background section of this notice, MSIX has been operational since 2007 and, accordingly, many SEAs have already submitted most of the MDEs approved under the Department's information collection (OMB Approval Number 1810–0683) for their States' migratory children. For purposes of the start-up data submissions required under these proposed regulations, SEAs would not be required to resubmit to MSIX any MDEs they have already submitted. However, a small number of SEAs have not yet submitted any data to MSIX, and those that have done so may not have submitted all of the

required data, particularly the additional MDEs added in 2011. (Of course, none of the SEAs has submitted the new MDE identified in the Paperwork Reduction Act section and appendix of this notice.).

We note also that the Department initially collected MDEs in three phases, covering demographic data collected in Certificates of Eligibility, assessments, and course history for secondary students. However, MSIX has since eliminated the phased submission of MDEs, and there is no provision for phased submission of MDEs under the start-up or subsequent data submissions required under these proposed regulations.

This means, for example, that SEAs would be required to collect and submit to MSIX in their start-up submissions the assessment and course history data (applicable to the child's age and grade level) located in the State for children for whom the SEA may have previously submitted only demographic data. We propose to limit the start-up submission requirement to data for children considered eligible within the year preceding the effective date of the final regulations because of the added burden some SEAs would incur if they had to go back beyond one year in order to locate and collect assessment and course history data for these children from LEAs and non-migrant databases in the State.

Subsequent data submissions.

Newly documented migratory children. For every migratory child for whom an SEA documents eligibility for the MEP on or after the effective date of these regulations, proposed § 200.85(b)(3)(i)(A) would require the SEA to collect and submit to MSIX the MDEs required under paragraph (b)(1) within ten working days of documenting the child's eligibility for the MEP under § 200.89(c). This requirement would apply when an SEA determines that a migratory child has made a qualifying move and documents the child's eligibility on a Certificate of Eligibility; it would not apply when an SEA subsequently verifies that a previously identified migratory child is still a resident in the State. Unless a child is secondary school-aged, an SEA would not be required under proposed § 200.85(b)(3)(i)(A) to collect and submit MDEs in existence before the SEA's documentation of the child's eligibility for the MEP.

If the newly documented migratory child is secondary school-aged (whether or not the child is currently enrolled in school), proposed § 200.85(b)(3)(i)(B) would require an SEA to collect and submit to MSIX MDEs from the most recent secondary school in that State attended previously by the child, if any, and also to notify MSIX within 30 calendar days if one of its local operating agencies obtains records from a secondary school attended previously by the student in another State.

End of term submissions. Proposed § 200.85(b)(3)(ii) provides that within 30 calendar days of the end of the fall, spring, summer, and intersession terms, an SEA must collect and submit to MSIX all updates to MDEs and all newly available MDEs for migratory children who were eligible for the MEP during the term and for whom the SEA previously submitted data to MSIX. (If the SEA has not previously submitted data to MSIX for a particular migratory child to be included in an end of term submission, then the submission would fall under the timeframes and other specific requiremenis of paragraph (b)(2)(start-up data submissions) or (b)(3)(i) (newly documented migratory children).) Note that this proposed end of term submission requirement would apply even if the migratory child is no longer enrolled in school at the end of the term so long as the child was eligible for the MEP sometime during the term.

In addition, when a migratory child's MEP eligibility expires before the end of a school year, the proposed regulations would require an SEA to submit to MSIX all MDE updates and newly available MDEs for the child through the end of the school year in which the child is enrolled. Likewise, an SEA would be required to submit all MDE updates and newly available MDEs for any child who continues to receive MEP-funded services under section 1304(e) of the ESEA (continuation of services) after expiration of the child's eligibility for the MEP.

Change of residence submissions. Proposed § 200.85(b)(3)(iii) would require that within four working days of the date that MSIX notifies an SEA that a migratory child has changed residence to a new school district within the State or is newly documented as a migratory child in another State, the SEA must submit to MSIX all MDE updates and all MDEs that have become newly available to the SEA or one of its local operating agencies since the SEA's last data submission to MSIX for the child. If the MDEs are not available to the SEA or local operating agency when the SEA receives a change of residence notice from MSIX, the SEA would need to submit the MDEs to MSIX within four working days of the date that the SEA or its local operating agency has the MDE.

Proposed § 200.85(b)(3) would require an SEA to comply with specified timelines for subsequent data submissions throughout the entire calendar year whether or not local operating agencies or LEAs in the State are closed for summer or intersession periods.

Reasons: Proposed § 200.85(b)(3) is needed to establish reasonable and definite timeframes within which SEAs must submit MDEs to MSIX after their start-up data submissions. MSIX will transmit a migratory child's Consolidated Migrant Student Record immediately upon request of a local operating agency or non-project LEA. However, MSIX can meet its intended purpose of facilitating proper enrollment, grade and course placement, and credit accrual for migratory children only if the information in MSIX is complete, accurate, and current. This means that SEAs must submit new, updated, and newly available MDEs, including certain prior secondary school records, for migratory children within these timeframes.

We note, however, that these proposed timeframes represent the maximum amount of time that an SEA may take to submit MDEs to MSIX, not an ideal practice. For example, most States that have large migrant populations currently upload data to MSIX nightly; others have organized their systems to update MSIX whenever the value for an MDE has changed. We encourage SEAs to follow these practices and submit available data as promptly as possible so that school officials will have access to the most up-to-date information for enrolling, placing, and accruing credits for migratory children.

Newly documented migratory children. Section 200.89(c)(1) of the current regulations requires an SEA and its local operating agencies to use the Certificate of Eligibility form established by the Secretary to document the State's determination of the eligibility of migratory children for the MEP. A consensus was reached during the Department's MSIX consultations with SEAs and other MEP stakeholders that an SEA could be expected to submit a migratory child's MDEs to MSIX within ten working days of the date that the SEA documents under § 200.89(c)(1) that the child is eligible for the program. We believe that this timeframe appropriately balances the need for local operating agencies and non-project LEAs to have access to data as quickly as possible for enrollment, grade and course placement, and credit accrual purposes with fiscal and administrative

constraints faced by SEAs and local operating agencies that would have to respond to requests for such data.

In particular, experience suggests that although migratory children could move at any time, newly documented migratory children are unlikely to move again within ten working days. We recognize that the ten working-day starting point will vary depending on an SEA's process for approving and accepting a child's Certificate of Eligibility. Regardless of the process an SEA uses to make this determination, however, we agree with MEP stakeholders that ten working days from the date that an SEA documents a child's eligibility for the MEP should allow sufficient time for the SEA to gather and submit the necessary MDEs to MSIX. We take this position because, except for secondary school-aged individuals, proposed § 200.85(b)(3)(i)(A) would require an SEA to collect and submit to MSIX only MDEs that exist at the time the SEA documents the child's eligibility for the MEP.

We agree with the MEP stakeholders who have advised us consistently over the years that it is secondary school-aged students who are most adversely affected when information about their prior coursework and assessments is not available promptly after they migrate to a new area. In order to address this problem, we propose to require an SEA to collect and submit to MSIX those MDEs that were gathered prior to documentation of MEP eligibility for migratory children who previously attended secondary school in the same State.

In these cases, proposed § 200.85(b)(3)(i)(B) would require an SEA to collect and submit MDEs from the most recent secondary school in that State attended previously by the newly documented migratory child, if any. We are proposing this requirement so that when the migratory child makes a qualifying move, the new State or school district will have more complete data on the student's high school record for enrollment, course placement, and credit accrual purposes than it would have if the SEA submitted only data that came into existence in the State after the date it documented the child as eligible for the MEP.

We specifically invite public comment on our expectation that MDEs from the student's most recent secondary school in the State would contain MDEs from any secondary school in the same State in which the student previously enrolled.

For a migratory child who was not previously documented as eligible for the MEP in that State, the proposed regulations do not require an SEA to submit MDEs for the period prior to the new documentation. As such, a State that newly documents the eligibility of a child who previously attended secondary school in another State, but who was never identified as eligible for the MEP in that other State, would not be able to obtain the child's previous secondary school records from MSIX.

In these circumstances, we are proposing in § 200.85(b)(3)(i)(B)(2) to require an SEA (in State A) to notify MSIX within 30 calendar days if one of its local operating agencies obtains secondary school records from another State (State B) so that when the migratory child moves again, the new district can use MSIX to quickly locate the child's prior coursework and other secondary school records. We are not proposing to require the SEA of State B to transfer a student's previous secondary school records to State A because of the added administrative burden that would be associated with students who were never identified as migratory in State B, particularly as we understand that many of these transfers occur in summer or intercession months when school districts are closed. We also believe that, provided a student remains enrolled for an adequate period, the LEA in State A where a student transfers will eventually incorporate any prior secondary school course placements from State B into the student's records in State A, and that the SEA in State A will submit those MDEs to MSIX under the end of term submissions, described below.

We specifically ask for public comment as to whether these proposed regulations address adequately the problem of obtaining course placement records of secondary school-aged migratory children in a timely manner without overly burdening MEP participants.

End of term submissions. MEP stakeholders also generally agreed that, for children already identified in MSIX, 30 calendar days from the end of a school term (including summer and intersession terms) was a reasonable timeframe for an SEA to update a child's MSIX record and provide any newly available MDEs, such as State assessment data. Here again, we realize that a child could move at any time before or after the end of the term. However, the proposed regulations in § 200.85(b)(3)(iii) would call for a much faster, four-working day timeframe for submitting MDEs when MSIX notifies an SEA that a child has been identified in another location that seeks information from MSIX. As such, we believe that the 30-day timeframe for end of term submissions in proposed § 200.85(b)(3)(ii) reflects an appropriate balance between the need for MSIX to be able to provide current and accurate records and the need for SEAs, local operating agencies, and non-project LEAs to manage their staff-time and workloads.

By proposing to require SEAs to update and provide newly available MDEs to MSIX at the end of each term even when a migratory child's MEP eligibility expires before the term or school year has ended, the proposed regulations would help ensure that MSIX has available the most complete and up-to-date information should the child again become eligible for the MEP based on a subsequent move to a new location. Without these requirements, there would be a gap in MSIX data for the period between expiration of the child's eligibility and the submission of updated data to MSIX if the child is documented as eligible again in a new location. We believe that this approach is more efficient than relying solely on the SEA's responsibility under proposed § 200.85(b)(3)(iii) to submit MDEs within four working days of learning from MSIX that the child has been identified as migratory in another location. For similar reasons, the proposed regulations would require an SEA to update MDEs during any period of time in which a migratory child whose eligibility has expired continues to receive MEP services under section 1304(e) of the ESEA.

Change of residence submissions. Once an SEA has documented the MEP eligibility of a migratory child and submitted the MDEs to MSIX, MSIX thereafter may notify the SEA when that child has been newly documented as eligible for the MEP in another State or has changed residence to a new local operating agency within the same State. In these circumstances, proposed § 200.85(b)(3)(iii)(A) would require the SEA to submit to MSIX, within four working days of receipt of a change of residence notification from MSIX, updated MDEs that have become available to the SEA or its local operating agencies since the SEA's last submission of MDEs for the child. While we recognize that this is a very short timeframe, MEP and school personnel in the new State or district need critical information on the most mobile migratory children as soon as possible to allow them to make appropriate decisions regarding enrollment, grade and course placement, and accrual of secondary course credits.

We note that an SEA would be required under proposed

§ 200.85(b)(3)(ii) to submit updated and newly available MDEs to MSIX within 30 days of the end of the most recent school term in which the child was enrolled. While this provision would help keep MSIX up to date for migratory children who have not yet moved again, it would not meet the needs of children who have already migrated to a new school district, where school officials and staff need records from the former school district as quickly as possible.

Proposed § 200.85(b)(3)(iii)(B) recognizes that an SEA or local operating agency may not be able to submit new or updated MDEs for a child at the time the SEA receives a change of residence notification from MSIX because the information is not yet available. For example, a State or local operating agency may not have a child's scores for State reading and mathematics assessments for some time after the child has already migrated to a new State or school district. In these cases, the proposed regulation would require an SEA to submit the new or updated MDEs to MSIX within four working days of the date that the SEA or one of its local operating agencies obtains the MDEs. By this we mean that the information has been processed by the local school district, other local operating agency, or other responsible party, such as a contractor for the SEA, and could be collected by the SEA. Without such a provision, SEAs would be under no obligation to submit to MSIX those MDEs that an SEA or one of its local operating agencies obtains after the standard, four-day submission period has lapsed.

Under proposed § 200.85(b)(3), the fact that a school district or other local operating agency is closed for the summer (or other vacation period) would not relieve an SEA of its obligation to collect and submit MDEs to MSIX that are available to one of its local operating agencies. Allowing an SEA to defer submission of MDEs until after the child's district or other local operating agency reopens after a vacation period would defeat the purpose of the proposed subsequent data submission requirements. We note that consistent with sections 1304(b)(3) and 1308(b)(2) of the ESEA, an SEA's costs of making arrangements with its local operating agencies and non-project districts to secure needed MDE information, including under the subsequent data submission requirements in proposed § 200.85(b)(3), would be allowable costs of the MEP.

Use of Consolidated Migrant Student Records. Proposed § 200.85(c)(1) would require SEAs to use, and to require each of their local operating agencies to use, Consolidated Migrant Student Records to help ensure proper participation in the MEP, school enrollment, grade and course placement, and accrual of high school credits, for all migratory children who have changed residence to a new school district within the State or in another State. Under proposed § 200.85(c)(2), SEAs also would be required to encourage non-project LEAs to use Consolidated Migrant Student Records for these same purposes. Proposed § 200.85(c)(3) would require SEAs to establish procedures, develop and disseminate guidance, and provide training to SEA, local operating agency, and non-project LEA personnel who have been designated by the SEA as authorized MSIX users under proposed § 200.85(f)(2) to ensure that Consolidated Migrant Student Records are used for the purposes provided in proposed § 200.85(c)(1).

Reasons: Migratory children will benefit from the expedited availability of records in MSIX only if school registrars, counselors, MEP specialists, and other local and State officials and staff use the system for its intended purposes—ensuring that migratory students receive proper enrollment, grade and course placement, and accrual of high school credits. Because staff may be inclined to opt for the familiarity of existing systems and methods that do not include or provide for a nationwide data exchange, proposed § 200.85(c)(1) is needed to ensure that SEAs and local operating agencies actually use Consolidated Migrant Student Records from MSIX, and that MSIX therefore fulfills its intended purposes.

No similar requirement is proposed for non-project LEAs because they do not receive MEP funds. However, proposed § 200.85(c)(2) and (c)(3) would ensure that these LEAs are familiar with the added benefits for migratory children of using a student's Consolidated Migrant Student Record. Proposed § 200.85(c)(3) is needed also to ensure that SEAs properly train authorized users in the appropriate use of the MSIX online system as well as the information contained in the Consolidated Migrant Student Record.

MSIX data quality. Proposed § 200.85(d)(1) would require SEAs to use reasonable and appropriate methods to ensure that all data submitted to MSIX are accurate and complete, and to require each of their local operating agencies to do the same.

Proposed § 200.85(d)(2) would require SEAs to respond promptly, and ensure that each of their local operating agencies responds promptly, to any request by the Department for information needed to meet the Department's responsibility for the accuracy and completeness of MSIX data under the Privacy Act of 1974, as amended (Privacy Act).

Reasons: The data in MSIX will help school officials make correct decisions about enrollment, grade and course placement, and accrual of high school credits for migratory children only if SEAs take reasonable steps to ensure that records of migratory children submitted to MSIX are accurate and complete. If the information that SEAs submit to MSIX is not accurate and complete, then Consolidated Migrant Student Records from MSIX cannot and will not be used as intended under section 1308(b)(2) of the ESEA. (Proposed regulations requiring SEAs also to respond to requests to correct data in MSIX are discussed later in this notice in connection with proposed § 200.85(e).)

In addition, MSIX is a "system of records" under the Privacy Act. See the system of records notice published in the **Federal Register** at 72 FR 68572, 68576 (Dec. 5, 2007). The MSIX is implemented through a Department contract, and therefore the Department and its contractor are responsible for complying with applicable Privacy Act requirements in the maintenance and operation of MSIX. In particular, 5 U.S.C. 552a(e)(6) requires the Department and its contractor to make reasonable efforts to assure that MSIX records are accurate, complete, timely, and relevant.

These proposed regulations are needed to help the Department meet its responsibility under this provision of the Privacy Act. The requirement that MSIX records be accurate and complete is addressed by proposed § 200.85(d) (along with proposed § 200.85(e), which addresses requests to correct the records); the timeliness requirement is addressed in proposed § 200.85(b); and the relevance requirement is addressed through the MDEs required by the Secretary. Proposed § 200.85(d) helps to ensure that migrant students have accurate and complete records; in particular, proposed § 200.85(d)(2) would ensure that SEAs and local operating agencies help the Department carry out its responsibility to engage in reasonable efforts to maintain accurate and complete records in MSIX, and to respond to any civil action that might be brought under the Privacy Act (5 U.S.C. 552a(g)(1)(C) or (D)) alleging failure to maintain accurate and complete records in MSIX.

Finally, as noted above in the Background section of this notice, the Department plans to use MSIX to

generate MEP child counts for State funding purposes and to meet reporting requirements related to the national migrant child population. Proposed § 200.85(d) is thus also needed to ensure that the Department has the most accurate, complete, and timely data that is reasonably possible for these purposes.

Procedures for MSIX data correction by parents, guardians, and migratory children. Proposed § 200.85(e) would require each SEA that receives a grant of MEP funds to establish and implement written procedures to allow a parent or guardian of a migratory child, or a migratory child, to ask an SEA to correct or determine the correctness of MSIX data.

These written procedures would need to meet the following minimum regulatory requirements. Under proposed § 200.85(e)(1)(i), within 30 calendar days of receipt of a data correction request from a parent, guardian, or migratory child an SEA would need to (A) send a written or electronic acknowledgement to the requester; (B) investigate the request; (C) decide whether to revise the data as requested; and (D) send the requester a written or electronic notice of the SEA's decision. This process would occur outside of MSIX.

Under proposed § 200.85(e)(1)(ii), an SEA would have to submit any revised data to MSIX within four working days of its decision to revise the data; an SEA would not need to notify MSIX if it decided not to revise data as requested. Under proposed § 200.85(e)(1)(iii), if a parent, guardian, or migratory child asks an SEA to correct or determine the correctness of data that was submitted to MSIX by another SEA, the SEA would be required to send the data correction request to the SEA that had submitted the data to MSIX within four working days of its receipt. This process also would occur outside of MSIX. An SEA that receives an MSIX data correction request from another SEA under this provision would need to respond as if it had received the request directly from the parent, guardian, or migratory child.

Under proposed § 200.85(e)(2), an SEA would need to respond, and ensure that its local operating agencies respond, within ten working days to a request by the SEA of another State for information needed by that SEA to respond to a data correction request by a parent, guardian, or migratory child under proposed § 200.85(e)(1). This process, too, would occur outside of MSIX. (Note that procedures for SEAs to respond to requests by MSIX itself to resolve data matching and other data integrity issues internal to MSIX are discussed in connection with proposed § 200.85(f)(1).)

Proposed § 200.85(e)(3) would require an SEA to respond within ten working days to a request from the Department for information it needs to respond to an individual's request to correct or amend a Consolidated Migrant Student Record under the Privacy Act, 5 U.S.C. 552a(d)(2), and 34 CFR 5b.7. This process would occur outside of MSIX as well.

Reasons: MSIX is a system of records under the Privacy Act, 5 U.S.C. 552a. As such, subject individuals have a right under paragraph (d)(2) of the statute and Department regulations codified at 34 CFR § 5b.7(a) to ask the responsible Department official to correct or amend a Consolidated Migrant Student Record that the individual believes is not accurate, timely, complete, or relevant or necessary to accomplish a Department function. Our purpose for proposing § 200.85(e) is not to duplicate or supplant these rights under the Privacy Act but to provide a more limited and accessible procedure for individuals who want only to correct an inaccurate record and who would be more likely to do so if given an opportunity at the State or local level. These proposed regulations, and § 200.85(e)(3) in particular, are also needed because the Department cannot respond to a request to correct or amend an MSIX record under the Privacy Act without the intervention of SEAs because MSIX contains only records submitted by the SEAs.

Parents and guardians of migratory children and those children themselves often have the most accurate information about a migratory child and his or her family, such as whether a child attended a particular school or already completed a specific course, and they have a strong interest in ensuring that MSIX data are accurate. These proposed regulations advance that interest by requiring SEAs to develop and implement written procedures, within established timeframes, for (1) receiving and responding to requests by these individuals to correct or determine the correctness of records that have been or would be submitted to MSIX, and (2) sending any revised and corrected data to MSIX.

Moreover, the proposed regulations would facilitate MSIX data correction by allowing SEAs to establish their own procedures in the most efficient and effective possible manner (within specified timeframes). We anticipate, for example, that most SEAs would require parents, guardians, and migratory children to submit their MSIX data correction requests to a local operating agency and would delegate to these agencies most of the SEA's responsibilities under these proposed regulations for investigating requests and communicating with requesters, other SEAs and local operating agencies, and the Department. The proposed requirement in § 200.85(e)(1)(iii) would also provide parents, guardians, and migratory children with a single, local point where they could request MSIX data correction, even when the questionable data had been submitted to MSIX by the SEA of another State.

We believe that the proposed timeframes for these MSIX data correction procedures will help to ensure that incorrect data are removed from MSIX as quickly as possible, while providing sufficient time for SEAs to seek further information and resolve any conflicts. We note that, while an SEA would have 30 calendar days overall to respond to an individual's request and four working days from the date of its decision to submit any revised data to MSIX, under § 200.85(e)(2) we propose that an SEA or local operating agency would have nearly one-half of that time (i.e., ten working days) to provide information that an SEA in another State needs to respond to a request it has received from a parent, guardian, or migratory child to correct MSIX information. Similarly, in § 200.85(e)(3) we propose that an SEA or local operating agency would have the same ten working-day time period in which to respond to a request from the Department for information the Department needs to respond to a request to correct or amend records under the Privacy Act.

We specifically seek public comment on whether these are reasonable timeframes for SEAs and local operating agencies to complete their work and respond to the requester.

MSIX data protection. Under proposed § 200.85(f)(1), each SEA that receives a grant of MEP funds would enter into and carry out its responsibilities under an MSIX Interconnection Agreement, an MSIX Interconnection Security Agreement, and other information technology (IT) agreements required by the Secretary in accordance with applicable Federal requirements.

SEAs would be required under proposed § 200.85(f)(2) to establish and implement written procedures to protect the integrity, security, and confidentiality of Consolidated Migrant Student Records, whether in electronic or print format, through appropriate administrative, technical, and physical safeguards established in accordance

with the MSIX Interconnection Agreement and MSIX Interconnection Security Agreement. An SEA's written procedures would have to include, at a minimum, reasonable methods to ensure that (i) the SEA permits access to MSIX only by authorized users at the SEA, its local operating agencies, and LEAs in the State that are not MEP local operating agencies but where a migratory child has enrolled; and (ii) the SEA's authorized users obtain access to and use MSIX records only for authorized purposes as described in proposed § 200.85(c)(1).

Under proposed § 200.85(f)(3), before providing authorized users with access to MSIX an SEA would require that they complete the User Application Form approved by the Secretary, which is available currently at *https://msix.ed.gov*. An SEA would also be permitted to develop its own documentation for approving user access to MSIX provided that it contains the same information as the User Application Form approved by the Secretary. Proposed § 200.85(f)(4) would require SEAs to retain the documentation required for approving user access to MSIX for three years after the SEA terminates the user's access.

Reasons: The proposed regulations are needed to ensure that, in connecting to MSIX and allowing individuals to obtain access to the electronic student records system, SEAs protect the integrity, security, and confidentiality of Consolidated Migrant Student Records through appropriate administrative, technical, and physical safeguards.

Currently, this is accomplished through specific provisions in the MSIX Interconnection Agreement and MSIX Interconnection Security Agreement that SEAs, in accordance with various Federal requirements, must enter into before they may participate in MSIX. In particular, OMB Circular A–130 Appendix III and National Institute of Standards and Technology Special Publication 800–47, which implement requirements of the Computer Security Act of 1987 and the Information Technology Management Reform Act of 1996, require Federal agencies to obtain written management authorization before connecting their IT systems to other systems based on an acceptable level of risk. Similarly, the MSIX Interconnection Agreement and MSIX Interconnection Security Agreement are part of the means by which the Department meets its responsibilities under the Privacy Act, 5 U.S.C. 552a(e)(10), for establishing appropriate safeguards to ensure the security and confidentiality of records, and to protect against any anticipated threats or hazards to their security or integrity that could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is maintained in MSIX. As such, proposed § 200.85(f) is needed to help the Department meet its IT data security responsibilities under the Privacy Act.

The proposed regulations would help to ensure that SEAs comply with all Federal information security requirements applicable to MSIX by requiring that they execute and implement satisfactory IT agreements with the Department as a condition of receiving a grant of MEP funds and of connecting to and accessing the MSIX system. We note that the Department's MSIX IT agreements with participating States also include provisions related to various internal processing requirements applicable to SEAs that help ensure the integrity of Consolidated Migrant Student Records. For example, there are MSIX work rules that require SEAs to resolve data match and other data discrepancy issues within specified timeframes. An SEA's failure to comply with these internal MSIX work rules is a breach of its IT agreements and would constitute a violation of proposed § 200.85(f)(1).

Because Consolidated Migrant Student Records contain personally identifiable information (PII) on all migratory children, the proposed regulations are needed to ensure that SEAs limit access to authorized users and for authorized purposes. However, while the number of users in each SEA, local operating agency, or non-project LEA would likely be limited, we anticipate that, consistent with their MSIX data protection procedures, SEAs will promote the maximum use of Consolidated Migrant Student Records at State and local levels in order to meet the needs of migratory children who have moved to a new LEA or State.

In terms of the data protection procedures that SEAs would be required to implement under these proposed regulations, we note that the restrictions on redisclosure of PII from education records in the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. 1232g(b)(3) and 34 CFR part 99.35(c)(2), do not apply to FERPA-protected PII that is disclosed to and by MSIX because Federal law (section 1308(b)(2) of the ESEA) specifically authorizes and requires the redisclosure of MDEs to the Department (i.e., FERPA-protected PII). However, FERPA's restrictions on redisclosure still apply to PII from education records that LEAs and SEAs obtain from MSIX and subsequently maintain in their own data systems.

In order to ensure that MSIX users are aware of the Department's rules of behavior governing the use of MSIX and that the Department can effectively monitor use of MSIX, as well as promptly respond to any actual or potential security breaches, the proposed regulations in § 200.85(f)(3) and (f)(4) would require SEAs to collect and maintain minimum documentation identifying MSIX users and their authorizing supervisors. The OMB-approved User Application Form (OMB Approval No. 1810–0686) contains the minimum information that the Department needs for this purpose, including a certification signed by the proposed user to abide by the MSIX rules of behavior issued by the Department. Under proposed § 200.85(f)(3), an SEA may use either this OMB-approved form or another document that the SEA has developed that contains the information required by the OMB-approved form. By requiring SEAs to retain their records authorizing access to MSIX for a minimum of three years, the Department may gain access to these records when needed consistent with the general three-year record retention period in 34 CFR 80.42.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

This proposed regulatory action is a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing these proposed regulations only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these proposed regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive Orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The Secretary believes that the proposed regulations are necessary in order for the Department to implement effectively the requirement in section 1308(b) of the ESEA that the Secretary ensure the linkage of migrant student record systems and for the effective implementation of the MEP by States and local agencies serving migrant children. The Secretary also believes that the requirements contained in these proposed regulations represent a careful balance between placing burden on States and other agencies providing services to migrant children and meeting the need for collecting and maintaining updated, accurate information about this mobile population in order to ensure timely transfer of pertinent school records when migrant children move from one school to another.

The Secretary also believes that the proposed regulations are necessary because implementation of a statutorily required system for transferring migrant student records will not be completely successful if the system does not contain complete, updated, and accurate student records and if not all States use the system as the official mechanism for transferring migrant student records. Although MSIX has been operational since 2007 and most States now submit data on their migrant children to the system voluntarily, not all States submit data on all the migrant children they have documented as eligible or submit all the required data elements. These data elements (known as "minimum data elements," or "MDEs") encompass three types of information: Basic information on migrant children (including their eligibility for migrant services and school enrollment information, if any), also known as core data elements; information pertaining to State assessments; and information about high school credits and grades, which pertains only to secondary students.

As described in the following paragraphs, the Department estimates that the total cost to participating SEAs of implementing these proposed regulations is approximately $18,516,444 for the first year, and $15,986,441 annually thereafter. The estimated burden per eligible child, amortized over three years, is approximately one hour and 10 minutes, at an approximate cost of $38.54 per year. These estimates cover all proposed regulatory requirements, including the costs of information collection activities, which are discussed separately under the heading *Paperwork Reduction Act of 1995*. As of September 2012, 22 States have provided complete start-up submissions for all MDEs; an additional 27 States have provided partial start-up submissions; and only one State has not provided any data to MSIX. Thus, the first-year estimate excludes start-up costs that have already been incurred by participating SEAs since MSIX began operating in 2007, as well as costs for using records, data quality, data protection, and data correction (activities required under § 200.85(c)–(f)) for those 22 States that have provided complete start-up submissions.

These costs will not all be borne by the States and their local operating agencies; the Department provides resources to States, both monetary and non-monetary, to assist them in implementing MSIX activities successfully. For example, in 2007 the Department paid for contractors to work with States to develop system interfaces that allow State data systems housing migrant student data to connect to MSIX directly, avoiding the need to enter information into MSIX manually if it already exists in a data system. In 2008 and 2010 the Department provided modest funding to States under the MSIX Data Quality program that could be used for developing these interfaces, improving the quality of migrant student data, and submitting data to MSIX, and the Department expects to provide such funding in the future. In addition, the Department has provided extensive technical assistance to States on issues of data quality and security not only through the MEP, but also through the State Longitudinal Data System program and as part of the implementation of the Education Data Exchange Network and other data collections that are part of the ED*Facts* system. Each of these activities will result in reduced costs of implementing these proposed regulations. Further, and most importantly, States may use MEP funds to cover the costs associated with implementing the proposed regulations (albeit with the result that less MEP funding is then available for direct services). A more detailed discussion of

the costs of each regulatory requirement follows.

In order to help calculate the time estimates associated with the various proposed data submission requirements, the Department surveyed State officials in nine States with varying numbers of migrant children regarding the time it takes them to collect and enter these data in their State data systems; the Department used for its estimates the median number of minutes that States provided in their responses. Estimates of the numbers of migrant children for whom States will submit information to MSIX were derived from Consolidated State Performance Reports (CSPRs) for the 2010–2011 program year and include the number of migrant children ages 0–21 that States reported as eligible for MEP services in program year 2010–2011 (418,643), the number of eligible K–12 children enrolled in school (298,159), the number of eligible secondary students (83,838), and the number of migrant students reported as having taken State assessments (125,293). The hourly cost used for these estimates was $33.02, the mean hourly earnings for State and local government management, professional, and related occupations reported by the U.S. Bureau of Labor Statistics in its National Compensation Survey: Occupational Earnings in the United States, 2010.

The Secretary estimates that the one-time cost for providing start-up submissions to MSIX under proposed § 200.85(b)(2), excluding costs that were incurred by States before these proposed regulations, is approximately $2,077,537.

That figure assumes that State and local officials take approximately 53 minutes per student to collect, enter into the State data system, and submit to MSIX general demographic and enrollment data elements that pertain to all migrant children who have been documented as eligible for the program; approximately 5 minutes per student for the data elements pertaining to students who participate in State assessments; and approximately 55 minutes per student for the course history data elements pertaining only to eligible secondary students.

The Secretary estimates that the annual costs for complying with proposed § 200.85(b)(3), which covers subsequent submissions to MSIX of data on newly documented migrant children, updates to MSIX at the end of every school term, and updates to MSIX if a receiving State or local agency notifies a sending State or local agency that a migrant child has moved, will be approximately $15,338,820. Within that estimate, the Department estimates the annual costs of implementing the requirements under proposed § 200.85(b)(3)(i), covering collection and submission of data to MSIX for newly documented migratory children, at $5,681,377. The Department estimates the annual number of newly documented migrant children to be 121,602 based on the number of qualifying moves for migrant children that States reported to the Department in section 2.3.1.5 of the CSPR for program year 2010–2011. The number of newly documented migrant children for whom there will be data elements pertaining to assessment data (36,394) and secondary schooling (22,855) is based on the proportion of those students in the population of migrant students enrolled in grades K–12 during school year 2010–2011. The Department assumes the same time estimates used for calculating burden for collecting and submitting data for start-up submissions as are assumed for the calculations of other proposed data submission requirements under proposed § 200.85(b)(2). Based on responses to the Department's survey of States discussed above, the Department also estimates an additional effort of 1 hour and 10 minutes per student to collect data elements for a secondary student who previously attended another secondary school in the same State (proposed § 200.85(b)(3)(i)(B)(*1*)) and another 40 minutes to determine if, and notify MSIX when, a local agency has received secondary school records from out of State for a newly documented secondary student (proposed § 200.85(b)(3)(i)(B)(*2*)).

The cost estimate for implementing the requirements under proposed § 200.85(b)(3)(ii), end of term submissions, is $9,618,004. The estimate assumes that States must provide updated data for every migrant child once over the course of each year for most, but not all, of the data elements pertaining to all children, and that that effort will take approximately 42 minutes per migrant child. The time burden, which the Department estimated based on the experience of Department staff who have worked on migrant programs at the State level, also assumes a smaller burden for this effort than that for start-up data submissions because some States have developed automated processes for collecting this information and providing these updates to MSIX.

MSIX is structured so that many of the data elements in a student's record must be updated every year; for example, when a student finishes a grade level the student must be marked as "withdrawn" from that grade, and when the student enters the following grade the next school year the student is then marked as "enrolled" in the new grade. Thus, updates may happen throughout the school year, but will likely only occur once a year, for a subset of the data elements required for start-up submissions. There are a smaller number of data elements, such as birth city, that would not require an update. In addition, the estimate assumes that States will need five minutes per student for the data elements pertaining to those who participate in State assessments, the same effort as for start-up submissions, as those assessments are administered only once a year. The Department's estimate also assumes 55 minutes per student for the data elements pertaining only to secondary students, the same effort as for start-up submissions, as the Department's previously discussed survey asked States to report their estimated average burden for data elements for secondary students regardless of the number of courses in which secondary students were enrolled.

The estimate for the annual costs of implementing the requirements under proposed § 200.85(b)(3)(iii), change of residence submissions, is approximately $39,438. This estimate is based on the 637 requests that receiving States or local agencies (i.e., States or local agencies where migrant students moved) made through MSIX in the 2010–2011 school year to request records from sending States or local agencies (i.e., a student's previous location of enrollment). This number is low because, apart from the proposed end of term data submission requirements, the proposed regulations require a sending State to update a student record only if it receives notification from a receiving State or local agency (through MSIX) that it has enrolled a student formerly enrolled in the sending State. However, the proposed regulations do not require receiving States (or their local agencies) to notify the student's former location that the student has changed residence. This allows a State or local agency enrolling a student the flexibility to determine if there are data missing from a student's MSIX record, and send a notification (through MSIX) to a student's former location requesting an updated student record only if needed.

In addition, the Department expects that, as implementation of these regulations takes effect, MSIX records will be updated regularly and data elements will not likely be missing, thus reducing the need for a State or local

agency to request data elements from another location upon a student's change of residence. Furthermore, proposed § 200.85(b)(3)(ii) requires SEAs to update MSIX records at the end of each term; therefore, States and local agencies are most likely to use MSIX to request records from a previous location under § 200.85(b)(3)(iii) only for students moving in the middle of the term. An analysis of MSIX data on the timing of student moves during school year 2010–2011 showed that approximately 52 percent of the moves occurred during the summer months, after the end of the school year; that proportion is 63 percent if the moves that occurred in January are included, all of which should further reduce the number of data submissions under the proposed change of residence provision in § 200.85(b)(3)(iii).

The estimate for the total costs of implementing the proposed requirements under § 200.85(c), using consolidated migrant student records contained in MSIX; § 200.85(d), establishing rules pertaining to the quality of data submitted to MSIX; and § 200.85(f), establishing rules pertaining to the protection of data submitted to MSIX, is approximately $1,099,180. The Department estimates that the main costs for implementing these requirements are associated with the time that will be needed to establish policies and procedures to address the use of MSIX, data quality, and data protection; develop and disseminate the guidance and procedures to SEA and local personnel; and provide training to State and local personnel who have access to MSIX.

In order to minimize the burden on States of complying with these proposed requirements, the Department developed a template for a State manual to assist the States in developing policies and procedures for using MSIX, ensuring data quality, and protecting the data; the Department also developed a training kit for State officials to use in carrying out training within their States. Based on the experience of Department staff who have worked on migrant programs at the State level, the Department estimates that each State will spend approximately 120 hours developing policies and procedures with the aid of the template; using the same cost per hour used for the proposed data submission requirements, the one-time cost of establishing policies and procedures will be an estimated $198,120. To calculate the costs of training State and local personnel in the use of MSIX and associated policies and procedures, the Department estimates 10 person-hours per State for developing training sessions using the training kit and 2-hour training sessions for approximately 3,577 users of MSIX. (This estimate is based on 2,365 current active users, which is expected to increase by 25 percent during the first year these proposed regulations are implemented and 10 percent for each of the following two years.) Based on the same cost per hour used for the proposed data submission requirements, the total training cost is an estimated $252,735.

In addition, State personnel will likely need the assistance of an information technology professional at the State level to run reports and monitor the data collected and submitted to MSIX, to review system security, and to work with other State or local personnel to remedy any concerns or problems with the data. The Department estimates that it will take 32 hours per month for one computer support specialist per State to accomplish this work, at a salary of $23.60 an hour (the mean hourly earnings for computer support specialists in State and local government reported by the U.S. Bureau of Labor Statistics in its National Compensation Survey: Occupational Earnings in the United States, 2010), for a total of $344,371. The estimate also includes an additional $301,895 for complying with proposed § 200.85(c), using consolidated records in MSIX, to meet costs associated with development of electronic interfaces and communications between State data systems and MSIX. The Department provided resources for this work, as discussed earlier, and estimates that the burden associated with doing this work is approximately 241 hours per State using the same methodology as that used to estimate the time needed for start-up submissions. The estimate further includes an additional $49,607 for complying with the requirement in proposed § 200.85(f) that MSIX users fill out user application forms, which the Department estimates at 5 minutes, and for a supervisor to review a user application form and other documentation in order to determine whether to grant access to MSIX to an applicant, which the Department estimates at 20 minutes, for a total of 25 minutes to grant access to a user. This cost is based on 3,577 users (as discussed previously) and the same labor cost as that used to calculate the proposed data submission requirements.

The estimate for implementing the proposed requirements under § 200.85(e), procedures for MSIX data correction by parents, guardians, and migratory children, is approximately $908. Based on responses to the Department's survey of States discussed above, the Department estimates the number of requests to States to correct data to be one per State per year and that each request will take approximately 38 minutes to acknowledge, review, make any necessary corrections to the data, and notify the requester of the resolution to the request. In addition, the Department, based on its experience in implementing MSIX to date, estimates receiving six requests per year nationally for data correction from parents, guardians, or migrant children, and anticipates that States will similarly require an average of 38 minutes to address any requests from the Department on this matter. The cost per hour used is the same as that used to estimate start-up data submissions.

While it is difficult to quantify the benefits of these proposed regulations, we believe that they will provide important benefits to migrant children and their families and to States and local agencies, particularly for the approximately 26 percent of migrant students who move across school district boundaries each year (based on data States reported for school year 2010–2011). Overall, one of the major benefits of these proposed regulations is that instantaneous access to records of children who have previously been identified as migrant will reduce the time it takes to enroll a student in a new school and the time needed for placing a student in appropriate classes. Prompt placement is necessary not only to ensure continuity of schooling and other services, but also to ensure that students receive the maximum benefits they are entitled to under MEP, as the program limits the amount of time that migrant children may receive services. Prompt access to records also reduces the likelihood of duplication of services and helps ensure that students are placed in the right classes, reducing the likelihood that a student will repeat classes or be placed in an inappropriate class, actions that adversely affect students academically and emotionally. For secondary school students, the benefits will also include having a record documenting credit accrual, thus increasing the likelihood that a student will graduate from high school on a timely basis.

As MSIX incorporates information about inoculation records, it also helps prevent duplication of vaccinations, an unnecessary additional expense for families and community health systems. Most States require students to be vaccinated, at a minimum, for polio, diphtheria, tetanus, pertussis, measles,

mumps, rubella, hepatitis B, and varicella. The combined cost per dose as of July 2012 for these vaccinations under the Center for Disease Control vaccine contracts (established for the purchase of vaccines by immunization programs that receive CDC immunization grant funds, such as State health departments) was approximately $144, and the average cost of the same vaccine to the private sector was approximately $210. Reducing duplicate vaccinations also preserves the vaccine supply for others in the community. In addition, MSIX incorporates a flag for students with acute or chronic medical conditions, thus instantly alerting school personnel enrolling a migrant student to the fact that the student may need additional support services and referrals to medical care.

We further note that these proposed regulations were informed by the Department's and the States' previous experience in implementing a migrant student record transfer service in the 1970s through the 1990s. The Migrant Student Record Transfer System (MSRTS) was a national, computer-based system for records collection and transfer established in response to a 1969 congressional mandate requiring the creation of a service for transmitting educational and health records for migrant students. MSRTS was terminated in 1995 due both to concerns about the accuracy and usefulness of the data in the system and to the lack of uniformity in the data reported to the system. In addition, many users considered MSRTS too slow and burdensome, as the computer technology used still relied largely on a paper-based system for collecting and reporting information that did not incorporate technological advancements efficiently, making it an inefficient mechanism for meeting its mission. These proposed regulations have been designed to ensure that MSIX users have ready access to complete, up-to-date records that they may trust, and to ensure that the transfer of those records through MSIX occurs efficiently.

The proposed requirement that agencies serving migrant children use MSIX and the Consolidated Migrant Student Records MSIX generates would ensure not only that information in MSIX is used, but also that the agencies acquire an interest in ensuring the quality and timeliness of the data they provide to and obtain from the system. Other benefits would include access to migrant records that are current, accurate, secure, and complete, and that contain data that may be currently maintained in different systems within States; for example, data from State assessments may not be maintained in the same system where student health records are maintained. States' current voluntary participation in MSIX reflects the fact that this service is valuable to them and enables them to better serve one of their most vulnerable populations.

For these reasons, the Department believes that the benefits of these proposed regulations would significantly exceed the somewhat minor estimated costs, much of which would be met with Federal resources.

Elsewhere in this section under *Paperwork Reduction Act of 1995*, we identify and explain burdens specifically associated with information collection requirements.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum "Plain Language in Government Writing" require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make these proposed regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulations be easier to understand if we divided them into more (but shorter) sections? (A "section" is preceded by the symbol "§" and numbered heading; for example, § 200.85.)
- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulations easier to understand? If so, how?
- What else could we do to make the proposed regulations easier to understand?

To send any comments that concern how the Department could make these proposed regulations easier to understand, see the instructions in the **ADDRESSES** section.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities because these proposed regulations affect primarily SEAs. SEAs are not defined as "small entities" in the Regulatory Flexibility Act. The only small entities that could be affected by the proposed regulations would be small local operating agencies that receive MEP subgrants from an SEA or entities that contract with SEAs to provide various services in connection with MSIX activities. Local operating agencies would be required to submit data on migratory children to a State's data system under timeframes identified in the proposed regulations. However, the costs of doing so would likely be financed through the State's MEP award and would not impose a significant financial burden that small entities would have to meet from non-Federal resources.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps ensure that: The public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Section 200.85 contains information collection requirements. Under the PRA the Department has submitted a copy of this section to OMB for its review.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

Minimum data elements (MDEs) consist of 72 data elements that reflect the minimal information needed to ensure proper enrollment, grade and course placement, and accrual of secondary course credits for migratory children. The MDEs, and the various information sources through which they are currently obtained, would not change as a result of the proposed regulations except for the collection of one new MDE related to the records of secondary school-aged children.

Thirty of the MDEs are collected and entered into State data systems through

the information collection requests (ICRs) for the Department's Education Data Exchange Network (EDEN) (OMB Control Number 1875–0240) and for the Migrant Education Program (MEP) Certificate of Eligibility (COE) and related regulations (OMB Control Number 1810–0662). There is no need to account here for the burden of collecting, maintaining, and submitting to MSIX these 30 MDEs because these MDEs are already collected and maintained for other purposes, and we have assumed that submission of these MDEs to MSIX would occur automatically once a State's electronic interface with MSIX has been established.

Forty-one of the remaining 42 MDEs are collected and entered into the State data systems under the existing MSIX ICR (OMB Control Number 1810–0683). In addition to creating a new MDE, the proposed regulations would change the parties to whom the collection applies as well as the content, timing, and circumstances of submissions of data under the existing ICR. As a result, we propose to amend and restate the MSIX ICR to reflect, among other things, a new burden analysis and supporting statement. In the final regulations we will display the existing MSIX ICR OMB control number 1810–0683 on all information collection requirements in these proposed regulations and adopted in the final regulations.

Section 200.85—Responsibilities of SEAs for the Electronic Exchange Through MSIX of Specified Health and Educational Information of Migratory Children

Proposed § 200.85 would require SEAs to collect, maintain, and submit to MSIX educational and health information on migrant children who move from one State or district to another. This information would enable SEAs to reduce educational disruptions for migrant children, make timely and accurate school placements, ensure academic credit for school work completed, streamline academic progression toward graduation requirements, and provide complete academic records as needed for postsecondary education and employment opportunities. The exchange of health information through MSIX would also help reduce unnecessary immunizations of migrant children because of a lack of timely, accurate health information.

Estimates of Annualized Burden to SEA Respondents

For the 42 MDEs not covered by other information collections, the total burden for all SEA respondents in the first three years after the effective date of the proposed regulations is estimated at 465,866 hours per year. This amounts to an average of 9,317 hours per year for each of the 50 participating SEAs. Because eligibility for MEP services varies greatly among the States, we have also estimated the overall burden as 1,113 hours annually per 1,000 eligible children to enable individual SEAs to assess the burden of the information collection.

These estimates were developed by program and contract staff with experience in the State-level administration of the MEP based upon consultation with States, analysis of the information reported by each State in its 2010–2011 CSPR (OMB Number 1810–0614), and State data submitted previously to MSIX. Note, the estimated burden to collect the MDE information includes the effort to enter the data in the appropriate State information systems for electronic transmission to MSIX.

In calculating the burden of this information collection, we have not included the burden associated with start-up submissions previously made to MSIX in whole or in part. In calculating the burden associated with subsequent data submissions, our estimates quantify the total annualized burden to SEAs, and do not specify the incremental burden to those SEAs that have previously collected, maintained, and submitted to MSIX any or all the MDEs covered by the MSIX ICR relating to subsequent data submissions.

See the discussion below for a further explanation of the burden related to specific regulatory provisions. Additional information about the basis of the burden estimates in this document is available at *www.reginfo.gov*. Click on Information Collection Review. The proposed collection is identified as proposed collection [1810–0683 ED–2013–ICCD–0154].

Start-Up Data Submissions (§ 200.85(b)(2)(i))

As of September 2012, twenty-two States had already met the requirement to collect and submit to MSIX MDEs for every migrant child considered eligible in the State within the preceding year; an additional 27 States had provided partial start-up submissions; and only one State has not provided any data to MSIX. We used these figures for our start-up data submissions calculations. Start-up data is a one-time requirement for each SEA; submissions are required to be completed no later than 90 calendar days after the effective date of the final regulations. Amortized over three years, the annualized burden of the requirement for the remaining 28 States is estimated to be 21,651 hours per year in total and 773 hours per year per SEA. All subsequent data submission requirements are covered by the other information collection activities described below.

Newly Documented Migratory Children (§ 200.85(b)(3)(i)(A))

The annualized burden of the requirement for 50 States to collect and submit the MSIX MDEs within 10 days of documenting the eligibility of each new migratory child is estimated at 109,435 hours per year in total and 2,189 hours per SEA. Documenting the eligibility of migratory children is an ongoing process, and we estimate the burden would remain at a constant level in each of the three years that this information collection covers.

Newly Documented Migratory Children With Prior Secondary School Records in the Same State (§ 200.85(b)(3)(i)(B)(1))

The annualized burden of the requirement for SEAs to collect and submit to MSIX MDEs from the most recent secondary school attended previously within the State is estimated at 26,664 hours per year in total and 533 hours per year for each SEA. Collecting and submitting secondary school information for newly documented migratory children is an ongoing process, and we estimate the burden would remain at a constant level in each of the three years that this information collection covers.

Newly Documented Migratory Children With Secondary School Records From Another State (§ 200.85(b)(3)(i)(B)(2))

The annualized burden of the requirement for SEAs to notify MSIX within 30 days of obtaining out-of-state secondary school records for a newly documented migratory child is estimated at 15,609 hours per year in total and 312 hours per year for each SEA. Our burden estimate includes a one-time effort for each State to modify its State data system and MSIX interface to collect and submit a new MDE to indicate whether or not out-of-state school records are present at an LEA for a migrant student (this one-year effort is amortized over the three years of the collection). Documenting migratory children is an ongoing process, and the burden remains at a constant level in each of the three years that this information collection covers.

End of Term Submissions (§ 200.85(b)(3)(ii))

The annualized burden of the requirement to collect and submit updated and newly available MDEs to MSIX within 30 days after the end of each educational term for all eligible MEP children is estimated at 291,278 hours per year in total and 5,826 hours per year per SEA. This is an ongoing process, and the burden remains at a constant level in each of the three years that this information collection covers.

Notice of Change of Residence Submissions (§ 200.85(b)(3)(iii))

The annualized burden of the requirement to collect and submit to MSIX all new and updated MDEs within four working days of receiving notification from MSIX that a migratory child has changed residence is estimated at 1,194 hours per year in total and 24 hours per year per SEA. This is an ongoing process, and we estimate the burden would remain at a constant level in each of the three years that this information collection covers.

Parental Request to SEAs for MSIX Data Correction (§ 200.85(e)(1)(ii))

The annualized burden for SEAs to submit revised data to MSIX within four working days of the decision to correct previously submitted data following a request from a parent, guardian, or student is estimated at 31 hours per year in total and .06 hours per year per SEA. This is an ongoing process, and we estimate the burden would remain at a constant level in each of the three years that this information collection covers.

Parental Request to the Department for MSIX Data Correction (§ 200.85(e)(3))

The annualized burden for SEAs to respond within 10 working days to a request from the Department for information needed by the Department to respond to an individual's request to correct or amend a Consolidated Migrant Student Record under the Federal Privacy Act is estimated at four hours per year in total and 0.1 hour per year per SEA. This is an ongoing process, and we estimate the burden would remain at a constant level in each of the three years that the information collection covers.

COLLECTION OF INFORMATION

Reporting activity	Description	Total burden
1. Start-up Data Submission § 200.85(b)(2)(i)	Collect and submit to MSIX MDEs (applicable to child's age and grade level) for every migrant child whom the SEA considered eligible for MEP services within one year preceding the effective date of the regulations.	21,651
2. Newly Documented Migratory Children § 200.85(b)(3)(i)(A)	Collect and submit to MSIX all MDEs (applicable to child's age and grade level) for newly documented migrant students.	109,435
3. Newly Documented Migratory Children with Secondary School Records in the Same State § 200.85(b)(3)(i)(B)(1).	Collect and submit all applicable MDEs from the most recent secondary school previously attended by the student within the same State.	26,664
4. Newly Documented Migratory Children with Secondary School Records from Another State § 200.85(b)(3)(i)(B)(2).	Notify MSIX if one of its local operating agencies obtains records from a secondary school previously attended by the migrant student in another State.	15,609
5. End of Term Submissions § 200.85(b)(3)(ii)	Collect and submit to MSIX all MDE updates and newly available MDEs for migratory children who were eligible for the MEP during the term and for whom the SEA previously submitted data.	291,278
6. Change of Residence Submissions § 200.85(b)(3)(iii)	Collect and submit to MSIX all newly available MDEs and MDE updates that have become available to the SEA or one of its local operating agencies.	1,194
7. Parental Request for MSIX Data Correction § 200.85(e)(1)(ii).	If an SEA determines that data previously submitted to MSIX should be corrected as the result of a request from a parent, guardian, or migrant student, the SEA must submit revised data.	31
8. Response to the Department § 200.85(e)(3)	Submit information requested by the Department needed to respond to an individual's request to amend a record under the Privacy Act.	4

If you want to comment on the proposed information collection requirements, please send your comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for U.S. Department of Education. Send these comments by email to *OIRA_DOCKET@omb.eop.gov* or by fax to (202) 395–6974. You may also send a copy of these comments to the Department contact named in the **ADDRESSES** section of this preamble or submit them electronically through the Federal eRulemaking Portal at *www.regulations.gov* by selecting Docket ID number ED–2013–ICCD–0154.

We have prepared an ICR for this collection. In preparing your comments you may want to review the ICR, which is available at *www.reginfo.gov*. Click on Information Collection Review. This proposed collection is identified as proposed collection [1810–0683 ED–2013–ICCD–0154].

We consider your comments on this proposed collection of information in—

- Deciding whether the proposed collection is necessary for the proper performance of our functions, including whether the information will have practical use;
- Evaluating the accuracy of our estimate of the burden of the proposed collection, including the validity of our methodology and assumptions;
- Enhancing the quality, usefulness, and clarity of the information we collect; and
- Minimizing the burden on those who must respond. This includes exploring the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, to ensure that OMB gives your comments full

consideration, it is important that OMB receives your comments by January 27, 2014. This does not affect the deadline for your comments to us on the proposed regulations.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Assessment of Educational Impact

In accordance with section 411 of the General Education Provisions Act, 20 U.S.C. 1221e–4, the Secretary particularly requests comments on whether these proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Federalism

Executive Order 13132 requires us to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. "Federalism implications" means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The proposed regulations in § 200.85 may have federalism implications. We encourage State and local elected officials to review and provide comments on these proposed regulations.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT.**

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department. (Catalog of Federal Domestic Assistance Number 84.011: Title I, Education of Migrant Children.)

List of Subjects in 34 CFR Part 200

Education of disadvantaged, Elementary and secondary education, Grant programs-education, Indians-education, Infants and children, Juvenile delinquency, Migrant labor, Private schools, Reporting and recordkeeping requirements.

Dated: December 13, 2013.

Arne Duncan,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary of Education proposes to amend part 200 of title 34 of the Code of Federal Regulations as follows:

PART 200—TITLE I—IMPROVING THE ACADEMIC ACHIEVEMENT OF THE DISADVANTAGED

■ 1. The authority citation for part 200 continues to read as follows:

Authority: 20 U.S.C 6301 through 6578, unless otherwise noted.

■ 2. Section 200.81 is amended by:

■ A. Redesignating paragraphs (h) through (k) as paragraphs (m) through (p).

■ B. Redesignating paragraph (g) as paragraph (j).

■ C. Redesignating paragraphs (d) through (f) as paragraphs (f) through (h).

■ D. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively.

■ E. Adding new paragraphs (b), (e), (i), (k), and (l).

The additions read as follows:

§ 200.81 Program definitions

* * * * *

(b) *Consolidated Migrant Student Record* means the MDEs for a migratory child that have been submitted by one or more SEAs and consolidated into a single, uniquely identified record available through MSIX.

* * * * *

(e) *Migrant Student Information Exchange (MSIX)* means the nationwide system administered by the Department for linking and exchanging specified health and educational information for all migratory children.

* * * * *

(i) *Minimum Data Elements (MDEs)* means the health and educational information for migratory children that the Secretary requires each SEA that receives a grant of MEP funds to collect, maintain, and submit to MSIX, and use under this part. MDEs may include—

(1) Immunization records and other health information;

(2) Academic history (including partial credit, credit accrual, and results from State assessments required under the Elementary and Secondary Education Act);

(3) Other academic information essential to ensuring that migratory children achieve to high academic standards; and

(4) Information regarding eligibility for services under the Individuals with Disabilities Education Act.

* * * * *

(k) *MSIX Interconnection Agreement* means the agreement between the Department and a State educational agency that governs the interconnection of the State student records system and MSIX, including the terms under which the agency will abide by the agreement based upon its review of all relevant technical, security, and administrative issues.

(l) *MSIX Interconnection Security Agreement* means the agreement between the Department and a State educational agency that specifies the technical and security requirements for establishing, maintaining, and operating the interconnection between the State student records system and MSIX. The MSIX Interconnection Security Agreement supports the MSIX Interconnection Agreement and documents the requirements for connecting the two information technology systems, describes the security controls to be used to protect the systems and data, and contains a topological drawing of the interconnection.

* * * * *

■ 3. Section 200.84 is revised to read as follows:

§ 200.84 Responsibilities for evaluating the effectiveness of the MEP and using evaluations to improve services to migratory children.

(a) Each SEA must determine the effectiveness of its MEP through a written evaluation that measures the implementation and results achieved by the program against the State's performance targets in § 200.83(a)(1), particularly for those students who have

priority for service as defined in section 1304(d) of the ESEA.

(b) SEAs and local operating agencies receiving MEP funds must use the results of the evaluation carried out by an SEA under paragraph (a) of this section to improve the services provided to migratory children.

(Authority: 20 U.S.C. 6394)

■ 4. Section 200.85 is revised to read as follows:

§ 200.85 Responsibilities of SEAs for the electronic exchange through MSIX of specified health and educational information of migratory children.

(a) *MSIX State record system and data exchange requirements.* In order to receive a grant of MEP funds, an SEA must collect, maintain, and submit to MSIX MDEs and otherwise exchange and use information on migratory children in accordance with the requirements of this section. Failure of an SEA to do so constitutes a failure under section 454 of the General Education Provisions Act, 20 U.S.C. 1234c, to comply substantially with a requirement of law applicable to the funds made available under the MEP.

(b) *MSIX data submission requirements*—(1) *General.* In order to satisfy the requirements of paragraphs (b)(2) and (3) of this section, an SEA that receives a grant of MEP funds must submit electronically to MSIX the MDEs applicable to the child's age and grade level that the Secretary has determined are needed to implement section 1308(b)(2) of the ESEA.

(2) *Start-up data submissions.* (i) No later than 90 calendar days after [EFFECTIVE DATE OF FINAL RULE], an SEA must collect and submit to MSIX each of the MDEs described in paragraph (b)(1) of this section applicable to the child's age and grade level for every migratory child whom the SEA considered eligible for MEP services in accordance with § 200.89(c) within one year preceding the effective date of the final regulations.

(ii) An SEA must make start-up data submissions to MSIX for a migratory child whether or not the SEA has a current Certificate of Eligibility under § 200.89(c) for the child at the time the SEA submits the data to MSIX under this paragraph (b)(2).

(3) *Subsequent data submissions.* An SEA must comply with the following timelines for subsequent data submissions throughout the entire calendar year whether or not local operating agencies or LEAs in the State are closed for summer or intersession periods.

(i) *Newly documented migratory children.* For every migratory child for whom an SEA documents eligibility for the MEP under § 200.89(c) on or after the effective date of these regulations—

(A) An SEA must collect and submit to MSIX the MDEs described in paragraph (b)(1) of this section within ten working days of documenting the child's eligibility. The SEA is not required to collect and submit MDEs in existence before its documentation of the child's eligibility for the MEP except as provided in paragraph (b)(3)(i)(B) of this section; and

(B) An SEA that documents the eligibility of a secondary school-aged migratory child must also—

(*1*) Collect and submit to MSIX MDEs from the most recent secondary school in that State attended previously by the newly documented migratory child; and

(*2*) Notify MSIX within 30 calendar days if one of its local operating agencies obtains records from a secondary school attended previously by the newly documented migratory child in another State.

(ii) *End of term submissions.* (A) Within 30 calendar days of the end of an LEA's or local operating agency's fall, spring, summer, or intersession terms, an SEA must collect and submit to MSIX all MDE updates and newly available MDEs for migratory children who were eligible for the MEP during the term and for whom the SEA submitted data previously under paragraph (b)(2) or (b)(3)(i) of this section.

(B) When a migratory child's MEP eligibility expires before the end of a school year, an SEA must submit all MDE updates and newly available MDEs for the child through the end of the school year in which the child is enrolled. This submission includes all MDE updates and newly available MDEs for any child who continues to receive MEP services under section 1304(e) of the ESEA after expiration of MEP eligibility.

(iii) *Change of residence submissions.* (A) Within four working days of receiving notification from MSIX that a migratory child in its State has changed residence to a new local operating agency within the State or has been newly documented as a migratory child in another State, an SEA must collect and submit to MSIX all new MDEs and MDE updates that have become available to the SEA or one of its local operating agencies since the SEA's last submission of MDEs to MSIX for the child.

(B) An SEA or local operating agency that does not have a new MDE or MDE update for a migratory child when it receives a change of residence notification from MSIX must submit the MDE to MSIX within four working days of the date that the SEA or one of its local operating agencies obtains the MDE.

(c) *Use of Consolidated Migrant Student Records.* In order to help ensure proper participation in the MEP, school enrollment, grade and course placement, and accrual of all appropriate high school credits, each SEA that receives a grant of MEP funds must—

(1) Use, and require each of its local operating agencies to use, the Consolidated Migrant Student Record for all migratory children who have changed residence to a new school district within the State or in another State;

(2) Encourage LEAs that are not local operating agencies receiving MEP funds to use the Consolidated Migrant Student Record for all migratory children described in paragraph (c)(1) of this section; and

(3) Establish procedures, develop and disseminate guidance, and provide training in the use of Consolidated Migrant Student Records to SEA, local operating agency, and LEA personnel who have been designated by the SEA as authorized MSIX users under paragraph (f)(2) of this section.

(d) *MSIX data quality.* Each SEA that receives a grant of MEP funds must—

(1) Use, and require each of its local operating agencies to use, reasonable and appropriate methods to ensure that all data submitted to MSIX are accurate and complete; and

(2) Respond promptly, and ensure that each of its local operating agencies responds promptly, to any request by the Department for information needed to meet the Department's responsibility for the accuracy and completeness of data in MSIX in accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(6) and (g)(1)(C) or (D).

(e) *Procedures for MSIX data correction by parents, guardians, and migratory children.* Each SEA that receives a grant of MEP funds must establish and implement written procedures that allow a parent or guardian of a migratory child, or a migratory child, to ask the SEA to correct or determine the correctness of MSIX data. An SEA's written procedures must meet the following minimum requirements:

(1) *Response to parents, guardians, and migratory children.* (i) Within 30 calendar days of receipt of a data correction request from a parent, guardian, or migratory child, an SEA must—

(A) Send a written or electronic acknowledgement to the requester;

(B) Investigate the request;

(C) Decide whether to revise the data as requested; and

(D) Send the requester a written or electronic notice of the SEA's decision.

(ii) If an SEA determines that data it submitted previously to MSIX should be corrected, the SEA must submit the revised data to MSIX within four working days of its decision to correct the data. An SEA is not required to notify MSIX if it decides not to revise the data as requested.

(iii)(A) If a parent, guardian, or migratory child asks an SEA to correct or determine the correctness of data that was submitted to MSIX by another SEA, within four working days of receipt of the request, the SEA must send the data correction request to the SEA that submitted the data to MSIX.

(B) An SEA that receives an MSIX data correction request from another SEA under this paragraph must respond as if it received the data correction request directly from the parent, guardian, or migratory child.

(2) *Response to SEAs.* An SEA or local operating agency that receives a request for information from an SEA that is responding to a parent's, guardian's, or migratory child's data correction request under paragraph (e)(1) of this section must respond in writing within ten working days of receipt of the request.

(3) *Response to the Department.* An SEA must respond in writing within ten working days to a request from the Department for information needed by the Department to respond to an individual's request to correct or amend a Consolidated Migrant Student Record under the Privacy Act of 1974, as amended, 5 U.S.C. 552a(d)(2) and 34 CFR 5b.7.

(f) *MSIX data protection.* Each SEA that receives a grant of MEP funds must—

(1) Enter into and carry out its responsibilities in accordance with an MSIX Interconnection Agreement, an MSIX Interconnection Security Agreement, and other information technology agreements required by the Secretary in accordance with applicable Federal requirements;

(2) Establish and implement written procedures to protect the integrity, security, and confidentiality of Consolidated Migrant Student Records, whether in electronic or print format, through appropriate administrative, technical, and physical safeguards established in accordance with the MSIX Interconnection Agreement and MSIX Interconnection Security Agreement. An SEA's written procedures must include, at a minimum, reasonable methods to ensure that—

(i) The SEA permits access to MSIX only by authorized users at the SEA, its local operating agencies, and LEAs in the State that are not local operating agencies but where a migratory child has enrolled; and

(ii) The SEA's authorized users obtain access to and use MSIX records solely for authorized purposes as described in paragraph (c) of this section;

(3) Require all authorized users to complete the User Application Form approved by the Secretary before providing them access to MSIX. An SEA may also develop its own documentation for approving user access to MSIX provided that it contains the same information as the User Application Form approved by the Secretary; and

(4) Retain the documentation required for approving user access to MSIX for three years after the date the SEA terminates the user's access.

(Approved by the Office of Management and Budget under control number 1810–0683)

(Authority: 20 U.S.C. 6398)

[FR Doc. 2013–30260 Filed 12–26–13; 8:45 am]

BILLING CODE 4000–01–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 249 December 27, 2013

Part V

Department of Homeland Security

Coast Guard

33 CFR Part 1

Assessment Framework and Organizational Restatement Regarding Preemption for Certain Regulations Issued by the Coast Guard; Proposed Rule

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 1

[Docket No. USCG–2008–1259]

RIN 1625–AB32

Assessment Framework and Organizational Restatement Regarding Preemption for Certain Regulations Issued by the Coast Guard

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to issue a rule containing its assessment framework for, and restating its position regarding, the federalism implications of regulations issued under the authority of various statutes within Titles 33 and 46 of the United States Code. This notice requests comments on the proposal and, pursuant to Executive Order 13132, invites State and local governments to consult during its development.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before March 27, 2014, or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments, identified by Coast Guard docket number USCG–2008–1259, using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these methods. For instructions on submitting comments, see the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Lieutenant Commander Lineka Quijano, Office of Maritime and International Law, Coast Guard, telephone 202–372–3865. If you have questions on viewing or submitting material to the docket, call Ms. Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–1259), indicate the specific section of this document to which each comment applies, and provide the reason for each suggestion or recommendation. You may submit your comments and material online, or by fax, mail, or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, select the Advanced Docket Search option on the right side of the screen, insert "USCG–2008–1259" in the Docket ID box, press Enter, and then click on the balloon shape in the Actions column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, click on "Search for Dockets," insert the docket number for this rulemaking (USCG–2008–1259) in the Docket ID box, press Enter, and then click on the item in the Docket ID column. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

C. Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

D. Public Meeting

We do not now plan to hold a public meeting. However, you may submit a request for a public meeting to the Docket Management Facility at the address under **ADDRESSES**, explaining why one would be beneficial. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

II. Abbreviations

APPS Act to Prevent Pollution from Ships
CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive Order
FR Federal Register
MARPOL International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978
NEPA National Environmental Policy Act
PTSA Port and Tanker Safety Act of 1978
PWSA Ports and Waterways Safety Act of 1972
SMS Safety Management System
U.S.C. United States Code

III. Background and Purpose

A. Background

Courts have consistently upheld and reinforced the preemptive effect of Federal regulations for maritime vessels. See, *e.g., Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1 (1824); *Sinnot* v. *Davenport*, 63 U.S. (22 How.) 227 (1859); *Moran* v. *New Orleans*, 112 U.S. 69 (1884); *Kelly* v. *Washington ex rel Foss Co.*, 302 U.S. 1 (1937); *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978); *U.S.* v. *Locke*, 529 U.S. 89 (2000). As the U.S. Supreme Court recently explained, the "authority of Congress to regulate interstate navigation, without embarrassment from intervention of the separate States and resulting difficulties with foreign nations, was cited in the Federalist Papers as one of the reasons for adopting the Constitution. *E.g.*, The Federalist Nos. 44, 12, 64. In 1789, the First Congress enacted a law by which vessels with a federal certificate were entitled to 'the benefits granted by any law of the United States.' Act of Sept. 1, 1789, ch. 11, § 1, 1 Stat. 55." *Locke*, 529 U.S. at 99.

The Coast Guard is one of the primary Federal agencies responsible for the promulgation, implementation, and enforcement of Federal maritime regulations, including the implementation of international shipping treaties to which the United States is a party. The Coast Guard has asserted in the past and believes today that consistent standards of universal application and enforcement, coupled with Federal initiatives to meet unique regional concerns, best meet local and national safety and environmental goals with the least disruption to maritime commerce. To that end, the Coast Guard in the past has relied on development of case law and compliance with Congressional intent to ensure that, where appropriate, the preemptive impact of Federal vessel regulations is preserved.

In light of recent Federal cases and the Presidential Memorandum on Preemption issued on May 20, 2009, the Coast Guard believes that a clear agency statement of the preemptive impact of our regulations, particularly those regulations issued prior to the promulgation of Executive Order 13132, Federalism, can be of great benefit to State and local governments, the public, and regulated entities. Therefore, the Coast Guard intends to revise its assessment framework and issue a general restatement of preemption, coupled with specific statements regarding regulations issued under the authority of statutes with preemptive effect, including, among others, the Ports and Waterways Safety Act (PWSA) of 1972, as amended (33 U.S.C. 1223 *et. seq.)*. The Coast Guard proposes to add subpart 1.06 to Title 33 of the Code of Federal Regulations to allow easy access to this assessment framework and organizational restatement by interested persons and parties.

B. General Preemption Principles

Preemption of State law has its basis in the Supremacy Clause of the U.S. Constitution, Article VI, clause 2. The U.S. Supreme Court has determined that three general theories of preemption apply in the context of the regulation of vessels. First, express preemption applies when Congress, by an express statement, specifically precludes State regulation in a given area. The prohibition against State pilotage regulations for coastwise vessels found at 46 U.S.C. 8501 is an example of express preemption, as is the prohibition against State regulation of Great Lakes pilotage found at 46 U.S.C. 9306.

Second, field preemption applies when the Federal regulatory regime pervades a specific area of regulation to the extent that courts conclude that Congress has left no room for State regulation. Even in the absence of an express statement by the Coast Guard or the promulgation of regulations, State rules are preempted where Congress has intended to occupy the field. Thus, a State may not regulate in areas found to be field preemptive. For example, 46 U.S.C. 3703 lists several fields of regulation, including the design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of tank vessels, for which State action is preempted, regardless of whether the Coast Guard has issued particular regulations in that field.

Third, conflict preemption, which in the maritime regulation context is somewhat different from traditional conflict analysis jurisprudence, applies in cases where the Coast Guard has regulated, or affirmatively decided not to regulate, on a particular subject and a State attempts to regulate on the same subject. Factors to consider in determining whether the regulations are within the same subject include whether the State regulation conflicts with Federal law, whether compliance with both the State law and Federal law is impossible, and whether State law stands as an obstacle to the accomplishment of the full purpose of the Federal law. The Coast Guard believes that nearly all regulations currently issued under the authority of 33 U.S.C. 1231 have preemptive effect under a conflict preemption analysis.

Pursuant to Executive Order 13132, the Coast Guard must, to the extent practicable, publish federalism summary impact statements regarding any regulation that has federalism implications and that preempts State law. In the past, the Coast Guard issued federalism statements indicating that certain preemptive regulations had no federalism implications. Although these regulations were based on authorities that clearly expressed Congress' preemptive intent, the Coast Guard did not describe as clearly as it could have the full nature of the preemption. This practice was consistent with the Coast Guard's view that the regulations did not have any new federalism implications; rather they simply reflected a long standing federalism position in regard to maritime regulation. This proposed regulation seeks to make the Coast Guard's view of the preemptive impact of certain regulations more obvious. The Coast Guard's view is that the intent of Congress to preempt is so clear in express preemption and numerous PWSA situations that the Coast Guard has no discretion in the matter; the

agency was merely fulfilling the direction of Congress consistent with the Supremacy Clause of the U.S. Constitution and therefore did not believe that more particular federalism statements were required. However, in light of recent Federal cases signaling that more explicit preemption statements are instructive and helpful, and in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009, the Coast Guard proposes to clarify and restate the preemptive impact of its regulations. We welcome comments from the public on this proposal.

IV. Discussion of Proposed Rule

A. Preemption Analysis for the PWSA

As amended by the Port and Tanker Safety Act of 1978 (PTSA), the PWSA contains two Titles. Title I authorizes the Coast Guard to promulgate regulations to implement measures for controlling vessel traffic or for protecting navigation and the marine environment. 33 U.S.C. 1223(a)(1). Title II requires the Coast Guard to promulgate regulations addressing the design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification and manning of vessels. 46 U.S.C. 3703(a). With the enactment of 46 U.S.C. Chapter 37 into positive law (Pub. L. 98–89, 97 Stat. 521 (1983)), the distinction between the two titles has legally disappeared. However, reference to Title I and II makes a convenient analytical tool still used by both the courts and the Coast Guard to conduct preemption analyses of regulations issued under these authorities. The Coast Guard will continue to refer to both Titles I and II in this rulemaking and future federalism statements implicating the PWSA.

B. Preemption Restatement for PWSA Title I

In the *Ray* and *Locke* cases cited in section III.A. of this preamble, the U.S. Supreme Court held that the relevant inquiry under Title I of the PWSA, with respect to a State's power to impose navigational operating rules, is whether the Coast Guard has promulgated its own requirement on the subject or has decided that no such requirement should be imposed at all. *Ray,* 431 U.S. 171–172; *Locke,* 529 U.S. 108–110. In such cases, the Coast Guard's regulation, or decision that no regulation should be promulgated, must be given preemptive effect over State laws addressing the same or similar subject matter, even when those State laws are not otherwise inconsistent with Federal law. Where the Coast Guard has neither promulgated its own regulation nor made a determination that no regulation should be promulgated, a State may regulate, so long as the regulation is based on the peculiarities of local waters that call for special precautionary measures.

With these conflict preemption principles in mind, the Coast Guard reiterates its position that any regulations issued under the authority of PWSA Title I are intended to have preemptive impact over State law covering the same subject matter in the same geographic area (as delimited in the Federal regulation), unless the Coast Guard states otherwise in the preamble to the final rule in question.

One exception to the general preemption restatement articulated above is for the enforcement of Coast Guard safety and security zones promulgated under the authority of PWSA Title I by State or local officers. In 46 U.S.C. 70118, Congress specifically authorized State law enforcement officers to enforce Coast Guard safety and security zones. This statute is implemented by the Coast Guard through memoranda of agreement with State and local law enforcement agencies. As such, the Coast Guard's view is that enforcement by State or local officers operating in accordance with a memorandum of agreement between the Coast Guard and the officer's parent agency of safety and security zones promulgated pursuant to PWSA Title I is not preempted.

Another exception to the general preemption restatement articulated above is for State maritime facility regulations that are more stringent than the Coast Guard maritime facility regulations in 33 CFR part 105. State maritime facility regulations will not be preempted so long as these State laws or regulations are more stringent than what is required by 33 CFR part 105 and no actual conflict or frustration of an overriding need for national uniformity exists.

For currently existing rules issued under the authority of PWSA Title I, a listing of Coast Guard determinations regarding preemptive impact is contained in section E, below, and in proposed section 2.1 of the appendix to subpart 1.06. For rules issued after publication of this restatement and assessment framework, the general intentions, presumptions, and policies described above apply, and this rulemaking will be referred to in the Federalism section of the preamble to each final rule published in the **Federal Register**, along with the federalism analysis required pursuant to Executive Order 13132. A statement that the Coast Guard intends to preempt State law (if applicable) will also be included in the codified regulation in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009.

C. Preemption Restatement for PWSA Title II

The *Locke* case reaffirmed the ruling announced in *Ray*. It held that regulations issued pursuant to PWSA Title II concern subjects that are reserved exclusively to the Federal government, as implemented by the Coast Guard. Thus State regulation in the field described in 46 U.S.C. 3703(a) is preempted at all times. This field contains categories regarding the design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of tank vessels. In accordance with these rulings, and to meet the intent of Congress, the Coast Guard's view is that State regulation relating to the aforementioned aspects of tank vessels is field preempted, regardless of whether the Coast Guard has made any regulatory determinations on the subject in question. A listing of regulations already issued under the authority of PWSA Title II, including the applicable Title II category, is provided in section E, below, and in proposed section 2.2 of the appendix to subpart 1.06. For regulations issued under this authority in the future, the preemption restatement and assessment framework described in this paragraph will apply, and this policy will be referred to in the Federalism section of the preamble to each final rule issued under this authority, along with the federalism analysis required pursuant to Executive Order 13132. A statement that the Coast Guard intends to preempt State law will also be included in the codified regulation in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009.

D. Preemption Restatement for PWSA Title I/Title II "Overlap" Regulations

Both the *Locke* and *Ray* Courts recognized that some regulations may not fit cleanly into either Title I of Title II of the PWSA. *Locke,* 529 U.S. at 111–12. For example, a State prohibition on the transit of large tankers through State waters might be subject to a Title I analysis if the prohibition were based on local peculiarities, or a Title II analysis if it were based on a State judgment that large tankers are generally unsafe. In *Locke,* several factors were developed to aid in determining the title in which a particular State regulation should be categorized. *Id.* The Coast Guard also recognizes this potential

ambiguity as to its own regulations and will conduct what the *Locke* Court described as an "overlap analysis" in the promulgation and application of its regulations. While the *Locke* Court used the overlap analysis as a means of categorizing a particular State regulation as either falling under a Title I (generally controlled by conflict preemption principles) or a Title II category (controlled by field preemption principles), the Coast Guard believes the overlap analysis factors described by the *Locke* Court are equally useful in categorizing a particular Federal regulation. In conducting an overlap analysis the following factors, derived from *Locke,* are considered: (1) The type of regulations the Coast Guard has actually promulgated under the applicable Title II specific category, as this may aid in determining the scope of the Title II field, and indicates that State regulation of this specific category is field preempted; (2) whether an identical State regulation would be based on conditions unique to a particular port or waterway (*e.g.*, a Title I regulation is one based on water depth or other local peculiarities); (3) whether an identical State regulation would be of limited extraterritorial effect, not requiring the tank vessel to modify its primary conduct outside the specific body of water purported to justify the local rule; and (4) whether an identical State regulation would pose a minimal risk of innocent noncompliance, would not affect vessel operations outside the jurisdiction, would not require adjustment of systemic aspects of the vessel, and would not impose a substantial burden on the vessel's operation within the local jurisdiction itself. Factors 2 through 4 are indicators that, in the absence of a Federal determination on the subject, an identical State regulation might not be field preempted by Title II, and therefore appropriate for conflict preemption analysis under Title I.

After considering all these factors, the Coast Guard will determine whether the regulation is categorized under Title I or Title II. The Coast Guard determinations as to its existing regulations which may be subject to an "overlap analysis," are listed in section E, below, and in proposed section 2.3 of the appendix to subpart 1.06. Where the Coast Guard has determined that the regulation falls under PWSA Title II, the applicable category is also listed. For regulations issued in the future, this section will apply, and the determinations will be stated in the preamble to the final rule, along with the federalism analysis required pursuant to Executive Order 13132. A statement that the Coast Guard intends to preempt State law will also be included in the codified regulation in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009.

E. Listing of Current Regulations With Preemptive Impact Pursuant to the PWSA

After applying the principles described above, the Coast Guard has determined that by operation of the PWSA, current and future State law is preempted with respect to the following Coast Guard regulations issued under the authorities of Titles I and II of the PWSA:

Title I—33 CFR parts 64, 101, 103, 104, 105 (for State maritime facility laws that are either less stringent or actually conflict with or frustrate an overriding need for national uniformity), 120, 128, 161, 166, 167, 169 and 401.

Title II—with respect to tank vessels only—33 CFR parts 157, 163, and 168. 46 CFR parts 2, 8, 13, 15, 30, 31, 32, 34, 35, 36, 38, 39, 50, 52, 53, 54, 56, 57, 58, 59, 61, 62, 63, 64, 98, 105, 110, 111, 112, 113, 150, 151, 153, 154, 159, 160, 161, 162, 163, 164, 170, 172, 174, 175, 178, 179, and 199.

Some Coast Guard regulations are grounded in, and issued under the authority of, both titles of the PWSA. Using the overlap analysis described above, the Coast Guard has made the following determinations:

In 33 CFR part 155, the following sections are grounded in Title II authority, and cover fields that are foreclosed from regulation by a State: 155.100 through 155.1030, 155.1055 through 155.1060, 155.1110 through 155.1120, and 155.1135 through 155.1150.

In 33 CFR part 156, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 156.118, 156.215, 156.220, 156.230, 156.300 and 156.310. In 33 CFR part 156, the following sections are grounded in Title II authority, and cover fields that are foreclosed from regulation by a State: 156.100 through 156.115, 156.120 through 156.210, 156.225, and 156.320 through 156.330.

In 33 CFR part 160, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 160.1 through 160.7, 160.105 through 160.107, and 160.115 through 160.215. In 33 CFR part 160, the following regulations as applied to tank vessel operations are grounded in Title II, and cover fields that are foreclosed from regulation by a State: 160.101, 160.103, 160.109, 160.111 and 160.113.

In 33 CFR part 162, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 33 CFR 162.1 through 162.40, 162.65 through 162.65(b)(3), 162.65(b)(4)(ii) through 162.65(b)(6), 162.75 through 162.75(b)(5)(iv), 162.75(b)(6) through 162.80(a)(1), 162.80(a)(3) through 162.90(b)(2)(iii), 162.90(b)(2)(vi) through 162.90(b)(3)(iv), 162.90(b)(4)(ii) through 162.117(h)(2), 162.120 through 162.125(a), 162.125(b)(3) through (5).

In 33 CFR part 162, the following sections are promulgated pursuant to Title II, and cover fields that are foreclosed from regulation by a State: 162.65(b)(4)(i) operation and equipping, 162.75(b)(5)(v) operation and equipping, 162.75(b)(5)(vi) operation, 162.80(a)(2) operation and equipping, 162.90(b)(2)(iv) manning, 162.90(b)(2)(v) operation, 162.90(b)(4)(i) operation and equipping, 162.117(h)(3) and (4) operation, 162.255(e)(1) and (2) operation and equipping, and 162.255(e)(3) operation.

In 33 CFR part 164, the following sections are promulgated under Title I and therefore preempt any similar, identical or contrary State regulation: 33 CFR 164.01, 164.02, 164.03, 164.11(c), 164.11(e), 164.11(f)–(i), 164.11(k)–(n), 164.11(p), 164.11(q), 164.19(b), 164.19(c), 164.51, 164.53, 164.55, 164.61, 164.70, 164.78(a)(3)–(8) and 164.82(c). The following sections are grounded in Title II authority, and cover fields that are foreclosed from regulation by a State: 33 CFR 164.11(b), 164.11(d), 164.11(j), 164.11(o), 164.11(r) through 164.19(a), 164.25 through 164.46, 164.72 through 164.78(a)(2), and 164.78(b) through 164.82(b).

In 33 CFR part 165, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 165.1 through 165.150(b)(4), 165.150(b)(6) through 165.501(d)(2), 165.501(d)(4) through 165.501(d)(5), 165.501(d)(7) through 165.510(d), 165.510(f)(1) through 165.510(f)(3), 165.510(f)(9) through 165.540(f)(6), 165.540(f)(9) through 165.803(e)(2), 165.803(g) through 165.810(e), 165.810(f)(2), 165.811(a) through 165.811(c), 165.811(e) through 165.923(b)(2)(ii)(D), 165.923(b)(2)(ii)(F) through 165.1152(d)(1), 165.1152(d)(3) through 165.1181(d)(1), 165.1181(d)(3) through 165.1704(c)(1), 165.1704(c)(3) through 165.1704(c)(5), and 165.1706 through 165.2030.

The following sections in 33 CFR part 165 are grounded in Title II, and cover

fields that are foreclosed from regulation by a State: 165.150(b)(5) manning, 165.501(d)(3)(i)–(ii) and (6) equipping, 165.510(e) operation, 165.510(f)(4) operation, 165.510(f)(5) manning, 165.510(f)(6) operation, 165.510(f)(7) and (8) equipping, 165.540(f)(7) and (8) equipping, 165.803(e)(3) and (4) equipping, 165.803(f)(1)–(3) equipping, 165.810(f)(1) manning, 165.810(f)(3) equipping, 165.811(d) equipping, 165.923(b)(2)(ii)(E) equipping, 165.1152(d)(2) operation, 165.1181(d)(2) operation, and 165.1704(c)(2) and (6) equipping.

F. Preemption Restatement and Assessment Framework for Regulations Issued Under the Authority of 46 U.S.C. Chapter 32

Chapter 32 of Title 46, U.S. Code, describes the regime of regulation for certain vessels that must comply with the International Safety Management Code that is found in Chapter IX of the Annex to the International Convention for the Safety of Life at Sea, 1974, as amended (SOLAS). This regime requires that certain vessels create and implement a Safety Management System (SMS) and carry onboard and maintain a proper certificate issued by the Coast Guard reflecting a current SMS. 46 U.S.C. 3203 requires the Coast Guard to issue regulations which mandate the implementation of an SMS to which the Chapter applies which identifies: (1) A safety and environmental protection policy; (2) instructions and procedures to ensure the safe operation of those vessels and protection of the environment in compliance with international and United States law; (3) defined level of authority and lines of communications between, and along, personnel on shore and on the vessel; (4) procedures for reporting accidents and nonconformities with 46 U.S.C. Chapter 32; (5) procedures for preparing for and responding to emergency situations; and (6) procedures for internal audits and management reviews of the system. This describes a pervasive scheme of safety management for those vessels to which 46 U.S.C. Chapter 32 applies. Such a pervasive scheme, coupled with the strong mandate that the Coast Guard "shall prescribe regulations," considered in light of the significant Congressional interest to create a uniform maritime regulatory regime, suggests that Congress intended to fill the field related to SMS on all vessels to which 46 U.S.C. Chapter 32 applies, and to any other vessels Congress has made subject to Coast Guard SMS regulation. *See Locke*, 529 U.S. 113–116.

Therefore, the Coast Guard's view is that the field of vessel safety management is foreclosed from State regulation by 46 U.S.C. Chapter 32, regardless of whether the Coast Guard has issued regulations on the subject or not, and regardless of the existence of conflict between the State and Coast Guard regulation. A listing of current Coast Guard regulations issued pursuant to this authority is provided in section G, below, and in proposed section 3 of the appendix to subpart 1.06. For future regulations issued under this authority, the Coast Guard will cite to this rulemaking in the preamble to the final rule, and will conduct the federalism analysis required pursuant to Executive Order 13132. A statement that the Coast Guard regulations are in a field foreclosed from State regulation will also be included in the codified regulation in accordance with the Presidential Memorandum on preemption issued on May 20, 2009.

G. Regulations Issued Pursuant to 46 U.S.C. Chapter 32

All of the regulations in 33 CFR part 96 have been prescribed under the authority of 46 U.S.C. Chapter 32, and cover fields that are foreclosed from regulation by a State.

H. Preemption Restatement and Assessment Framework for Regulations Issued Under the Authority of 46 U.S.C. Chapter 33

Chapter 33 of Title 46, U.S. Code, describes the regime of regulation for vessels "subject to inspection" by the U.S. Coast Guard. Vessels "subject to inspection" is a term of art developed by Congress. It refers to various types of vessels listed in 46 U.S.C. 3301 subject to a comprehensive, pervasive regime of Federal regulation. By contrast, "uninspected vessels," such as most commercial fishing vessels and recreational vessels, are subject to Coast Guard regulation, but under a much less comprehensive and prescriptive scheme of Federal regulation. The U.S. Supreme Court has long recognized the field preemptive impact of the Federal regulatory regime for inspected vessels. See, *e.g.*, *Kelly* v. *Washington ex rel Foss*, 302 U.S. 1 (1937) and *Locke*, 529 U.S. 113–116. Therefore the Coast Guard's view is that the regulatory regime created by 46 U.S.C. 3306 in the areas of design, construction, alteration, repair, operation, superstructures, hulls, fittings, equipment, appliances, propulsion machinery, auxiliary machinery, boilers, unfired pressure vessels, piping, electric installations, accommodations for passengers and crew, sailing school instructors, sailing school students, lifesaving equipment and its use, firefighting equipment, its use and precautionary measures to guard against fire, inspections and tests related to these areas and the use of vessel stores and other supplies of a dangerous nature covers fields that are foreclosed from regulation by a State. These fields are foreclosed from State regulation regardless of whether the Coast Guard has issued a particular regulation on the subject or not, and regardless of the existence of conflict between the State and Coast Guard regulation. A listing of current Coast Guard regulations issued pursuant to this authority is provided in section I, below, and in proposed section 4 of the appendix to subpart 1.06. For future regulations issued under this authority, the Coast Guard will cite to this preemption statement in the preamble to the final rule, and will conduct the federalism analysis required pursuant to Executive Order 13132. A statement that the Coast Guard regulations are in a field foreclosed from State regulation will also be included in the codified regulation in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009.

I. Regulations Issued Pursuant to 46 U.S.C. Chapter 33

The following regulations issued pursuant to 46 U.S.C. Chapter 33 cover fields that are foreclosed from regulation by a State: 46 CFR parts 70, 71, 76, 78, 90–93, 95–98, 105, 107–108, 110–122, 125–134, 147, 147A, 148, 150–151, 153–154, 159–164, 166–169, 170–174, 175–185, 188–190, 193–196, and 199.

J. Preemption Restatement and Assessment Framework for Regulations Issued Under the Authority of 46 U.S.C. 3717 and 6101

Section 5 of the PTSA provides that "the Secretary shall establish a marine safety information system" for tank vessels. 46 U.S.C. 3717 requires that, among other data, the marine safety information system shall include the name of each person with an ownership interest in the vessel, details of compliance with financial responsibility requirements of applicable laws or regulations, registration information (including all changes in the name of the vessel), and a record of all inspections and examinations conducted under 46 U.S.C. 3714.

46 U.S.C. 6101 states that "The Secretary shall prescribe regulations on the marine casualties to be reported and the manner of reporting." The statute requires, among other things, the reporting of the death of an individual, serious injury to an individual, material

loss of property, material damage affecting the seaworthiness or efficiency of the vessel, and significant harm to the environment.

The Supreme Court has held that "Congress intended that the Coast Guard regulations be the sole source of a vessel's reporting obligations . . . ." and that Coast Guard regulations promulgated pursuant to the authority of 46 U.S.C. 3717 and 6101 were not intended by Congress "to be cumulative to those enacted by each political subdivision whose jurisdiction a vessel enters." *Locke*, 529 U.S. 115–116. Therefore, the Coast Guard's view is that regulations issued under the authority of 46 U.S.C. 3717 as part of a marine safety information system and under 46 U.S.C. 6101 for marine casualty reporting requirements cover fields foreclosed from regulation by a State. These fields are foreclosed from State regulation regardless of whether the Coast Guard has issued regulations on the subject or not, and regardless of the existence of conflict between the State and Coast Guard regulation. A listing of current Coast Guard regulations issued pursuant to this authority is provided in section K, below, and in proposed section 5 of the appendix to subpart 1.06. For future regulations issued under this authority, the Coast Guard will cite to this preemption statement in the preamble to the final rule, and will conduct the federalism analysis required pursuant to Executive Order 13132. A statement that the Coast Guard regulations are in a field foreclosed from State regulation will also be included in the codified regulation in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009.

K. Regulations Issued Pursuant to 46 U.S.C. 3717 and 6101

The following regulations issued pursuant to 46 U.S.C. 3717 and 6101 cover fields that are foreclosed from regulation by a State: 33 CFR 151.15, 151.26(b)(3), 153.203, 155.1035(b), 164.61, part 173 subpart C; 46 CFR 4.05–1 through 4.05–10, 35.15–1, 197.484 through 197.488, and 401.260.

L. Preemption Restatement and Assessment Framework for Regulations Issued Under the Act To Prevent Pollution From Ships, 33 U.S.C. 1901–1912

The Act to Prevent Pollution from Ships (APPS) is the domestic law implementing the "International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto," otherwise referred to as MARPOL 73/78 or MARPOL. To the extent an international agreement creates a standard that is embodied in Coast Guard regulations or is formally recognized by the Coast Guard as applicable pursuant to domestic law (in this case, APPS), that standard will also preempt a contrary State law. Under international law, an international treaty or agreement is binding on all political subdivisions of the ratifying nation, and a party would not be excused from compliance because of the actions of a political subdivision. Because international agreements reflect the intentions of nation-states, the Supreme Court has emphasized that any concurrent power held by States in fields that are the subject of international agreements is "restricted to the narrowest of limits." *Hines* v. *Davidowitz*, 312 U.S. 52, 68 (1941). Accordingly, whether viewed through the lens of preemption by treaty or interference with the Federal government's exclusive authority to conduct the foreign affairs of the United States, the Supreme Court has repeatedly struck down State laws that conflict with duly promulgated Federal law touching on matters of international concern. See, *e.g.*, *Zschernig* v. *Miller*, 389 U.S. 429 (1968); *United States* v. *Pink*, 315 U.S. 203 (1942); *United States* v. *Belmont*, 301 U.S. 324 (1937). This foreign affairs based preemption analysis is also buttressed by the traditional Congressional recognition of a uniform and consistent pattern of Federal regulation of shipping. The Coast Guard recognizes there are certain and limited express statements of non-preemption related to APPS such as in Section 2003 of Public Law 100–220, among others, which will be considered in any related preemption analysis. A listing of current Coast Guard regulations issued pursuant to this authority is provided in section M, below, and in proposed section 6 of the appendix to subpart 1.06. For future regulations issued under this authority, the Coast Guard will cite to this preemption restatement in the preamble to the final rule, and will conduct the federalism analysis required pursuant to Executive Order 13132. A statement that the Coast Guard intends to preempt State law (if applicable) will also be included in the codified regulation in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009.

M. Regulations Issued Pursuant to 33 U.S.C. 1901–1912

The following regulations issued pursuant to 33 U.S.C. 1901–1912 preempt conflicting, similar, or identical State or local laws or regulations with the exception of State or local laws or regulations specifically permitted by Section 2003 of Public Law 100–220 or other similar express statutory authority: 33 CFR part 151, Subpart A; 33 CFR 155.100 through 155.130, 155.350 through 155.400, 155.430, 155.440, 155.470, 155.1030(j) and (k), 155.1065(g), and all the regulations in 33 CFR part 157.

N. Preemption Restatement and Assessment Framework for Regulations Issued Under Authorities Not Described Above

Other regulations issued by the Coast Guard after the effective date of the final rule may have preemptive impact. In such cases, the Coast Guard's view is that such regulations, in order to more fully address the requirements of Executive Order 13132, will also in their preamble contain a preemption analysis that states the legal rationale for concluding whether the regulation has preemptive impact. A statement that the Coast Guard intends to preempt State law (if applicable) will also be included in the codified regulation in accordance with the Presidential Memorandum on Preemption issued on May 20, 2009. For regulations that are currently issued and not specifically addressed in this proposed Assessment Framework and Organization Restatement of Preemption, the preemptive analysis and principles recited herein will be used to determine any preemptive effect, unless there are specific preemption exceptions applicable to the particular statute or regulations in question. The absence of an express preemptive statement in a regulation or rule preamble is not determinative of the preemptive impact of the regulation, considering that the true preemptive intent of the regulation is reflected in the underlying Congressional authority and intent.

O. Preemption Restatement and Assessment Framework for Certain Coast Guard Determinations That No Regulations Should Issue

In some cases, the Coast Guard makes a determination that no regulations are needed on certain subjects or in a certain geographic area. These determinations can have preemptive impact over a contrary State determination. For example, this was true in cases of negative determinations made under Title I of the PWSA or pursuant to the preemption provisions of the Federal Motorboat Safety Act of 1971, 46 U.S.C. 4301 *et seq.* *See, e.g., Locke*, 529 U.S. at 109 and *Ray*, 435 U.S. at 171–172, Cf. *Spreitsma* v. *Mercury Marine*. 537 U.S. 51, 66 (2002). These

negative determinations can be made in several ways, including, but not limited to: Formal decisions in response to the recommendations of advisory committees, correspondence in response to Congressional inquiries regarding an area of regulation, or in response to requests or actions by State and local governments, the marine industry, or the public where the USCG's decision is intended to have preemptive effect. Negative determinations may or may not be published in the **Federal Register**, so long as they are published in a medium likely to reach the affected audience as the decision of the Coast Guard on the question of preemption. Regardless of the method used to record and publish a Coast Guard preemptive determination not to regulate, negative determinations made after the effective date of the final rule in this matter should contain a statement of the preemptive impact of such negative determinations, although the mere absence of such a statement of preemptive impact does not necessarily indicate that the determination is not preemptive.

V. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below, we summarize our analyses based on 13 of these statutes or executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 ("Regulatory Planning and Review") and 13563 ("Improving Regulation and Regulatory Review") direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review. The Office of Management and Budget has not reviewed it under that Order. This proposed rule would only clarify, not change, the preemptive status of Coast Guard regulations. We expect this proposed rule would not result in additional impacts on the U.S. economy.

This proposed rule is intended to clarify the preemptive effect of Federal regulatory regimes, and articulate the assessment framework used by the Coast Guard for evaluating the preemptive impact of future Coast Guard regulations based on their underlying statutory schemes. The assessment framework is based on the federalism analysis pursuant to Executive Order 13132. The Coast Guard currently performs federalism analyses under Executive Order 13132, if applicable. The Coast Guard would not require additional resources to implement this proposed rule.

By clarifying the preemption framework, the Coast Guard hopes to avoid or reduce confusion related to States and local governments' attempts to regulate in preempted areas. This action does not alter the preemptive effect of any Federal statute or regulation, and does not affect the relationship between the national government and the State and local governments.

We expect no additional cost impacts to State and local governments or industry from this proposed rule because it only restates and clarifies the status of Federal and State laws as it exists. This proposed rule does not alter in any way the rights of States. However, we expect this proposed rule to be beneficial to the maritime industry because it avoids potential conflicts between State and Federal regulations.

B. Small Entities

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to consider whether regulatory actions would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

As previously discussed, we estimate this proposed rule would not impose additional costs and would have no additional impact on small entities because it does not alter the preemptive impact of any particular regulation or impose any direct costs on small entities, but rather clarifies the preemptive status of certain regulations, as presented in section IV—Discussion of Proposed Rule.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment to the Docket Management Facility at the addresses under **ADDRESSES**. In your comment, explain why you think it qualifies and how and to what degree this proposed rule would economically affect it.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Lieutenant Commander Lineka Quijano, Office of Maritime and International Law, Coast Guard, telephone 202–372–3865. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

D. Collection of Information

This proposed rule would not require a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order. This regulation, in and of itself, does not change or alter the Coast Guard's view on the law of preemption, or the preemptive impact of our existing regulatory regime. Likewise, it does not serve to prospectively give preemptive impact to any future regulatory effort. As we make clear below, many of the statutes we administer, and many of our regulations, have preemptive impact. In keeping with the intent of Congress, and the spirit of Executive Order 13132 and the Presidential Memorandum on Preemption issued on May 20, 2009, the purpose of this rulemaking is to identify those statutes and regulations the Coast Guard considers to be preemptive. We also clarify and restate the principles and procedures by which the Coast Guard identifies and promulgates regulatory determinations with preemptive impact. This proposed rule discusses existing law on preemption; it identifies the laws and regulations that have preemptive effect. It clarifies (but

does not alter) the Coast Guard's view on the preemptive effect of its regulations. Nonetheless, the Coast Guard recognizes the key role State and local governments may have in making regulatory determinations. Accordingly, the Coast Guard encourages State and local governments to participate in the development of this rulemaking, and will, if we receive comments from States, consult with the States pursuant to Executive Order 13132. We will also make available to the Director of the Office of Management and Budget any written communications submitted by State and local officials. Any future rulemaking covering an area the Coast Guard considers to have preemptive impact pursuant to this proposed policy will also be promulgated in accordance with E.O. 13132 or its successors.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector, of $100,000,000 [adjusted for inflation] or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This proposed rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

H. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Nevertheless, the Coast Guard welcomes input from Federally recognized Indian tribes.

K. Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under the "Public Participation and Request for Comments" section of this preamble. This rule involves regulations that are editorial or procedural and regulations concerning internal agency functions. This rule falls under paragraphs 34(a) and (b) of the Instruction. We seek any comments or information that may lead to discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 1

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of information, and Penalties.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 1 as follows:

PART 1—GENERAL PROVISIONS

■ 1. Add subpart 1.06 to read as follows:

Subpart 1.06—Assessment Framework and Organizational Restatement Regarding Preemption for Certain Regulations Issued by the Coast Guard

Sec.

Subpart 1.06—Assessment Framework and Organizational Restatement Regarding Preemption for Certain Regulations Issued by the Coast Guard

Authority: 14 U.S.C. 2 and 91; 33 U.S.C. 1223, 1231, 1903(b); 46 U.S.C. 3203, 3306, 3703, 3717, 4302, & 6101; Dept. of Homeland Security Delegation No. 0170.1.

§ 1.06–1 General Restatement Regarding Preemption and Preemption Assessment Framework.

(a) Preemption of State law has its basis in Article VI, clause 2, the Supremacy Clause of the U.S. Constitution. The Coast Guard follows the three general theories of preemption that the U.S. Supreme Court has determined apply in the context of the regulation of vessels.

(1) *Express preemption* applies when Congress, by an express statement, specifically precludes State regulation in a given area.

(2) *Field preemption* applies when the Federal regulatory regime pervades a specific area of regulation to the extent that courts conclude that Congress has left no room for State regulation. Even in the absence of an express statement by the Coast Guard or the promulgation of regulations, State rules are preempted where Congress has intended to occupy the field. Thus, a State may not regulate in areas found to be field preempted.

(3) *Conflict preemption* applies in cases where courts find that the State regulation conflicts with a Federal statute or regulation, where compliance with both the State law and Federal law or regulation is impossible, or where State law stands as an obstacle to the accomplishment of the full Federal purpose.

Note to paragraph (a): General Policy. Since the founding of the Republic, the Federal government has historically exercised the preeminent and preemptive role in regulating interstate and international shipping. Courts have consistently upheld and reinforced the preemptive effect of the Federal regulatory regime for vessels. See, *e.g.*, *Kelly* v. *Washington ex rel Foss Co.*, 302 U.S. 1 (1937); *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978); *U.S.* v. *Locke*, 529 U.S. 89 (2000). The Coast Guard is one of the primary Federal agencies responsible for the promulgation, implementation and enforcement of Federal shipping regulations, including the implementation of international shipping treaties to which the United States is a party. The Coast Guard's policy position is that consistent standards of universal application and enforcement, coupled with Federal initiatives to meet unique regional concerns, best meet local and national safety and environmental goals with the least disruption to maritime commerce. Thus, in many cases, the Coast Guard regulations preempt non-federal regulatory or enforcement actions, consistent with the principles described in paragraph (a) of this section. The Coast Guard does not intend, through the publication of this policy, to affect any regulation promulgated pursuant to authority under which Congress has expressed an intention not to preempt State or local law or regulation.

(b) *Procedures.* In cases where a Coast Guard regulatory determination has preemptive impact, the Coast Guard will use the following procedures to identify and communicate that impact:

(1) For regulations promulgated under the authority of a statute that is discussed in this subpart, but issued prior to [EFFECTIVE DATE OF FINAL RULE], the Coast Guard has published a listing of the preemptive impacts in the appendix to subpart 1.06 of this part, although that listing is not intended to be exclusive.

(2) For regulations promulgated under the authority of a statute that is discussed in this subpart, issued after [EFFECTIVE DATE OF FINAL RULE], those final rules will contain a reference to and a statement of the applicability of the preemption policies in this subpart. The preambles of those rules will also contain a report of the results of the consultative process with State and local governments required by Executive Order 13132.

(3) For regulations promulgated under the authority of a statute that is not discussed in this subpart, issued prior to [EFFECTIVE DATE OF FINAL RULE], the Coast Guard will issue preemption analyses and determinations on a case by case basis, ~~as~~ necessary. Any such determination will include a report on the results of the consultative process required under Executive Order 13132, if applicable. Any party seeking a Coast Guard preemption determination for a regulation covered by this paragraph may do so by writing to the Commandant (CG–0941), Attn: Office of Maritime and International Law, U.S. Coast Guard Stop 7213, 2703 Martin Luther King Jr Avenue SE., Washington, DC 20593–7213.

(4) For regulations promulgated under the authority of a statute not discussed in this subpart, issued after [EFFECTIVE DATE OF FINAL RULE], those final rules will contain a reference to the applicability of the general preemption policy in this subpart, as well as a statement of the preemptive impact of the specific statutes and regulations in question. The preambles of those rules will also contain an analysis of the preemptive impact and a report of the results of the consultative process with State and local governments required by Executive Order 13132, if applicable.

(5) In cases where the Coast Guard has made a determination not to regulate on a certain subject or in a certain geographic area, the procedures for identifying and communicating the preemptive impact of such negative determinations are:

(i) For negative determinations issued prior to [EFFECTIVE DATE OF FINAL RULE], the Coast Guard will issue preemption analyses and determinations on a case by case basis, as necessary. Any such determination will include a report on the results of the consultative process required under Executive Order 13132, if applicable. Any party seeking a Coast Guard preemption determination for a negative determination covered by this paragraph may do so by writing to the Commandant (CG–0941), Attn: Office of Maritime and International Law, U.S. Coast Guard Stop 7213, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7213.

(ii) For negative determinations issued after [EFFECTIVE DATE OF FINAL RULE], the Coast Guard negative determination will contain a reference to the applicability of the preemption principles in this subpart, as appropriate, as well as a statement of the preemptive impact of the negative determination. The negative determination will also contain a report of the results of the consultative process with State and local governments required by Executive Order 13132, if applicable.

§ 1.06–10 Restatement Regarding Preemption and Assessment Framework for the Ports and Waterways Safety Act and Regulations Issued Under Its Authority.

(a) *General.* The Ports and Waterways Safety Act of 1972 (Pub. L. 92–340, 86 Stat. 424), as amended by the Port and Tanker Safety Act of 1978 (Pub. L. 95–474, 92 Stat. 1471) (collectively the "PWSA") contained two titles. Title I is codified at 33 U.S.C. 1221–1232. Title II is codified at 46 U.S.C. Chapter 37. This subpart refers to the PWSA by title, not section.

(b) *PWSA Title I* (1)—*Preemptive effect.* Conflict preemption principles apply to PWSA Title I. Any regulations or negative determinations issued by the U.S. Coast Guard under the authority of PWSA Title I are intended to have preemptive impact over State law covering the same subject matter in the same geographic area (as delimited in the Federal regulation), unless the Coast Guard states otherwise in the preamble to the final rule or the negative determination in question. This does not include enforcement of Coast Guard safety and security zones created under the authority of Title I of the PWSA when done by State or local officers, pursuant to 46 U.S.C. 70118 and a memorandum of agreement between the Coast Guard and the State or local

enforcement agency in question. Also, this does not include State maritime facility regulations that are more stringent than the Coast Guard maritime facility regulations in 33 CFR part 105. State maritime facility regulations will not be preempted so long as these State laws or regulations are more stringent than what is required by 33 CFR part 105 and no actual conflict or frustration of an overriding need for national uniformity exists.

(2) *Procedures.* For rules or negative determinations issued under the authority of PWSA Title I and promulgated prior to [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(1) and (b)(5)(i) of this subpart apply. For rules or negative determinations issued after [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(2) and (b)(5)(ii) of this subpart apply.

(c) *PWSA Title II*—(1) *Preemptive effect.* Field preemption principles apply to PWSA Title II. State regulations relating to the design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of tank vessels are preempted, regardless of whether the Coast Guard has made any regulatory determinations on the subject in question.

(2) *Procedures.* For rules issued under the authority of PWSA Title II and promulgated prior to [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(1) of this subpart apply. For rules issued after [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(2) of this subpart apply. In addition, the preambles to those final rules will contain a determination as to which PWSA Title II category or categories are applicable.

(d) *PWSA Title I/Title II Overlap.* In cases where a regulation could be classified as either Title I or Title II, the Coast Guard conducts the "overlap analysis" described in the U.S. Supreme Court decision in *United States* v. *Locke*, 529 U.S. 89, 111–112 (2000). For regulations issued prior to [EFFECTIVE DATE OF FINAL RULE], the Coast Guard has published a listing of our overlap analyses in the appendix to subpart 1.06 of this part. For regulations issued after [EFFECTIVE DATE OF FINAL RULE], the result of the overlap analysis will be contained in both the preamble and the text of those final rules.

§ 1.06–20 Restatement Regarding Preemption and Assessment Framework for 46 U.S.C. Chapter 32 and Regulations Issued Under Its Authority.

(a) *Preemptive effect.* Field preemption principles apply to 46 U.S.C. Chapter 32. Regulations issued by the Coast Guard under the authority of 46 U.S.C. Chapter 32 in the field of vessel safety management cover a field foreclosed from regulation by a State, regardless of the existence of conflict between the State and Coast Guard regulation.

(b) *Procedures.* For rules issued under the authority of 46 U.S.C. Chapter 32 and promulgated prior to [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(1) of this subpart apply. For rules issued after [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(2) of this subpart apply. In addition, the preambles to those final rules will contain a determination as to which 46 U.S.C. Chapter 32 category or categories are applicable.

§ 1.06–30 Restatement Regarding Preemption and Assessment Framework for 46 U.S.C. Chapter 33 and Regulations Issued Under Its Authority.

(a) *Preemptive effect.* Field preemption principles apply to 46 U.S.C. Chapter 33. Regulations issued by the Coast Guard under the authority of 46 U.S.C. 3306 in the fields of design, construction, alteration, repair, operation, superstructures, hulls, fittings, equipment, appliances, propulsion machinery, auxiliary machinery, boilers, unfired pressure vessels, piping, electric installations, accommodations for passengers and crew, sailing school instructors, sailing school students, lifesaving equipment and its use, firefighting equipment, its use and precautionary measure to guard against fire, inspections and tests related to these fields, and the use of vessel stores and other supplies of a dangerous nature cover fields that are foreclosed from regulation by a State. These fields are foreclosed from State regulation regardless of the existence of conflict between the State and Coast Guard regulation.

(b) *Procedures.* For rules issued under the authority of 46 U.S.C. 3306 and promulgated prior to [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(1) of this subpart apply. For rules issued after [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(2) of this subpart apply. In addition, the preambles to those final rules will contain a determination as to which 46 U.S.C. 3306 category or categories are applicable.

§ 1.06–40 Restatement Regarding Preemption and Assessment Framework for 46 U.S.C. 3717 and 6101 and Regulations Issued Under Their Authority.

(a) *Preemptive effect.* Field preemption principles apply to 46 U.S.C. 3717 and 6101. Any regulation issued by the Coast Guard under the authority of 46 U.S.C. 3717 or 46 U.S.C. 6101 covers fields that are foreclosed from State regulation. These fields are foreclosed from State regulation regardless of the existence of conflict between the State and Coast Guard regulation.

(b) *Procedures.* For rules issued under the authority of 46 U.S.C. 3717 or 6101 and promulgated prior to [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(1) and (b)(5)(i) of this subpart apply. For rules issued after [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(2) and (b)(5)(ii) of this subpart apply.

§ 1.06–50 Restatement Regarding Preemption and Assessment Framework for The Act To Prevent Pollution From Ships, Codified at 33 U.S.C. 1901 to 1912 and Regulations Issued Under Its Authority.

(a) *Preemptive effect.* Conflict preemption principles apply to 33 U.S.C. 1901–1912. With the exception of State or local laws or regulations specifically permitted by section 2003 of Public Law 100–220 or other similar express statutory authority, any regulation issued by the Coast Guard under the authority of 33 U.S.C. 1901–1912 has preemptive impact over similar, identical, or contrary State law.

(b) *Procedures.* For rules or negative determinations issued under the authority of 33 U.S.C. 1901–1912 and promulgated prior to [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(1) and (b)(5)(i) of this subpart apply. For rules or negative determinations issued after [EFFECTIVE DATE OF FINAL RULE], the procedures in § 1.06–1(b)(2) and (b)(5)(ii) of this subpart apply.

Appendix to Subpart 1.06—Regulations With Preemptive Effect

1. *Scope.* This Appendix sets out the preemptive effect of certain Coast Guard regulations as they existed on [EFFECTIVE DATE OF FINAL RULE]. It amplifies the assessment framework set out in subpart 1.06 by providing examples, taken from existing law, of the different preemption analyses described in subpart 1.06. It also provides information on the Coast Guard's analytical approach to the listed regulations. This appendix does not list all regulations that may have preemptive effect, nor does it describe in totality the preemptive effect of all Federal statutes governing every Coast Guard activity. This appendix does not account for developments occurring after

[EFFECTIVE DATE OF FINAL RULE]. For regulations not listed in this appendix, refer to the preemption assessment framework in 33 CFR 1.06–1.

2. *Regulations with Preemptive Impact Pursuant to the Ports and Waterways Safety Act.*

2.1 *Regulations in effect an [EFFECTIVE DATE OF FINAL RULE] and having the preemptive effect described in 33 CFR 1.06–10(b) pursuant to Title I of the Ports and Waterways Safety Act.* 33 CFR parts 64, 101, 103, 104, 105 (for State maritime facility security laws that are either less stringent or that actually conflict with or frustrate an overriding need for national uniformity), 120, 128, 161, 166, 167, 169 and 401.

2.2 *Regulations in effect an [EFFECTIVE DATE OF FINAL RULE] covering fields foreclosed from State regulation as described in 33 CFR 1.06–10(c) pursuant to Title II of the Ports and Waterways Safety Act.* With respect to tank vessels only: 33 CFR parts 157, 163, and 168; 46 CFR parts 2, 8, 13, 15, 30, 31, 32, 34, 35, 36, 38, 39, 50, 52, 53, 54, 56, 57, 58, 59, 61, 62, 63, 64, 98, 105, 110, 111, 112, 113, 150, 151, 153, 154, 159, 160, 161, 162, 163, 164, 170, 172, 174, 175, 178, 179, and 199.

2.3 *Regulations in effect an [EFFECTIVE DATE OF FINAL RULE] and appropriate for analysis under the "overlap analysis" described in 33 CFR 1.06–10(d).*

Using the overlap analysis described in 33 CFR 1.06–10(d), the Coast Guard has made the following determinations:

(a) In 33 CFR part 155, the following sections are grounded in Title II authority, and therefore cover fields foreclosed from State regulation: 155.100 through 155.1030, 155.1055 through 155.1060, 155.1110 through 155.1120, and 155.1135 through 155.1150.

(b) In 33 CFR part 156, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 156.118, 156.215, 156.220, 156.230, 156.300 and 156.310.

(c) In 33 CFR part 156, the following sections are grounded in Title II authority, and therefore cover fields foreclosed from State regulation: 156.100 through 156.115, 156.120 through 156.210, 156.225, and 156.320 through 156.330.

(d) In 33 CFR part 160, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 160.1 through 160.7, 160.105 through 160.107, and 160.115 through 160.215.

(e) In 33 CFR part 160, the following regulations as applied to tank vessel operations are grounded in Title II, and therefore cover fields foreclosed from State regulation: 160.101, 160.103, 160.109, 160.111 and 160.113.

(f) In 33 CFR part 162, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 33 CFR 162.1 through 162.40, 162.65 through 162.65(b)(3), 162.65(b)(4)(ii) through 162.65(b)(6), 162.75 through 162.75(b)(5)(iv), 162.75(b)(6) through 162.80(a)(1), 162.80(a)(3) through 162.90(b)(2)(iii), 162.90(b)(2)(vi) through 162.90(b)(3)(iv), 162.90(b)(4)(ii) through 162.117(h)(2), 162.120 through 162.125(a), 162.125(b)(3) through (5).

(g) In 33 CFR part 162, the following regulations are promulgated pursuant to Title II, and therefore cover fields foreclosed from State regulation: 162.65(b)(4)(i) operation and equipping, 162.75(b)(5)(v) operation and equipping, 162.75(b)(5)(vi) operation, 162.80(a)(2) operation and equipping, 162.90(b)(2)(iv) manning, 162.90(b)(2)(v) operation, 162.90(b)(4)(i) operation and equipping, 162.117(h)(3) and (4) operation, 162.255(e)(1) and (2) operation and equipping, and 162.255(e)(3) operation.

(h) In 33 CFR part 164, the following regulations are promulgated under Title I and therefore preempt any similar, identical or contrary State regulation: 33 CFR 164.01, 164.02, 164.03, 164.11(c), 164.11(e), 164.11(f)–(i), 164.11(k)–(n), 164.11(p), 164.11(q), 164.19(b), 164.19(c), 164.51, 164.53, 164.55, 164.61, 164.70, 164.78(a)(3)–(8) and 164.82(c).

(i) In 33 CFR part 164, the following sections are grounded in Title II authority, and therefore cover fields foreclosed from State regulation: 33 CFR 164.11(b), 164.11(d), 164.11(j), 164.11(o), 164.11(r) through 164.19(a), 164.25 through 164.46, 164.72 through 164.78(a)(2), and 164.78(b) through 164.82(b).

(j) In 33 CFR 165, the following sections are grounded in Title I authority, and therefore preempt any similar, identical or contrary State regulation: 33 CFR 165.1 through 165.150(b)(4), 165.150(b)(6) through 165.501(d)(2), 165.501(d)(4) through 165.501(d)(5), 165.501(d)(7) through 165.510(d), 165.510(f)(1) through 165.510(f)(3), 165.510(f)(9) through 165.540(f)(6), 165.540(f)(9) through 165.803(e)(2), 165.803(g) through 165.810(e), 165.810(f)(2), 165.811(a) through 165.811(c), 165.811(e) through 165.923(b)(2)(ii)(D), 165.923(b)(2)(ii)(F) (through 165.1152(d)(1), 165.1152(d)(3) through 165.1181(d)(1), 165.1181(d)(3) through 165.1704(c)(1), 165.1704(c)(3) through 165.1704(c)(5), and 165.1706 through 165.2030.

(k) In 33 CFR part 165, the following sections are grounded in Title II, and therefore cover fields foreclosed from State regulation: 165.150(b)(5) manning, 165.501(d)(3)(i)–(ii) and (6) equipping, 165.510(e) operation, 165.510(f)(4) operation, 165.510(f)(5) manning, 165.510(f)(6) operation, 165.510(f)(7) and (8) equipping, 165.540(f)(7) and (8) equipping, 165.803(e)(3) and (4) equipping, 165.803(f)(1)–(3) equipping, 165.810(f)(1) manning, 165.810(f)(3) equipping, 165.811(d) equipping, 165.923(b)(2)(ii)(E) equipping, 165.1152(d)(2) operation, 165.1181(d)(2) operation, and 165.1704(c)(2) and (6) equipping.

3. *Regulations in effect an [EFFECTIVE DATE OF FINAL RULE] and covering fields foreclosed from State regulation as described in 33 CFR 1.06–20.*

All of the regulations in 33 CFR part 96 have been prescribed under the authority of 46 U.S.C. Chapter 32, and therefore cover fields foreclosed from State regulation.

4. *Regulations in effect an [EFFECTIVE DATE OF FINAL RULE] and covering fields foreclosed from State regulation as described in 33 CFR 1.06–30.*

The following regulations issued pursuant to 46 U.S.C. Chapter 33 cover fields foreclosed from State regulation: 46 CFR parts 70, 71, 76, 78, 90–93, 95–98, 105, 107–108, 110–122, 125–134, 147, 147A, 148, 150–151, 153–154, 159–164, 166–169, 170–174, 175–185, 188–190, 193–196, and 199.

5. *Regulations in effect an [EFFECTIVE DATE OF PUBLICATION OF FINAL RULE] and covering fields foreclosed from State regulation as described in 33 CFR 1.06–40.*

The following regulations issued pursuant to 46 U.S.C. 3717 and 6101 cover fields foreclosed from State regulation: 33 CFR 151.15, 151.26(b)(3), 153.203, 155.1035(b), 164.61, part 173 subpart C; 46 CFR 4.05–1 through 4.05–10, 35.15–1, 197.484 through 197.488, 401.260.

6. *Regulations in effect on [EFFECTIVE DATE OF FINAL RULE] and having the preemptive effect described in 33 CFR 1.06–50.*

The following regulations issued pursuant to 33 U.S.C. 1901 through 1912 preempt similar, identical, or contrary State or local laws or regulations with the exception of State or local laws or regulations specifically permitted by Section 2003 of Public Law 100–220 or other similar express statutory authority: 33 CFR part 151, subpart A; 33 CFR 155.100 through 155.130, 155.350 through 155.400, 155.430, 155.440, 155.470, 155.1030(j) and (k), 155.1065(g), and all the regulations in 33 CFR part 157.

Dated: December 5, 2013.

F.J. Kenney,

Rear Admiral, U.S. Coast Guard, Judge Advocate General.

[FR Doc. 2013–29714 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–15–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 249 December 27, 2013

Part VI

Department of Agriculture

Commodity Credit Corporation

7 CFR Part 1493
CCC Export Credit Guarantee (GSM–102) Program and Facility Guarantee Program (FGP); Proposed Rule

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1493

RIN 0551–AA74

CCC Export Credit Guarantee (GSM–102) Program and Facility Guarantee Program (FGP)

AGENCY: Foreign Agricultural Service and Commodity Credit Corporation (CCC), USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise and amend the regulations that administer the Export Credit Guarantee (GSM–102) Program. Changes in this proposed rule incorporate program operational changes and information from press releases and notices to participants that have been implemented since the publication of the current rule, and include other administrative revisions to enhance clarity and program integrity. This proposed rule also incorporates certain changes as suggested in comments received in response to the initial publication of the proposed rule on July 27, 2011. These changes should increase program availability to all program participants and enhance access and encourage sales for smaller U.S. exporters. Changes are also intended to improve CCC's financial management of the program. The proposed rule would eliminate provisions for the Intermediate Export Credit Guarantee (GSM–103) Program, consistent with the repeal of authority to operate this program in the Food, Conservation, and Energy Act of 2008 (2008 Act).

DATES: Comments concerning this proposed rule must be received by January 27, 2014 to be assured consideration.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions to submit comments.
- *EMail: GSMregs@fas.usda.gov.*
- *Fax:* (202) 720–2495, Attention: "GSM102 Proposed Rule Comments".
- *Hand Delivery, Courier, or U.S. Postal delivery:* Amy Slusher, Deputy Director, Credit Programs Division, Foreign Agricultural Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Stop 1025, Room 5509, Washington, DC 20250–1025.

Comments may be inspected at 1400 Independence Avenue SW., Washington, DC, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays. A copy of this proposed rule is available through the Foreign Agricultural Service (FAS) homepage at: *http://www.fas.usda.gov/excredits/exp-cred-guar-new.asp*.

FOR FURTHER INFORMATION CONTACT: Amy Slusher, Deputy Director, Credit Programs Division; by phone at (202) 720–6211; or by email at: *Amy.Slusher@fas.usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Commodity Credit Corporation's (CCC) Export Credit Guarantee (GSM–102) Program is administered by the Foreign Agricultural Service (FAS) of the U.S. Department of Agriculture (USDA) on behalf of CCC, pursuant to program regulations codified at 7 CFR part 1493 and through the issuance of "Program Announcements" and "Notices to Participants" that are consistent with this program regulation. The current regulations became effective on November 18, 1994. Since that time, CCC has implemented numerous operational changes to improve the efficiency of the program, including an automated, Internet-based system for participants and revised program controls to improve program quality, reduce costs, and protect against waste and fraud. Also since that time, agricultural trade and finance practices have evolved. This proposed rule is intended to reflect these changes and to enhance the overall clarity and integrity of the program. In addition, the 2008 Act repealed the authority to operate the GSM–103 Program, and this change is reflected in the proposed rule.

On July 27, 2011, CCC published a Proposed Rule in the **Federal Register** (Vol. 76, No. 144, pages 44836–44855) revising and amending the regulations that administer the Export Credit Guarantee (GSM–102) Program. Changes in this proposed rule incorporated program operational changes and information from press releases and notices to participants that have been implemented since the publication of the current rule, and included other revisions to enhance clarity and program integrity. The deadline for comments on the proposed rule was October 26, 2011 (extended from the initial deadline of September 26, 2011, at the request of interested commenters). CCC received comments on the proposed rule from 20 parties, including U.S. exporters, U.S. cooperator groups, U.S. banks, foreign banks, foreign importer associations, and individuals (including one set of comments submitted jointly by a group of 12 interested parties).

Reason for Reissuing a Proposed Rule

CCC is reissuing this rule as a proposed rule instead of a final rule because, based on comments received on the initial proposed rule, it has made several significant changes and is providing the public with an additional opportunity for comment. Comments received and changes made by CCC are discussed below in the Section-by-Section Analysis. CCC is publishing this proposed rule with a comment period of 30 days from date of publication.

General Comments

Ten respondents provided general comments on the proposed rule. Three commenters indicated that there were a number of improvements to the proposed rule and that the proposed changes reflect the evolution of agricultural trade and finance practices and will enhance program clarity and integrity.

Three respondents expressed general concerns regarding the potential negative impact of the proposed changes on the GSM–102 program. One commenter suggested that the proposed rules on fees and tightened requirements for exporters would increase the cost of the program to exporters, who will pass on these costs to importers, negatively impacting the ability of the program to promote trade. One respondent expressed the need for modifications to ensure the program reflects commercial realities and facilitates trade. One respondent expressed concern that under the proposed rule, U.S. financial institutions could be caught in a situation where a guarantee is withdrawn without the assignee's knowledge.

Comments received from two respondents indicated that the proposed changes would render the GSM–102 program inoperable because: (1) The changes are inconsistent with international banking practices and procedures for letters of credit, making it less likely banks will participate; and (2) the program would become more cumbersome and costly for participants and discourage small business participation. These results would contradict the requirements of Section 202(k)(2) of the Agricultural Trade Act of 1978, specifically the requirements to maximize the export guarantees made available and used each year and to maximize the export sales of agricultural commodities.

CCC recognizes the validity of these concerns and is proposing changes to

make the rule more consistent with standard international finance practices and to reduce the burden on participants. These changes are discussed in detail in the Section-by-Section Analysis and are open for additional public comment to ensure CCC has met these objectives. As CCC noted in the initial proposed rule; however, many of the proposed changes are designed to protect the integrity of the program—specifically to increase program controls, mitigate against waste and fraud, and improve CCC's chances of recoveries in cases of default (which will benefit not only the program by reducing costs in the long term, but also benefit CCC's risk share partners and U.S. taxpayers). CCC is attempting to balance program integrity concerns with maintaining a viable program that supports U.S. agricultural exports, recognizing that the result may be certain program modifications that increase the burden on both participants and CCC.

One respondent indicated that the GSM–102 program is losing competitiveness versus commercial financing because: (1) Shifts have occurred in long- and short-term interest rates; (2) companies are penalized if they repay a loan midway through the repayment period; and (3) program fees are too high. This respondent also commented that the country risk classification for South Korea is too high (i.e., risky), and questioned whether the purpose of the proposed changes was to make the program more attractive to small and medium-sized enterprises (SMEs) at the expense of major exporters.

CCC does not control interest rates or the repayment arrangements between the importer and the foreign financial institution. With respect to program fees, CCC is subject to both statutory and trade policy requirements. While CCC acknowledges that program fees have increased since 2009, program use has remained strong (and consistent with historical use) during those years. However, CCC is open to receiving specific comments on how fees can be adjusted, within current program confines, to better promote program utilization. Country risk classifications are based on a U.S. Government interagency country risk assessment system and are updated every one to three years. CCC notes that participants continue utilizing the program to support sales to South Korea despite the current country rating and fee rates. While certain proposed changes are designed to improve the access of SMEs to the program, CCC does not intend for this improved access to be at the expense of major exporters. CCC's goal is a set of program rules that attempt to provide equity to all participants.

One commenter expressed concern that the proposed rule does not permit U.S. financial institutions to apply directly for GSM–102 payment guarantees, a practice that would allow the GSM–102 program to support additional U.S. exports. The commenter noted that other export credit agencies allow both exporters and banks to apply for coverage under their programs. CCC agrees that allowing U.S. financial institutions to apply for coverage is a change that should be considered for the GSM–102 program. It is also a significant change that would have numerous operational ramifications and would impact other program participants. As such, it needs to be carefully considered, and CCC was not prepared to implement this change in this proposed rule. CCC will continue to consider this idea going forward in the context of future regulatory changes.

One respondent asked if the proposed rule would go into effect during fiscal year 2012. The timing of implementation is uncertain until comments are received on the reissued proposed rule and additional comments considered.

Section-by-Section Analysis

The section-by-section discussions below include a summary of comments received on the proposed rule, CCC's responses to those comments, and a discussion of any additional changes made by CCC. In some instances, the numbering systems differ between the new and initial proposed rules. For purposes of this discussion, the numbering system of the new proposed rule will be used, except where otherwise indicated.

No comments were received on Subpart A, Restrictions and Criteria for Export Credit Guarantee Programs. CCC added § 1493.3(a)(3) to reflect that, in addition to consideration of country risk, CCC will not issue guarantees in connection with sales financed by foreign financial institutions that CCC determines cannot adequately service the debt.

Subpart B—CCC Export Credit Guarantee (GSM–102) Program Operations

Section 1493.10 General Statement

One commenter asked, with respect to language in paragraph (a) that GSM–102 guarantees are issued for terms up to three years, whether CCC envisions extending maximum tenor to three years for better risk countries within the near future. CCC cannot predict whether tenor will be extended to three years in the future, as maximum tenor is a function of both risk and policy considerations. CCC has eliminated the specific reference to three years in this paragraph.

Section 1493.20 Definition of Terms

CCC made a number of proposed revisions to this section based on comments received, and also removed the numbering within this section to allow it to be governed by alphabetical order. All defined terms have been capitalized throughout the proposed rule.

Affiliate

No comments were received on this definition. However, CCC revised this term to reflect its varied usage within the proposed rule. The term "affiliate" refers to: (1) An entity's organizational structure; and (2) related entities to which certain required certifications apply, specifically related to government-wide suspension and debarment. The original definition, taken from government-wide suspension and debarment regulations at 2 CFR Part 180, was too detailed with respect to general questions of organizational structure. Therefore, CCC has more generically defined "affiliate" for purposes of collecting organizational information. In cases where the term "affiliate" relates to suspension and debarment certifications, the reference to 2 CFR 180.905 has been added to clarify the definition that applies.

Definitions of Incoterms (Cost and Freight (CFR), Cost, Insurance and Freight (CIF), Free Alongside Ship (FAS), Free Carrier (FCA), Free on Board (FOB))

CCC received several comments related to Incoterms definitions in the proposed rule. Two respondents noted that the definitions did not reflect the 2010 version of Incoterms, effective January 1, 2011. One respondent indicated that the trading terms CFR, CIF, FAS, and FOB cover only the movement of goods by sea and inland waterway transport, and that the proposed rule contained no terms related to air, rail or truck shipments.

CCC agrees with these comments and has updated these definitions to reflect that all terms are as defined by Incoterms 2010, or as superseded. The definitions for CFR, CIF, FAS, and FOB have been updated to reflect that they apply only to sea and inland waterway transport, and Free Carrier (FCA) has been added for air, rail and truck shipments. Throughout the proposed

rule, references to Incoterms have been amended to include FCA. Additionally, CCC included a definition of "Incoterms" for clarity.

One respondent requested that CCC include a provision that requires all sales contracts to be subject to Incoterms. The definition of "Firm Export Sales Contract" in this section includes a requirement for delivery terms (FOB, C&F, FCA, etc.). CCC does not believe any changes are necessary in response to this comment.

Eligible Export Sale

This definition has been added to the proposed rule. CCC believes that a practice for some exporters has become to identify export transactions that occur outside of the GSM–102 program but nevertheless to register such exports under a GSM–102 payment guarantee. Under such practice, there is no expansion of U.S. exports, because the goods covered by the payment guarantee are shipped and paid for wholly apart from the benefit of the CCC guarantee. CCC believes this practice is inconsistent with the purpose of the GSM–102 program to increase exports of U.S. agricultural commodities. In these cases, there is no increase in U.S. agricultural exports, because the export sale would have occurred without the GSM–102 program. These sales improperly utilize program allocation that otherwise could be used to support exports that would not occur in the absence of the payment guarantee. Furthermore, these transactions create a liability for CCC for which there is no corresponding benefit to U.S. agricultural exports. In response to these concerns, which have been echoed by some program participants, CCC has added a definition of "eligible export sale" with the intent of prohibiting these types of transactions. CCC believes that this will help ensure that financing is coupled with an actual exporter movement of a U.S. agricultural commodity.

FAS Web Site

Although no comments were received, this definition has been deleted from the proposed rule because the Web site location is subject to change. The current Web site is *http://www.fas.usda.gov/excredits/ecgp.asp.* To avoid confusion with the term "Free Alongside Ship (FAS)," references to the FAS Web site were changed to "USDA Web site."

Final Date To Export

CCC received two comments on the definition of "final date to export." Because these comments relate specifically to § 1493.100 (*Terms and requirements of the Payment Guarantee*), these comments are discussed in that section. This definition was unnecessary and has been deleted.

Firm Export Sales Contract

One comment was received on the "Firm Export Sales Contract" definition, indicating that allowing an export sale to be contingent upon the CCC guarantee is contradictory to having a firm contract.

No changes were made to this definition. CCC does not believe there is any inconsistency between a "firm" contract and one that is contingent upon CCC's approval of a payment guarantee. The purpose of the GSM–102 program, as specified in § 1493.10(a), is to "expand U.S. Agricultural Commodity exports." An agricultural sale that will occur only with the presence of a GSM–102 payment guarantee is consistent with this goal and also allows flexibility for U.S. exporters. This definition specifies that the exporter and importer must be in agreement regarding the terms and conditions of the sale, thus requiring the details of the sales contract to have been worked out in advance of the exporter's application for the payment guarantee.

Foreign Financial Institution

Although no comments were received, CCC determined that the original definition unintentionally excluded multilateral and sovereign institutions. CCC revised it to specifically include these institutions as eligible, and also added a clarification that this definition encompasses foreign branches of U.S. financial institutions.

Foreign Financial Institution Letter of Credit (or Letter of Credit)

Two comments were received on this definition, which was not modified in the initial proposed rule. One commenter indicated that it is unclear whether the current definition covers the standard GSM–102 repayment mechanism, the sight letter of credit. The commenter suggested the definition be re-written to specifically cover the sight letter of credit and exclude the reference to a related obligation. A second commenter asked whether "related obligation" refers to a bank-to-bank agreement outside of the letter of credit.

CCC revised this definition, moving a portion of it to § 1493.90 (*Special requirements of the Foreign Financial Institution Letter of Credit and Terms and Conditions Document, if applicable*), and modifying the two options listed in the prior definition in an attempt to add clarity. The term "related obligation" has been changed to "Repayment Obligation" as noted below and refers to a commitment of the foreign financial institution to pay the exporter or the U.S. financial institution on deferred payment terms. Section 1493.90(a) specifies acceptable methods for documenting the repayment obligation. CCC believes these changes will clarify this term.

Holder of the Payment Guarantee

This definition has been added to the new proposed rule. Although no comments were received, CCC was concerned about potential confusion regarding the phrase "exporter or exporter's assignee" that appeared throughout the rule. This phrase typically is used to indicate CCC's risk-share partner in the transaction and the party responsible for filing notices of default and claims. To clarify in certain instances that CCC is referring to one specific party, CCC created the term "Holder of the Payment Guarantee." The new proposed rule has been updated throughout with this term where applicable.

Importer and Importer's Representative

Three comments were received on the definition of an importer, which required the importer to be physically located in the country or region of destination specified on the payment guarantee. One commenter explained that this may not always be possible due to unique local transit trade regulations, loan regulations, or tax consequences, and recommended instead that CCC add the term "presence of business" with defined requirements. A second commenter noted that requiring the importer to be physically located in the country is counter to free trade practices. The importer's location should not be of concern to CCC provided the goods arrive at the intended destination. Three commenters felt this change would have a negative impact on program utilization.

CCC agrees with these comments and modified the definition of "Importer" accordingly. The term "Importer's Representative" was added to the new proposed rule (in lieu of the term "presence of business"), along with additional requirements that are explained in the relevant section(s).

Intervening Purchaser

CCC received one comment asking if an intervening purchaser can be located in the United States. CCC does permit the intervening purchaser to be located

in the United States. No change is necessary to this definition.

Letter of Credit Account Party

One respondent suggested the term of "Letter of Credit Account Party" be changed to "Letter of Credit Applicant" and that the term "entity" in the definition be changed to "party" to be consistent with international banking practice and the Uniform Customs and Practice for Documentary Credits (UCP 600). CCC agrees that this term should be defined consistently with UCP 600; however, because it is used only once in the proposed rule, it has been deleted from the *Definitions of Terms* section. The UCP 600 definition is now referenced in § 1493.70(a)(4).

Notice to Participants

No comments were received on this definition, but it was deleted because the concept is explained in § 1493.10(b).

Principal

One respondent suggested the definition of "Principal" is too broad and requested that it be limited to the entity providing the relevant certifications, rather than applying to an array of individuals within the participating entity.

The term "principal" is used throughout the proposed rule to refer to: (1) Individuals who must submit documents under the program; and (2) individuals to whom certain required certifications apply, specifically related to government-wide suspension and debarment rules. Although CCC does not agree with the suggestion to apply this term only to the entity making the certifications, CCC acknowledges that the original definition, taken from government-wide suspension and debarment regulations at 2 C.F.R Part 180, was too detailed with respect to submission of documents under the program. Therefore, CCC more generically defined "Principal" for purposes of document submission. In cases where the term "principal" relates to the certifications for suspension and debarment, the reference to 2 CFR 180.995 was added to clarify the definition that applies.

Repayment Obligation

Although no comments were received on this definition, CCC changed the term "related obligation" to "Repayment Obligation." CCC believes the new terminology more accurately reflects that this term refers to a contractual commitment, rather than a particular document. Although the definition did not change, CCC added clarification that the repayment obligation must be documented using one of the methods described in § 1493.90.

System for Award Management (SAM)

Since publication of the initial proposed rule, the U.S. Government implemented the System for Award Management (SAM), a combined federal procurement and federal domestic assistance system. The Excluded Parties List System (EPLS) that participants must check for suspension and debarment purposes has been included in SAM; therefore, participants will now be required to check SAM. All references to EPLS in the new proposed rule were replaced with SAM. The current Web site is *www.sam.gov*. Any future updates will be provided on the USDA Web site.

Terms and Conditions Document

CCC added this definition to the proposed rule in response to comments received on § 1493.90 indicating that certain requirements were inappropriate for the letter of credit. CCC added flexibility for participants to use a separate document linked to the foreign financial institution letter of credit and stating the terms and conditions required by CCC. This concept is addressed in more detail in the discussion of § 1493.90.

U.S. Financial Institution

Although no comments were received on this definition, CCC determined that it may have unintentionally excluded U.S. branches of foreign financial institutions. CCC revised the definition to specifically include these institutions as eligible U.S. financial institutions.

Weighted Average Export Date

This term was added to the new proposed rule. CCC received requests from participants to allow the holder of the payment guarantee to bundle certain exports and utilize a credit period starting point other than the date of export of each individual shipment. CCC agrees with these requests and included this concept in § 1493.100(b). This option is described in further detail in the discussion of changes to § 1493.100.

Section 1493.30 Information Required for Exporter Participation

CCC received two comments on this section. One respondent asked how a determination of exporter ineligibility (paragraph (d)) would affect existing guarantees with that exporter. The commenter noted there is no specific provision for CCC to notify the assignee if an exporter is deemed ineligible. A second respondent suggested that currently qualified exporters be required to submit a description of their business activities and related information to prove that the exporter is a "true" exporter, even if the exporter has submitted an application within the past two years.

CCC made no changes in response to these comments. CCC determines at the time of application for the payment guarantee whether an exporter is currently eligible. If the exporter is ineligible at that time, no guarantee is issued. However, if a guarantee is issued and the exporter is subsequently deemed ineligible, there is no impact on the existing guarantee; therefore, there is no need for CCC to notify the assignee in this case.

In response to the second comment, CCC notes that the commenter provided no definition of "true" exporter. CCC has authority to collect the new information in § 1493.30 from current exporters based on paragraph (d), which states that an applicant may be deemed ineligible if the applicant cannot provide the information required in § 1493.30. Following publication of the final rule, CCC will determine whether, when and how to collect this information from currently approved exporters.

Section 1493.40 Information Required for U.S. Financial Institution Participation

CCC received one comment requesting clarification of whether submission of an annual report or 10–K is acceptable to meet the requirement for year-end audited financial statements in paragraph (a)(4). CCC confirms that the10–K annual report submitted to the Securities and Exchange Commission is acceptable to meet CCC's requirement for year-end audited financial statements. The "annual report to shareholders" (sent to shareholders prior to annual shareholders' meetings) can be submitted for informational purposes but does not meet the requirement for year-end audited financial statements, as the report generally does not include sufficient financial detail. No changes were needed in response to this comment.

Section 1493.50 Information Required for Foreign Financial Institution Participation

CCC received one comment requesting clarification of the impact on existing guarantees if CCC reduces or cancels a foreign financial institution's (FFI) participation limit (per paragraph (c) or (d)) or if the FFI is otherwise

deemed ineligible for participation (per paragraph (e)) after a guarantee has been assigned to a U.S. financial institution. The respondent also asked whether the U.S. financial institution would be notified whether the FFI is within its participation limit at the time a guarantee is assigned.

CCC determines prior to issuing a payment guarantee whether the foreign financial institution is eligible and has a sufficient participation limit for that guarantee. Except in cases of default as provided in § 1493.160(c), a change in the eligibility or participation limit of an FFI has no impact on existing payment guarantees. CCC will not notify a U.S. financial institution regarding changes in an FFI's participation limit, as there is no impact of such changes on existing guarantees. CCC considers an FFI's participation limit confidential; any questions regarding that limit should be directed to the FFI.

Although CCC deems that no changes are needed in response to these comments, two modifications were made to this section in the new proposed rule. In paragraph (a)(2), CCC clarified that applicants must provide year-end, audited financial statements in English, in accordance with the accounting standards established by the applicant's regulators. CCC does not have the resources to translate such information for review. Multilateral institutions not subject to local regulations in their country of domicile must provide financial statements in accordance with prevailing accounting standards. Paragraph (d) was modified to clarify that CCC has the right to cancel a foreign financial institution's limit if the FFI does not participate in the GSM–102 program for two consecutive fiscal years. CCC must review all foreign financial institutions annually to ensure their continued ability to repay debt guaranteed by CCC. Given the number of FFIs in the program, CCC must focus its limited resources on those institutions that participate. Those that choose not to participate for this length of time may be removed from eligibility, but may resubmit all information required under § 1493.50 for reconsideration. CCC also added requirements for annual year-end financial statements consistent with the changes made in paragraph (a)(2) of this section.

Section 1493.60 Certifications Required for Program Participation

Three comments were received related to this section. One respondent requested clarity on how U.S. and foreign financial institutions should document they are in compliance with all regulatory requirements and U.S. anti-money laundering and terrorist financing statutes.

CCC does not require that evidence of compliance be provided when submitting an application. As part of the application review process, CCC contacts the U.S. bank's regulator to verify compliance with regulatory requirements and can conduct follow up reviews at any time. CCC can verify compliance with U.S. anti-money laundering and terrorist financing statutes with the Office of Foreign Assets Control (OFAC).

A second respondent requested CCC limit the certifications to the U.S. financial institution and exclude company principals or, if not possible, then limit the term "principals" to bank shareholders. This respondent also requested that the regulation allow the Director to permit qualifications to the certifications, and requested the wording in paragraph (b) be changed from "are in compliance with" to "comply with." The commenter noted that the state of being in compliance with the regulation is a broader and more absolute concept than the act of complying with the regulation. The act of complying generally carries with it a good faith standard of knowing what the rules are on having mechanisms in place to ensure, to the extent possible, that the bank complies with them.

As noted in the discussion on *Definition of Terms* (§ 1493.20), the terms "principal" and "affiliate" have multiple uses in the program. With respect to the certifications found in § 1493.60(a), these terms have the specific meaning found in government-wide suspension and debarment regulations. Therefore, CCC has revised § 1493.60(a) to clarify that these certifications employ "principal" and "affiliate" as defined in 2 CFR 180.995 and 2 CFR 180.905, respectively. Because the GSM–102 program must comply with government-wide suspension and debarment rules, CCC made no changes to narrow the definition of "principal" and made no changes specifically in response to this comment. All applicants for participation must make the certifications required in § 1493.60 with respect to both the applicant and its principals, where required. For the same reason, CCC does not include a provision to allow the Director flexibility to change the certifications. However, in accordance with § 1493.40(a)(9), a U.S. financial institution must provide an explanation or documentation if it cannot include the certifications in its application. Further, paragraph (b) of § 1493.40 permits the Director to consider additional information from the applicant if the applicant fails to qualify.

CCC does not agree with the request to change the wording in the certifications in paragraph (b)(1) from "are in compliance with" to "comply with." The phrase "are in compliance with" means that the applicant is certifying to these statements at the time the certification is made. This is CCC's intent, and therefore, this wording remains.

A third respondent asked if CCC would provide specific wording for the certification statements. CCC notes that required wording has already been provided in § 1493.40(a)(9) and § 1493.50(a)(6) for U.S. and foreign financial institutions, respectively. These are general certification statements that, when made on a qualification application, encompass all of the certifications in § 1493.60. No changes were needed in response to this comment.

CCC modified § 1493.60(b)(2) in the new proposed rule, adding to this certification a requirement that relevant applicants be in compliance with the Foreign Corrupt Practices Act of 1977. CCC has previously reminded all program participants in a notice to participants that they are required to be in compliance with this Act. Exporters are required to certify that each GSM–102 transaction is compliant with this Act, and because it also applies to financial institutions doing business in foreign markets, CCC determined it was appropriate for financial institutions to make this certification as well.

Section 1493.70 Application for Payment Guarantee

CCC received three comments related to the requirement in paragraph (a)(16) that, upon request by CCC, the exporter must provide written evidence that the foreign financial institution specified in the application for payment guarantee has agreed to issue the letter of credit. Two commenters requested more detail about the type of written evidence CCC will require, the timeframe for providing it to CCC, and the consequence to the exporter if the information is not provided or the foreign financial institution letter of credit is never issued. Two respondents noted that it could be difficult and time-consuming to obtain such documentation, and therefore, one respondent requested that it only be required in cases where multiple exporters register under the same foreign financial institution's available line of credit. One respondent requested this provision be deleted or

that CCC obtain such evidence directly when needed.

CCC made no revisions in response to these comments. In certain country and regional allocations, multiple exporters register under a single, limited foreign financial institution (FFI) participation limit. This situation delays issuance of payment guarantees. CCC made past attempts to contact exporters and FFIs to determine which application is acceptable to the FFI. Different situations required different methods to obtain this information most efficiently. For this reason, CCC has chosen not to set a specific requirement, but instead will request documentation on a case-by-case basis to minimize burden. Under certain circumstances, CCC agrees that it may be appropriate for CCC to obtain this information independently of the exporter. In these cases, CCC will obtain the information; otherwise, it will be the exporter's responsibility.

CCC agrees that documentation is needed only under limited circumstances and intends to utilize this provision specifically in those circumstances. CCC will provide the exporter with a reasonable timeframe to obtain this information. If CCC determines, based on the documentation received, that an exporter has registered against an FFI's limit without the bank's knowledge or approval, that exporter will be required to modify or cancel its application for payment guarantee. However, there will be no consequence to the exporter if an FFI later determines not to issue the letter of credit, as CCC acknowledges that this situation can legitimately occur.

CCC made several changes to this section in the new proposed rule. In paragraph (a), CCC clarified that a firm export sales contract for an "Eligible Export Sale" must exist before an exporter submits an application for a payment guarantee. This change is consistent with the new prohibition in § 1493.100(f)(7) on transactions not meeting the definition of "Eligible Export Sale." A definition of this term was added to § 1493.20.

In paragraph (a)(1), CCC added that if the export sale is being registered under a regional allocation, the exporter must indicate the country or countries within the region to which the commodities will be exported. This will permit CCC to better track the destination of commodities under the program, although CCC recognizes that such information may not be final until reported in the evidence of export report.

In paragraph (a)(2), CCC proposes additional requirements if the importer is not located in the country or region of destination, but is instead utilizing an "Importer's Representative" in the country or region. As noted in the *Definition of Terms* discussion, allowance of this concept is in response to comments received to the initial proposed rule. Specifically, CCC proposes to require the name and address of the importer's representative that will be taking receipt of the commodities exported under the payment guarantee. CCC will routinely check these entities against the SAM and OFAC lists to ensure unauthorized parties are not serving this function in GSM-guaranteed export sales. CCC also modified the required statement regarding direct shipment of the registered commodities to the importer to allow for direct shipment to the importer's representative. This statement was previously found in paragraph (a)(5), but was moved to paragraph (a)(3) to clarify that it is required on all applications for payment guarantees, not simply those utilizing an intervening purchaser.

In paragraph (a)(4) of this section, CCC deleted the term "letter of credit account party" in response to the comment received on the definition in § 1493.20 and instead utilizes the definition of "applicant" directly from the UCP 600.

In paragraph (a)(9) of this section, CCC added that the commodity grade and quality specified in the application for the payment guarantee must be consistent with that specified in the firm export sales contract and foreign financial institution letter of credit. As noted in the discussion below on § 1493.90(a), CCC agrees with comments that this requirement should not be contained in the letter of credit and that the exporter should be responsible for ensuring this requirement is met. Therefore, this language has been added to the application for payment guarantee section. The exporter may be held liable if CCC pays a claim for default and determines that the cause of the default was a discrepancy, specifically related to this requirement, between the firm export sales contract and the foreign financial institution letter of credit.

Section 1493.80 Certification Requirements for Obtaining Payment Guarantee

Three comments were received regarding the practicality of having the exporter confirm that the importer is excluded from participation by the Excluded Parties List System (EPLS) or Office of Foreign Assets Control (OFAC) lists as required by paragraph (d) of this section. The respondents noted that both of these lists have standard disclaimers regarding potential errors and omissions. Because of these disclaimers, exporters can only certify that the importer or intervening purchaser is not on the list at the time of application. They cannot certify that the importer is not suspended, debarred or otherwise precluded. CCC agrees with these comments and modified the language in § 1493.80(d) to require the exporter to certify that neither the importer nor the intervening purchaser are present on these lists at the time of application for the payment guarantee. As discussed in the *Definition of Terms* section, references to EPLS were changed to SAM.

CCC made several additional changes to the certifications in the new proposed rule. A reference to the Foreign Corrupt Practices Act of 1977 was added to paragraph (b), consistent with this addition to the certification found at 1493.60(b). CCC also added a new certification in paragraph (f) of this section. The exporter will be required to certify that it is in compliance with the requirements for submitting evidence of export (EOE) reports for all existing payment guarantees. CCC faces continual issues with exporters not submitting these reports in a timely manner. In response, a new provision was added at 1493.130(c) in the initial proposed rule that will preclude acceptance of new payment guarantee applications if an exporter is not in compliance with EOE submission timelines. CCC determined it is appropriate to require exporters to certify in each application for payment guarantee that they are compliant with this requirement with respect to other existing payment guarantees. CCC hopes this certification will prompt exporters to be more vigilant about meeting EOE requirements.

Section 1493.90 Special Requirements of the Foreign Financial Institution Letter of Credit and the Terms and Conditions Document, if Applicable

Thirteen respondents submitted comments on § 1493.90. Overall, respondents indicated that many of the changes proposed by CCC are inconsistent with international banking practices and accepted guidelines for letters of credit as found in the Uniform Customs and Practice for Documentary Credits (UCP 600). They noted that requiring specific language will increase the time, costs, and risks associated with issuing the letter of credit and jeopardize the willingness of both U.S. and foreign financial institutions to participate. Several respondents suggested CCC provide a standardized

template for the letter of credit requirements to ensure participants comply with the provisions of this section, and allow such requirements to be contained in the special instructions of the letter of credit or in a separate document, such as a loan agreement. One respondent commented that CCC should enter a framework agreement with each approved foreign financial institution to cover the terms and conditions of this section so they are not required in every letter of credit.

In response to these comments CCC modified § 1493.90 and removed the requirement that the specified terms and conditions be contained in the foreign financial institution letter of credit. Instead, CCC added the concept of a "Terms and Conditions Document" that may accompany the letter of credit. This change will allow participants the flexibility of having the required language in either the letter of credit or a separate document. CCC also clarified in § 1493.90(a) that such terms and conditions may be contained in the letter of credit as a special instruction, but eliminated the option of a promissory note because of lack of use of this mechanism. Although CCC considered the option of developing a framework agreement for each approved foreign financial institution, some institutions preferred that the required terms be contained in the letter of credit or related document rather than a separate framework agreement.

Paragraphs (a) and (b) of this section were re-ordered in the new proposed rule: Paragraph (a) describes the option to use either the letter of credit or terms and conditions document to contain the special requirements found in paragraph (b). CCC added a proposed requirement in paragraph (a) that the letter of credit stipulate presentation of at least one original clean on-board bill of lading as a required document. A number of program participants have suggested this provision as a means of preventing non-eligible export sales. CCC would not require an original bill of lading be submitted at time of a claim, but would ensure that the letter of credit contained this provision.

Section 1493.90(b) now includes a listing of requirements of the letter of credit or terms and conditions document, which CCC believes eliminates the need for a standardized template. As noted in the *Definition of Terms* discussion, "related obligation" has been replaced with the term "Repayment Obligation." Two new requirements were added: Jurisdictional language in case of legal action (§ 1493.90(b)(2)) and a requirement to specify post-default interest terms (§ 1493.90(b)(4)). The language specifying legal jurisdiction was added to protect the interests of both CCC and its risk share partner in case of default, in hopes of increasing chances of recoveries if CCC takes legal action. CCC does not require a specific post default interest rate under the letter of credit, and this information is often omitted. Requiring the letter of credit to specify such interest terms (even if the rate is zero) will add clarity in cases where CCC has been subrogated the rights to recovery.

Seven comments were received on the requirement that the letter of credit specify the transaction is a bona fide trade transaction (§ 1493.90(a)(1) in the initial proposed rule). Three respondents indicated this language is not applicable to all GSM–102 transactions; therefore, in certain cases participants would be unable to comply. Two respondents suggested revised wording they believe would cover all GSM–102 guaranteed transactions. Three respondents requested that CCC define the terms "bona fide trade transaction" and "trade finance debt," while one respondent indicated this language may be confusing to foreign financial institutions because the documentary letter of credit is the internationally accepted mechanism for financing "bona fide" trade. One respondent pointed to the need for CCC to allow the Director to approve modifications to this language on a case-by-case basis to respond to an issuing bank's interpretation of the wording. One respondent requested that CCC permit refunds of guarantee fees if the foreign financial institution is unable to comply with this requirement, and another suggested this requirement be included as part of the foreign financial institution's initial qualification for the program. CCC agrees with the concerns expressed by participants and eliminated this requirement in the new proposed rule.

Five respondents provided comments on the requirement that the letter of credit contain an acceleration clause (§ 1493.90(b)(3)). One commenter indicated that acceleration clauses are not normally contained in letters of credit, and two commenters suggested this language be included in a framework agreement between the U.S. and foreign financial institution or in the special instructions in the letter of credit. Three commenters requested that CCC provide specific language to meet this requirement to ensure compliance, with one respondent requesting that the Director have the flexibility to allow modifications to this language.

As previously noted, CCC modified § 1493.90 to permit the requirements of this section, including the acceleration clause, to be contained in the special instructions of the letter of credit or in a separate terms and conditions document. CCC did not add specific required language for this clause, as CCC believes the requirement described in the regulation is sufficient. Past experience indicates that such clauses are not uncommon in letters of credit and that exporters and financial institutions have utilized them in the past; therefore, specific language is not necessary, nor is flexibility for the Director to allow language modifications.

Six respondents provided comments on the requirement that the commodity grade and quality specified in the sales contract be consistent with the commodity grade and quality in the letter of credit (§ 1493.90(a)(3) in the initial proposed rule). Most commenters indicated that this requirement is inconsistent with international banking standards found in the UCP 600. The letter of credit is a separate transaction from the sales contract and the payment obligation under the letter of credit is based on meeting documentary conditions, not upon performance of the underlying contract. Two respondents requested this provision be deleted. One respondent indicated that adding the commodity quality and grade to the letter of credit should not be problematic because this information is contained in the bill of lading and invoice, and another commenter suggested attaching the invoice to the letter of credit to convey this information. One commenter stated that it should be the responsibility of the exporter to certify this requirement.

CCC agrees with the comments that this language should not be part of the letter of credit and that the U.S. financial institution should not be responsible for verification and removed this language from § 1493.90 in the new proposed rule. However, CCC continues to believe this requirement is important to avoid defaults based on failure to comply with the underlying terms of the sale; therefore, changes in § 1493.70 (*Application for Payment Guarantee*) clarify that the exporter is responsible for ensuring this requirement is met.

Section 1493.100 Terms and Requirements of the Payment Guarantee

Although CCC received no formal comments on § 1493.100(b), *Period of guarantee coverage*, CCC is proposing modifications in this section in an attempt to facilitate container shipments under the program. The small dollar

value of individual container shipments often make the use of separate letters of credit for each shipment too costly, and the extended delivery period over which these shipments occur may require a long validity period for the letter of credit, increasing its costs. CCC hopes to mitigate these factors by giving participants the option to utilize either the date of export or a weighted average export date as the start of the credit period. By using a weighted average export date, the exporter and assignee can "bundle" all shipments having dates of export within a 30 calendar day period and have the credit period begin on the average date of these shipments, weighted by the guaranteed portion of the exported value of each shipment. Participants would be permitted to bundle all shipments within a 30 calendar day period, with the first 30 calendar day period beginning on the first date of export under the payment guarantee, the second 30 calendar day period beginning 31 calendar days after the first date of export, and so on until the final date to export specified on the payment guarantee.

For example, assume an exporter has three shipments as follows within a 30 calendar day period:

March 1 (first) shipment: $500,000 in guaranteed value

March 10 (second) shipment: $400,000 in guaranteed value.

March 25 (third) shipment: $800,000 in guaranteed value

The weighted average export date would be calculated as follows:

[Σ (day of the month) × (guaranteed value for that day)]/[Σ (total guaranteed value)]

In this example, the first shipment date would be the first day of the month; therefore, March 1 would be "1." The calculation is:

[(1 × 500,000) + (10 × 400,000) + (25 × 800,000)]/(500,000 + 400,000 + 800,000) = 24,500,000/1,700,000 = 14.4, or March 14.

If the exporter chooses to bundle these shipments, the weighted average export date would be March 14. The credit period for this bundle of shipments would, therefore, commence on March 14.

CCC also included the option for payment guarantee coverage to begin when ordinary interest begins to accrue, if such interest begins to accrue prior to the first date of export. This provision is found in the current regulation, but was inadvertently deleted in the initial proposed rule. It is CCC's policy to permit coverage of interest accrued prior to the date of export, although the payment guarantee does not become effective until the date of export. Interest may begin to accrue prior to the date of export in export sales made on the basis of FOB, U.S. interior points of loading, such as sales to Mexico shipped in trucks or railcars. The provisions of § 1493.100(b) indicate that the credit period can begin either upon the date of export or on the date that interest begins to accrue, whichever is earlier. A provision has been added to allow for the weighted average date when interest begins to accrue at the option of the holder of the payment guarantee.

Seven respondents submitted comments on § 1493.100. Three respondents disagreed with the elimination of the 30-day grace period found in the current regulation at § 1493.60(d). Two commenters noted that issues outside of the exporter's control, such as transportation delays, lack of container availability, and weather problems, may delay shipments. One commenter noted that the elimination of the grace period will impact both small and large businesses and is counter to the goals of the National Export Initiative, the Paperwork Reduction Act, and the intent of the proposed rule. One respondent commented that with a new cotton crop becoming available each August and September, the grace period provides the exporter additional time to work out shipping problems. During 2009/2010, the grace period was particularly helpful due to the transportation congestion and backlogs that occurred. One commenter stated that the 30-day grace period should be reinstated to match commercial realities, and that otherwise CCC should allow for guarantee fee refunds in cases where the exporter cannot make shipments within the designated time period. CCC agrees with these concerns and reinstated the 30-day grace period in § 1493.100(d) of the new proposed rule.

Three respondents provided comments on CCC's proposed changes to § 1493.100(e), *Reserve coverage for loading tolerances.* Two commenters noted that the most common tolerance in bulk agricultural contracts is plus or minus 10 percent and that CCC's guarantee should reflect that reality. CCC agrees and revised the proposed rule to allow for an upward loading tolerance of 10 percent. CCC will require exporters to pay the guarantee fee based on the mean loading tolerance (instead of the lower loading tolerance). Because reserve coverage ties up both country and foreign bank limits, CCC hopes that requiring exporters to pay the fee based on the mean loading tolerance will ensure that exporters are serious about the need for such coverage at time of application. One respondent asked if an exporter was entitled to a refund of the fee paid for reserve coverage if this coverage is not utilized. Although an exporter is not *entitled to* a fee refund for unutilized reserve coverage, CCC will consider such requests from exporters on a case-by-case basis if the exporter's inability to utilize such coverage was outside of the exporter's control. Exporters may be required to submit documentation to CCC to support such a request.

One comment was received on the requirement that the exporter file for a payment guarantee amendment within 15 calendar days of the final export date or CCC will cancel the exporter's reserve coverage. With bulk agricultural shipments, the exporter may be unable to determine the allocation of the shipped commodity across multiple registrations until the vessel reaches its final destination, which could be 30 to 40 days from the loading date. The respondent requested CCC allow the exporter 45 days from the date of export to file the amendment to utilize reserve coverage.

CCC does not agree with the suggestion to allow the exporter 45 days to file an amendment for reserve coverage. Reserve coverage allows exporters to hold program allocation that may not be utilized and could be made available to other exporters. However, CCC recognizes that exporters may need time past the final date to export to compile relevant documents and determine the final amount of coverage. Therefore, CCC increased this timeframe to 21 calendar days after the final export date. This timeframe is consistent with the evidence of export (EOE) reporting requirements, because the exporter will know by the submission of the final EOE what level of reserve coverage is needed.

CCC received four comments on § 1493.100(f), now titled *Certain export sales are ineligible for GSM–102 Payment Guarantees.* One commenter noted that the U.S. financial institution may be unable to determine at the time of taking assignment of a payment guarantee whether a transaction is prohibited. This respondent requested clarification on whether a prohibited transaction could be deemed ineligible for coverage after assignment. Two respondents requested similar clarification with respect to § 1493.100(f)(6), which prohibits coverage of a transaction that has been guaranteed by CCC under another payment guarantee. Specifically, these respondents requested assurance that CCG would not revoke coverage or take action against the assignee in this case.

CCC agrees that an assignee may not know that a transaction registered under the GSM–102 program is prohibited. Section 1493.180(e), *Action against the assignee,* states in part that CCC will not "hold the assignee responsible or take any action or raise any defense against the assignee for any action, omission, or statement by the exporter of which the assignee has no knowledge." If a prohibited transaction were registered under a payment guarantee, CCC would take action against the exporter, if warranted, but not against the assignee, provided the assignee had no knowledge that the transaction was prohibited. CCC believes that § 1493.180(e) protects the assignee in such cases and that no additional changes are needed in the proposed rule.

Two commenters proposed methods by which CCC could determine which individual or entity is the valid exporter if a transaction is registered under multiple payment guarantees, which is prohibited by § 1493.100(f)(6). One respondent noted that an exporter is unlikely to know if a second entity acquires its bills of lading and uses them to register export transactions under another guarantee. This commenter suggested that CCC detail in the regulations that the "valid" registrant should be either (1) the actual shipper of the goods (i.e., the exporter who arranges and pays to have the goods loaded onto the vessel); or (2) the exporter whose contract with its supplier indicates that neither the supplier, its affiliates, nor any third party has registered the goods under any U.S. government program. A second respondent suggested that the exporter of record should determine which entity holds the valid payment guarantee. A third respondent recommended that CCC require the exporter to make a certification with respect to § 1493.100(f)(6) in both its application for payment guarantee and evidence of export report.

CCC made no changes in response to these comments. Based on CCC's recent experience, there is not a single, most appropriate method for determining which exporter has the eligible export sale when an export sale is registered under more than one payment guarantee. By definition, only one eligible export sale can exist. This determination could involve contacting both exporters who registered the export sale; requesting and reviewing documents, such as bills of lading and/or bank and payment records; and contacting suppliers, importers or agents associated with the export sale. It is not possible for CCC to dictate in the rule all possible methods of making this determination. It also is unclear what is meant by "exporter of record" or how CCC could be assured that this entity validly holds a payment guarantee. Finally, CCC does not believe an exporter could certify that a transaction has not been registered by another entity under another payment guarantee, as the exporter may not know this was occurring. Therefore, CCC will review these transactions on a case-by-case basis to determine when a specific transaction is prohibited.

To further clarify this requirement, CCC added a prohibition on any transaction that is not an "Eligible Export Sale" in § 1493.100(f)(7). An explanation is found in the discussion of this term's definition in § 1493.20.

Three respondents commented on the proposed prohibition on coverage where the issuance of the foreign financial institution letter of credit is more than 30 calendar days after the date of export. Two respondents noted that the timing of letter of credit issuance is often outside of the exporter's control and legitimate factors exist that could delay issuance beyond 30 days, including delays in receiving bills of lading and approvals required by the foreign financial institution. Additionally, the exporter, foreign financial institution and applicant for the letter of credit may not develop the exact requirements of the letter of credit until after the exporter registers the sale with CCC. A third respondent noted that although most letters of credit meet the 30-day criteria, this requirement will negatively impact small- and medium-sized exporters, whose customers and issuing banks are slow in issuing letters of credit.

Although the proposed rule would allow the Director to make exceptions to this provision on a case-by-case basis, one commenter noted that such extension requests will add paperwork and delays and will, therefore, reduce the advantages of the GSM–102 program. One commenter stated that U.S. financial institutions would require proof that CCC had granted such an extension, which could delay payment to the exporter. One respondent noted that U.S. financial institutions would be required to implement a procedure at the time of examination of documents to verify the letter of credit issuance date. Such a process is not covered by the UCP 600, nor is it a standard international banking practice for the examination of documents. Further, the foreign financial institution would not know at the time of receiving the letter of credit application whether the letter of credit will be eligible, because the date of export is unknown at that time. One of the commenters indicated that CCC's transaction risk begins at the bill of lading date and that the letter of credit issuance should not affect CCC's risk profile. Two of the commenters requested this provision be deleted because it is inconsistent with standard banking practice and will hurt program utilization.

CCC made no changes in response to these comments. In the preamble to the initial proposed rule, CCC noted that it is increasingly common for exporters to obtain a payment guarantee and not have the required foreign financial institution letter of credit in place for an extended period of time after the export date. In some cases, the letter of credit is never issued and the transaction is cancelled by the exporter. The "cost" of such cancellations is that other exporters who may have utilized the allocation are unable to do so. This provision is not related to CCC's risk profile, nor is it intended to reduce CCC's risk. It is intended to ensure that exporters who register sales have legitimately worked with the importer (or other letter of credit applicant) and the foreign financial institution prior to registering for coverage and are not simply "rushing in" to garner a portion of the announced allocation, a practice that negatively affects other exporters (including small- and medium-sized exporters) by reducing their access to the program. Given that exporters typically have 90 days from the date of registration to export, a 30-day shipment grace period (which as noted previously, is being reinstated by CCC), and 30 days from shipment to issue the letter credit, participants have up to 150 days, or five months, to accomplish issuance of the letter of credit after the sale is registered with CCC. CCC believes this timeframe should be sufficient. CCC has, however, modified this provision to allow for issuance of the letter of credit up to 30 days after the weighted average export date, if this is the date utilized by the holder of the payment guarantee for the starting point of the credit term.

CCC acknowledges there may be an additional burden in requesting extensions to this provision, but will develop internal procedures for handling these requests to minimize paperwork and delays, including notifying assignees. CCC also acknowledges that verification of the issuance date of the letter of credit may not be a standard practice covered by UCP 600. However, the letter of credit issuance date is required in all letters of credit, and CCC does not consider comparison of this date against a bill of

lading date to be an undue burden on assignees.

Three respondents commented on the proposal to allow CCC to charge a fee for payment guarantee amendments (§ 1493.100(i)). One respondent noted that fees are intended to offset the transaction risk undertaken by CCC, and that fees for amendments could make a transaction unviable and are inconsistent with other export credit agency programs. Further, it would be time-consuming for CCC and the exporter to track these additional fees. This respondent requested the provision be eliminated. A second respondent asked for clarification on the elements of the payment guarantee that can be amended and the cost for each type of amendment. A third respondent suggested that exporters be permitted one free amendment with a $500 fee assessed thereafter.

CCC made no changes in response to these comments. Under the statute governing the program, CCC must work to ensure "to the maximum extent practicable, that risk-based fees associated with the guarantees cover, but do not exceed, the operating costs and losses over the long term." Processing payment guarantees and amendments incurs a cost that should be offset by fee revenue. CCC is routinely faced with a large number of amendment requests and views such fees as an option to offset the costs associated with amendments. Additionally, the proposed rule does not implement such a fee but simply gives CCC the right to charge a fee. No such fee rates have been developed, and CCC does not intend to modify the types of amendments that exporters can currently request. If CCC determines that such fees should be implemented, comments received from participants will be considered in developing these fees, and they will be posted on the USDA Web site.

Section 1493.110 Guarantee Fees

Five respondents commented on the provision in the proposed rule to determine guarantee fees through a competitive bidding process. Three respondents stated that an auction process would benefit larger exporters with the most information and financial resources to the detriment of small- and medium-sized exporters—counter to CCC's intent to increase program access for all U.S. exporters. One respondent noted that an auction process would create uncertainty in prices (as fees are often included in the exporter's sales quote), which could cause exporters to lose sales. Two respondents noted that the proposed rule did not contain specific parameters of an auction. One commenter stated that an auction would require establishment of minimum base fees, but in some cases current fees already exceed the market, making utilization cost-prohibitive. For an auction to work, these fees would need to be reduced. One respondent did not support the concept of an auction if it is intended only to garner increased fees for oversubscribed allocations. However, if CCC were willing to accept lower fees for underutilized allocations, the auction process could prompt program activity in underutilized markets and demonstrate that prices are truly market-based.

No changes were made in response to these comments. CCC has not determined whether to implement a competitive bidding process for fees and acknowledges that additional research is needed before this step could be taken. The proposed rule does not dictate such a process, but simply allows for it. As noted, any information or instructions under a competitive bidding process would be made public on the USDA Web site. However, CCC will consider these comments in deciding whether to utilize an auction process in the future.

Four respondents commented on paragraph (d), *Refunds of fees.* One commenter agreed that CCC should not refund fees under an auction scenario, as this would allow exporters to overbid with no consequence. This respondent also agreed that refunds should not be permitted when programs are over-subscribed, as otherwise, exporters can "over-apply" with no consequence. Because unutilized amounts are generally not returned to the allocations, this practice can prohibit full program use. However, two respondents noted that, given the changes in the proposed rule, CCC should permit fee refunds when circumstances outside of the exporter's control prohibit the exporter from utilizing the guarantee—particularly if the inability to get a letter of credit in place is outside of the exporter's control. If CCC cancels a guarantee, CCC should not be paid for risks not assumed. One respondent suggested that if an exporter receives anything less than 90 percent of its requested registration, CCC should refund the fee because any lesser amount prohibits the exporter from exercising the firm sales contract.

CCC made no changes in response to these comments. Given the myriad of potential scenarios, it is impossible to specify in the regulation all circumstances in which CCC would grant a fee refund. The general rule is that fees are non-refundable. However, CCC retained the caveat that the Director may grant a refund that he/she determines is in the best interest of CCC. CCC acknowledges that there will be cases when an exporter is unable to utilize a guarantee, including instances where a letter of credit is not issued, that will be outside an exporter's control. CCC will consider requests for refunds on a case-by-case basis. However, CCC fully expects that all parties to the transaction are familiar with the program regulations and have discussed a given transaction prior to the exporter's submission of an application for payment guarantee. Therefore, CCC expects fee refunds to be granted only on an exceptional basis. Participants are reminded that guarantee fees, in accordance with the program statute, are intended to cover not only CCC's risk but also its administrative costs. An application that is subsequently canceled by the exporter incurs an administrative cost.

One respondent asked for clarification regarding the types of refunds CCC has permitted in recent years. This respondent also requested that CCC return to its previous system of letting an exporter pay the guarantee fee after CCC accepts the exporter's application, as requiring the fee with the application has not solved oversubscription problems.

CCC allows refunds of fees only in exceptional circumstances. For example, if an importer decides post-shipment not to utilize the payment guarantee, CCC may refund the fee if the exporter submits relevant shipping documents with an explanation. Additionally, CCC has granted fee refunds post-shipment when the importing country implemented sanitary-phytosanitary restrictions prohibiting entry of the goods. CCC does not agree with the suggestion to allow submission of the guarantee fee after CCC accepts the exporter's application. CCC has had past problems with exporters not submitting guarantee fees in a timely manner. This creates a burden on CCC to repeatedly contact exporters to collect fees and ties up allocations that could be utilized by another exporter. Therefore, CCC is maintaining the requirement that fees be submitted with the exporter's application.

Section 1493.120 Assignment of the Payment Guarantee

One respondent commented on this section, stating that although the bank will complete required OFAC checks prior to engaging in a GSM–102 transaction, it should be CCC's responsibility to determine whether the foreign financial institution is excluded

from participation via the EPLS (now SAM) prior to issuing the payment guarantee.

CCC made no changes in response to this comment (although consistent with the previously described definition change, EPLS has been changed to SAM). Prior to issuance of a payment guarantee, CCC checks all participants in the transaction against both OFAC and SAM. However, USDA suspension and debarment regulations at 2 CFR 417.215(b) require primary tier participants under the export credit guarantee programs to check the EPLS (SAM) prior to entering a transaction at the first lower tier. The regulations at 2 CFR 417.222(a) state that "a transaction at the first lower tier might be a payment obligation of a foreign bank under an instrument, such as a loan agreement or letter of credit, to the U.S. financial institution assigned the guarantee . . . " The U.S. financial institution is a primary tier participant under the GSM–102 program and is, therefore, required to make this check against SAM.

In paragraph (b) of this section, CCC added that notices of assignment should be received by CCC within 30 calendar days of the date of assignment. It is important for CCC to know who the holder of the payment guarantee is for each guarantee, particularly when a default occurs. Some U.S. financial institutions delay submitting notices of assignment to CCC. This provision is a reminder that these notices should be submitted timely.

In response to comments discussed in § 1493.80, CCC modified the language in § 1493.120(c)(i) to require the U.S. financial institution to certify that the foreign financial institution is not present on the SAM or OFAC lists at time of acceptance of the notice of assignment. CCC made a similar change in paragraph (f) of this section, and also incorporated the newly defined terms "Holder of the Payment Guarantee" and "Terms and Conditions Document" where applicable.

No comments were received regarding § 1493.120(f); however, CCC made several clarifications to this language in the new proposed rule. Additionally, CCC determined that the required clauses in paragraph (f)(1)(iii) and (f)(1)(v) of this section in the initial proposed rule were unnecessary; both have been deleted.

Section 1493.130 Evidence of Export

Four respondents commented on this section. Two respondents requested that CCC reinstate the 30-day timeframe for filing the evidence of export report (EOE). Three commenters noted that it will be difficult for exporters to submit EOEs within ten days. An exporter may not receive bills of lading until well after loading and; therefore, may be unable to determine within ten days which shipment parcels apply to certain guarantees. One commenter explained that the 10-day timeframe will be problematic for container shipments of high value products. Hundreds of such containers can comprise a GSM–102 guaranteed sale and associated letter of credit, and the bills of lading for these shipments are often bundled over several months. A 10-day submission requirement for EOEs would, therefore, stop container shipments of high-value products under the program.

CCC acknowledges these concerns and increased the timeframe for EOE submission to 21 calendar days in the new proposed rule. The proposed rule permits requests for extension of this timeframe, which CCC will consider on a case-by-case basis. Further, the proposed rule does not call for cancelation of a guarantee where the exporter is unable to meet this timeframe. Instead, pursuant to paragraph (c) of this section, failure to meet the timeframe or receive an approved extension means that the exporter will be unable to submit applications for new payment guarantees until EOE submissions are current. CCC does not believe this consequence is tantamount to stopping an entire category of shipments under the program.

Two commenters stated that the current 30-day EOE submission requirement historically has not been enforced by CCC and that exporters have been instructed not to submit extension requests due to the burden this creates on CCC. Further, one respondent suggested that the budget and policy issues requiring timely EOEs only correspond to the middle and end of the fiscal year; therefore, CCC should consider enforcing this deadline only at those times, or at other critical dates as determined by CCC. Another commenter stated that the 10-day requirement places a priority on CCC's internal process over commercial realities.

CCC acknowledges that the 30-day submission requirement has not been enforced. This is because, under § 1493.80(b) of the current rule, CCC's recourse for late EOEs is to nullify the guarantee. This can only be done if CCC can demonstrate one of the consequences specified in § 1493.80(b). CCC has determined that, in most cases, late EOEs do not cause sufficient harm to CCC to warrant nullifying the associated guarantees. As a result, there effectively has been no recourse available to CCC for late EOEs and no purpose to requiring requests for extensions to the filing deadline.

Proposed changes to this section are specifically intended to provide CCC such recourse, and CCC fully intends to enforce the new requirement, including responding to requests for extensions. CCC does not agree that this requirement should only be enforced at the middle and end of a program (fiscal) year. Lack of timely EOEs negatively affects CCC's ability to accurately report on the GSM–102 program in its financial statements. Additionally, receipt of EOEs allows CCC to reduce usage against foreign bank and country limits to the extent that exporters do not export the full value of the guarantee. Absent EOEs, exporters may unnecessarily restrict utilization of foreign bank and country limits. Program availability is an issue throughout the year, not only at the middle and end of the fiscal year.

One respondent asked what CCC would consider a "legitimate circumstance" warranting a request for an EOE filing extension. There could be multiple reasons why CCC would permit an extension to the filing deadline. CCC cannot predict in advance what these circumstances will be. Approvals will be granted case-by-case, based on the explanation (and corresponding documentation, if any) provided by the exporter at the time of request.

One respondent stated that U.S. financial institutions are unable to determine whether an exporter has submitted an EOE on time, as CCC's on-line system does not contain an EOE submission date. Further, if CCC implements the shortened timeframe, assignees will require evidence that EOEs for assigned guarantees are submitted within the required timeframe.

CCC does not agree that the U.S. financial institution must be advised whether EOEs are submitted within the required timeframe or if CCC has granted an extension to this timeframe. The consequence of failure to comply with this requirement is that the exporter cannot submit applications for new payment guarantees per § 1493.130(c). There is no impact on the relevant guarantee if the EOE is late, no consideration of the timeliness of the EOE at the time of claim and, therefore, no impact on the assignee. However, CCC is willing to share this information with assignees upon request. CCC will consider adding this information to the GSM web-based system so that it is readily available to assignees.

Section 1493.140 Certification Requirements for the Evidence of Export

CCC received one comment on this section, with the respondent agreeing with CCC's proposal to remove the certification found at § 1493.90(c) in the current rule (which requires the exporter to certify that the letter of credit has been opened). No changes were needed in response to this comment. Consistent with changes made with respect to the SAM and OFAC certifications, CCC modified the certification at § 1493.140(d).

CCC added two certifications to the new proposed rule. In § 1493.140(b), CCC proposes to require the exporter to certify that the commodities under the payment guarantee were shipped directly to the importer (or to the importer's representative) in the destination country or region. This certification is intended to enhance compliance with the new requirements related to the importer's representative and to ensure the goods are shipped consistent with the information provided in the exporter's application for payment guarantee. When making this certification, an exporter is certifying that either the importer on the payment guarantee or the importer's representative, as specified in the application for the payment guarantee, is taking receipt of the goods in the destination country or region. If CCC determines that the agricultural commodities exported under a payment guarantee are shipped to an entity other than the importer or the importer's representative, the exporter will be in violation of the requirements of this sub-part and the certification statement made on the EOE. At § 1493.140(e), CCC added a certification that the transaction reported in the EOE is an "Eligible Export Sale." The meaning of this term is found in the discussion of § 1493.20. Because CCC will prohibit coverage of any transaction that does not meet the definition of "Eligible Export Sale," CCC will require exporters to certify that the transaction reported under the evidence of export report meets this requirement.

Section 1493.150 Proof of Entry

CCC received one comment on this section, noting that requiring proof of entry documentation with a claim for default (found in § 1493.170) would slow payments from the U.S. financial institution and negatively affect exporters' cash flows, as the proof of entry document is often outside of the exporter's control. Further, these cash flow problems will most notably affect small businesses.

CCC agrees with this comment, as well as additional comments received on this issue under § 1493.170. In response, CCC removed the requirement to provide proof of entry as a claims document. CCC added a statement to § 1493.150(b)(1) reminding exporters they must submit proof of entry documentation to CCC at the Director's request. Exporters are advised that CCC may request this documentation following submission of a claim for default by the holder of the payment guarantee. Assignees are reminded that pursuant to § 1493.191(d), *Misstatements or noncompliance by Exporter may lead to rescission of Payment Guarantee,* the assignee is held harmless for the exporter's failure to comply with proof of entry requirements provided that the assignee had no knowledge of the exporter's noncompliance at the time of taking assignment of the payment guarantee.

Section 1493.160 Notice of Default

Three respondents commented on CCC's proposal to change the notice of default submission timeframe from ten calendar days to five business days after the date payment is due from the foreign financial institution. Two respondents requested CCC retain the current timeframe, noting that the reduced timeframe poses an operational risk to the exporter or assignee and a reputational risk to the foreign financial institution. Specifically, the shorter time period does not allow sufficient time to resolve operational errors and oversights or to detect or reconcile missed payments. One respondent requested that the timeframe be extended to 60 days, due to possible discrepancies in presentation of documents under the letter of credit.

No changes were made in response to these comments. It is CCC's responsibility in a default to avoid jeopardizing additional taxpayer resources. CCC can only uphold this responsibility if it is notified immediately of a default and prevents issuance of additional guarantees with the defaulting institution. CCC does not believe this change poses undue risk upon the exporter or assignee. The timeframe is clear; if the holder of the payment guarantee knows that a payment has not been made, or cannot verify whether the payment has been made, the holder should submit the notice of default within the prescribed timeframe to protect its rights under the guarantee. CCC acknowledges the possibility of "technical" defaults that are due to oversight and quickly resolved. As the notice of default requires a reason for refusal to pay, this possibility will be conveyed to CCC on the notice of default. CCC will work with all parties to minimize any reputational risk to the foreign financial institution.

One respondent requested clarification on the meaning of the due date of the payment and what CCC considers to be a payment default. These clarifications can be found in paragraph (a) of this section. The "due date" is "the date that payment was due from the Foreign Financial Institution." A default is any case where "the Foreign Financial Institution issuing the Letter of Credit fails to make payment pursuant to the terms of the Letter of Credit or the Terms and Conditions Document."

CCC received comments from five respondents on paragraph (c) of this section regarding the impact of a default on other existing payment guarantees. One commenter noted several issues with this provision: (1) the guarantee may have been the basis for the exporter to enter the sale with the importer; (2) the exporter may not have a line of credit with another approved foreign financial institution; and (3) if the letter of credit has already been issued and confirmed, under UCP 600 rules it cannot be cancelled without the consent of all parties. The respondent also noted that when CCC issues a guarantee, it does so based on its assessment that the foreign financial institution is creditworthy throughout the 120-day maximum shipping period. If a default occurs, CCC should notify the exporter and continue to honor guarantees, provided the letter of credit is issued not later than 30 days following the final shipment date. The respondent noted that all parties would likely make a good faith effort not to ship additional product, but this may not be possible if the letter of credit has been issued and documents have been presented to the U.S. financial institution.

Three respondents noted that this change will make CCC's guarantee conditional. In contrast, the required payment mechanism (the letter of credit) would remain irrevocable. This situation would create significant additional risk to the U.S. financial institution and would require it to carry more capital and charge higher lending margins, thereby making financing under the program more costly. This cost would in turn be passed on to the exporters, making the program less attractive to all participants. Respondents requested this provision be revised or removed. One respondent requested that CCC allow the foreign financial institution time to resolve

technical payment issues without affecting existing payment guarantees.

In response to these comments, CCC revised paragraph (c) to reflect that CCC will only withdraw guarantee coverage of the defaulting foreign financial institution where the letter of credit has not yet been issued for the export sale. CCC agrees that once the letter of credit is issued and documents presented, the U.S. financial institution is obligated to make payment and the letter of credit cannot be canceled without consent of all parties. It is not appropriate for CCC to revoke its guarantee at this time. If a default occurs, CCC will provide written notice (likely via email) to all exporters and assignees with payment guarantees involving the defaulting foreign financial institution. CCC will not provide coverage for any letters of credit that are issued by the defaulting foreign financial institution on or after the date the exporter and assignee receive this notice from CCC. If CCC withdraws coverage of that foreign financial institution, the exporter will have the option of finding an alternate foreign financial institution within 30 calendar days or cancelling the guarantee (with a refund of the fee corresponding to any cancelled guarantee amount). CCC will also consider other requests for amendments from the exporter if needed to facilitate completion of the export sale. If the holder of the payment guarantee subsequently files a claim, CCC will confirm during the claim review process that the letter of credit was issued prior to CCC's notification. Although CCC recognizes that this policy creates risk for the exporter, which may have conditioned the sale upon the guarantee, CCC has a responsibility to protect against additional losses. If a default is technical in nature, this fact will be indicated on the notice of default and CCC will work with all parties to try to resolve the default without affecting existing payment guarantees.

Section 1493.170 Claims for Default

Three respondents commented on the requirement to submit proof of entry documentation at the time of claim under § 1493.170(a)(5)(iii) of the initial proposed rule. Two respondents noted that the U.S. financial institution does not typically receive this document because it is the exporter's responsibility. The U.S. financial institution has no assurance the exporter would provide it at time of claim or that it would be satisfactory to CCC. One respondent commented that with this requirement, the exporter would be paid when the goods arrived at destination rather than at export. This change would have a significant negative effect on the exporter's cash flow, especially for smaller exporters. In addition, the exporter must rely on the importer for this document and letters of credit would have to be issued for longer periods to accommodate the time needed to obtain the document, all of which would increase risk and costs to the exporter. There are no rules for determining the acceptability of these documents, which would increase review time and operational risks to U.S. financial institutions.

CCC agrees with these comments and eliminated the requirement to provide proof of entry at time of claim. CCC clarified in § 1493.150 that the exporter must provide this documentation to CCC at the request of the Director.

One respondent asked what CCC will accept as evidence of the repayment schedule required in paragraph (a)(3)(i). Although there is no specific document CCC requires to meet this provision, U.S. financial institutions typically submit a copy of the loan notification to the foreign financial institution, which contains the information required by paragraph (a)(3)(i). If the loan notification is not available, the U.S. financial institution may contact CCC with any questions regarding an alternate document.

One commenter suggested CCC move paragraph (d), *Alternative satisfaction of Payment Guarantees*, to § 1493.190. CCC does not agree because paragraph (d) is often invoked in response to a claim for default. Therefore, this paragraph remains in § 1493.170.

CCC made additional changes to this section in the new proposed rule. Paragraph (a), which describes the documents and information required in a claim for default, has been reorganized to group like requirements together, such as certifications, to make this section easier to follow. In paragraph (a)(1)(iii), a new certification was added requiring the holder of the payment guarantee to certify that conforming documents required by the letter of credit have been submitted to the negotiating bank or directly to the foreign financial institution (if the payment guarantee has not been assigned). This was added as part of CCC's effort to avoid claims for default due to document discrepancies. Paragraph (a)(3)(v) was modified to reflect that the evidence of export (EOE) report provided with the claim must be in conformity with the regulatory requirements for EOEs. A requirement was also added for the holder of the payment guarantee to provide written evidence of a repurchase if the defaulted amount was part of a transaction executed under a repurchase agreement. Receipt of this documentation will allow CCC to confirm that the repurchase occurred as required by § 1493.120(f)(1)(ii). CCC also updated this section with the new terms "Holder of the Payment Guarantee" and "Terms and Conditions Document" as relevant, and added additional detail to some of the requirements to clarify the information that must be provided.

Section 1493.180 Payment for Default

CCC received two comments on this section. One respondent requested that, with respect to the provision for accelerated payments in paragraph (d), CCC pay claims for accelerated amounts if payments under the letter of credit are required to be accelerated.

It is CCC's intent to pay claims for defaults on an accelerated basis if CCC requires the holder of the payment guarantee to invoke the acceleration provision in § 1493.90(b)(3). The purpose of paragraph (d) is to make clear that CCC will not make accelerated payments if the holder of the payment guarantee determined unilaterally to invoke the acceleration clause.

One respondent commented that under paragraph (e)(1), the assignee may not know if the exporter has complied with the reporting requirements under § 1493.130 and § 1493.140, and therefore requested this requirement be excluded from the limitation on the assignee's liability. CCC does not agree with this suggestion. The evidence of export report (EOE) is a required claim document under § 1493.170(a)(3)(v); therefore, the assignee should ensure that it receives this document from the exporter. Further, the assignee can review the program regulation to determine whether the EOE conforms with the requirements of § 1493.130 and § 1493.140. CCC acknowledges that the assignee may not know if the exporter includes inaccurate or false data or certifications in the EOE, but in such circumstances CCC would hold the assignee harmless provided the requirements of paragraph (e) are met. CCC has modified this provision to more broadly require that in order to be held harmless, the assignee must submit all required claims documents such that they "appear on their face" to conform with all requirements of § 1493.170. With this change CCC believes sub-paragraphs (1) and (2) of this provision are no longer needed.

Section 1493.190 Recovery of Defaulted Payments

CCC received no comments on this section. In the new proposed rule, CCC updated this section with the term

"Holder of the Payment Guarantee" as discussed in § 1493.20. Paragraph (e) from the initial proposed rule has been moved to the new section 1493.191 (see discussion below). In paragraph (c), *Allocation of recoveries,* CCC clarified that the "respective interest of each party" in a recovery is based on the date the claim is paid by CCC. In the paragraph *Cooperation in recoveries* (now paragraph (e)), CCC added that the exporter, whether or not the holder of the payment guarantee, is also required to cooperate with CCC to effect recoveries. In some instances, the exporter may have information or be able to take some action that would increase the likelihood of recoveries following a default.

Section 1493.191 Additional Obligations and Requirements

This section was added to the new proposed rule but is a compilation of existing provisions previously found in other sections, including § 1493.195, *Miscellaneous provisions.* CCC believes these provisions represent important obligations on participants and risked being overlooked; they have therefore been consolidated in this new section.

One respondent commented on paragraph (a) of this new section, previously found in § 1493.195, *Miscellaneous provisions,* noting that pursuant to privacy laws, USDA may be required to obtain a subpoena to review GSM–102 related documents unless the customer has provided prior written consent. CCC does not agree with this comment. Section 402(a)(1) of the Agricultural Trade Act of 1978, as amended, requires "each exporter or other participant under the program to maintain all records concerning a program transaction for a period of not to exceed 5 years after completion of the program transaction, and to permit the Secretary to have full and complete access, for such 5-year period, to such records." This statutory provision does not require USDA to obtain a subpoena for access to documents covered by this regulatory provision.

In the revised proposed rule, CCC modified paragraph (a) to clarify that the requirement for records maintenance and access to premises applies both to the exporter and the assignee. CCC also made changes to remind participants that they are expected to respond fully to any inquiries from CCC related to their program participation and any GSM–102 transactions. CCC felt it was necessary to clarify that participants must respond to verbal and written inquiries that do not specifically involve submission of documents. The title of this paragraph has been changed to reflect this addition. Paragraph (d), previously titled "Good faith," has been renamed "Misstatements or noncompliance by Exporter may lead to rescission of Payment Guarantee."

Section 1493.192 Dispute Resolution and Appeals

No comments were received on this section and no changes were made in the proposed rule.

Section 1493.195 Miscellaneous Provisions

Several of the provisions previously found in this section have been moved to the new § 1493.191, *Additional obligations and requirements.* No comments were received on paragraphs (a) and (b) of this section and CCC made no changes in the new proposed rule.

Executive Order 12866

This proposed rule is issued in conformance with Executive Order 12866. It has been determined to be not significant for the purposes of Executive Order 12866 and was not reviewed by OMB. A cost-benefit assessment of this rule was not completed.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988. This rule would not preempt State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. Before any judicial action may be brought concerning the provisions of this rule, the appeal provisions of 7 CFR part 1493.192 would need to be exhausted. This rule would not be retroactive.

Executive Order 12372

This program is not subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Executive Order 13132

This proposed rule has been reviewed under Executive Order 13132, "Federalism." The policies contained in this proposed rule do not have any substantial direct effect on States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government, nor does this proposed rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Executive Order 13175

The United States has a unique relationship with Indian Tribes as provided in the Constitution of the United States, treaties, and Federal statutes. On November 5, 2009, President Obama signed a Memorandum emphasizing his commitment to "regular and meaningful consultation and collaboration with tribal officials in policy decisions that have tribal implications including, as an initial step, through complete and consistent implementation of Executive Order 13175." This proposed rule has been reviewed for compliance with E.O. 13175 and CCC worked directly with the Office of Tribal Relations in the rule's development. The policies contained in this proposed rule do not have tribal implications that preempt tribal law.

Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because CCC is not required by 5 U.S.C. 553 or any other law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Environmental Assessment

CCC has determined that this proposed rule does not constitute a major State or Federal action that would significantly affect the human or natural environment. Consistent with the National Environmental Policy Act (NEPA), 40 CFR part 1502.4, "Major Federal Actions Requiring the Preparation of Environmental Impact Statements" and the regulations of the Council on Environmental Quality, 40 CFR parts 1500–1508, no environmental assessment or environmental impact statement will be prepared.

Unfunded Mandates

This proposed rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA). Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995, CCC is requesting comments from all interested individuals and organizations on a proposed revision to the currently approved information collection for this program. This revision includes proposed changes in information collection activities related to the regulatory changes in this proposed rule.

Title: CCC Export Credit Guarantee Program (GSM–102).

OMB Control Number: 0551–0004.

Type of Request: Revision of a currently approved information collection.

Abstract: This information collection is required to support the existing regulations and proposed changes to 7 CFR Part 1493, subpart B, "CCC Export Credit Guarantee (GSM–102) Program Operations," which establishes the requirements for participation in CCC's GSM–102 program. This revision reflects an expected increase in program participation due to the new proposed rule, and also incorporates the additional estimated burden to program participants as a result of certain new requirements in this proposed rule for exporters, U.S. and foreign financial institution qualification; applications for payment guarantees; notices of assignment; repurchase agreements; evidence of export reports; submission of claims for default; and appeals. This information collection is necessary for CCC to manage, plan and evaluate the program and to ensure the proper and judicious use of government resources.

Estimate of Burden: The public reporting burden for this collection of information is estimated to average 0.51 hours per response.

Respondents: U.S. exporters, U.S. financial institutions, and foreign financial institutions.

Estimated Number of Respondents: 96 per year.

Estimated Number of Responses per Respondent: 66 per year.

Estimated Total Annual Burden on Respondents: 3,224 hours.

Comments on this information collection must be received by February 25, 2014 to be assured consideration. Comments may be submitted to CCC in accordance with any of the methods specified for submitting comments to this proposed rule. All comments received in response to this notice will be a matter of public record.

E-Government Act Compliance

CCC is committed to complying with the E-Government Act to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services and for other purposes. The forms, regulations, and other information collection activities required to be utilized by a person subject to this rule are available at: *http://www.fas.usda.gov.*

Title 7—Agriculture

List of Subjects in 7 CFR Part 1493

Agricultural commodities, Exports.

For the reasons stated in the preamble, CCC proposes to amend 7 CFR part 1493 as follows:

PART 1493—CCC EXPORT CREDIT GUARANTEE PROGRAMS

■ 1. The authority citation for 7 CFR part 1493 continues to read as follows:

Authority: 7 U.S.C. 5602, 5622, 5661, 5662, 5663, 5664, 5676; 15 U.S.C. 714b(d), 714c(f)

■ 2. Subpart A is revised to read as follows:

Subpart A—Restrictions and Criteria for Export Credit Guarantee Program

Sec.

Subpart A—Restrictions and Criteria for Export Credit Guarantee Programs

§ 1493.1 General statement.

This subpart sets forth the restrictions that apply to the issuance and use of Payment Guarantees under the Commodity Credit Corporation (CCC) Export Credit Guarantee (GSM–102) Program and Facility Guarantee Program (FGP), the criteria considered by CCC in determining the annual allocations of Payment Guarantees to be made available with respect to each participating country and region, and the criteria considered by CCC in the review and approval of proposed allocation levels for specific U.S. Agricultural Commodities to these countries and regions.

§ 1493.2 Purposes of programs.

CCC is authorized to issue Payment Guarantees:

(a) To increase exports of U.S. Agricultural Commodities and expand access to trade finance;

(b) To assist countries, particularly developing countries and emerging markets, in meeting their food and fiber needs;

(c) To establish or improve facilities and infrastructure in emerging markets to expand exports of U.S. Agricultural Commodities; or

(d) For such other purposes as the Secretary of Agriculture determines appropriate.

§ 1493.3 Restrictions on programs and cargo preference statement.

(a) *Restrictions on use of Payment Guarantees.* (1) Payment Guarantees authorized under these regulations shall not be used for foreign aid, foreign policy, or debt rescheduling purposes.

(2) CCC shall not make Payment Guarantees available in connection with sales of U.S. Agricultural Commodities to any country that the Secretary determines cannot adequately service the debt associated with such sale.

(3) CCC shall not make Payment Guarantees available in connection with sales of U.S. Agricultural Commodities financed by any Foreign Financial Institution that CCC determines cannot adequately service the debt associated with such sale.

(b) *Cargo preference laws.* The provisions of the cargo preference laws do not apply to export sales with respect to which Payment Guarantees are issued under these programs.

§ 1493.4 Criteria for country and regional allocations.

The criteria considered by CCC in reviewing proposals for country and regional allocations will include, but not be limited to, the following:

(a) Potential benefits that the extension of Payment Guarantees would provide for the development, expansion, or maintenance of the market for particular U.S. Agricultural Commodities in the importing country;

(b) Financial and economic ability and/or willingness of the country of obligation to adequately service CCC guaranteed debt ("country of obligation" is the country whose Foreign Financial Institution obligation is guaranteed by CCC);

(c) Financial status of participating Foreign Financial Institutions in the country of obligation as it would affect their ability to adequately service CCC guaranteed debt;

(d) Political stability of the country of obligation as it would affect its ability and/or willingness to adequately service CCC guaranteed debt; and

(e) Current status of debt either owed by the country of obligation or by the participating Foreign Financial Institutions to CCC or to lenders protected by CCC's Payment Guarantees.

§ 1493.5 Criteria for agricultural commodity allocations.

The criteria considered by CCC in determining U.S. Agricultural Commodity allocations within a specific country or regional allocation will include, but not be limited to, the following:

(a) Potential benefits that the extension of Payment Guarantees would

provide for the development, expansion or maintenance of the market in the importing country for the particular U.S. Agricultural Commodity under consideration;

(b) The best use to be made of the Payment Guarantees in assisting the importing country in meeting its particular needs for food and fiber, as may be determined through consultations with private buyers and/or representatives of the government of the importing country; and

(c) Evaluation, in terms of program purposes, of the relative benefits of providing Payment Guarantee coverage for sales of the U.S. Agricultural Commodity under consideration compared to providing coverage for sales of other U.S. Agricultural Commodities.

3. Subpart B is revised to read as follows:

Subpart B—CCC Export Credit Guarantee (GSM–102) Program Operations.

Sec.

Subpart B—CCC Export Credit Guarantee Program (GSM–102) Operations

§ 1493.10 General statement.

(a) *Overview.* The Export Credit Guarantee (GSM–102) Program of the Commodity Credit Corporation (CCC) was developed to expand U.S. Agricultural Commodity exports by making available Payment Guarantees to encourage U.S. private sector financing of foreign purchases of U.S. Agricultural Commodities on credit terms. The Payment Guarantee issued under GSM–102 is an agreement by CCC to pay the Exporter, or the U.S. Financial Institution that may take assignment of the Payment Guarantee, specified amounts of principal and interest in case of default by the Foreign Financial Institution that issued the Letter of Credit for the export sale covered by the Payment Guarantee. Under the GSM–102 program, maximum repayment terms vary based on risk of default, as determined by CCC. The program operates in a manner intended not to interfere with markets for cash sales and is targeted toward those countries that have sufficient financial strength so that foreign exchange will be available for scheduled payments. In providing this program, CCC seeks to expand and/or maintain market opportunities for U.S. agricultural exporters and assist long-term market development for U.S. Agricultural Commodities.

(b) *Program administration.* The GSM–102 program is administered under the direction of the General Sales Manager and Vice President of CCC, pursuant to this subpart, subpart A, and any Program Announcements issued by CCC. From time to time, CCC may issue a notice to participants on the USDA Web site to remind participants of the requirements of the GSM–102 program or to clarify the program requirements contained in these regulations in a manner not inconsistent with this subpart and subpart A.

(c) *Country and regional program announcements.* From time to time, CCC will issue a Program Announcement on the USDA Web site to announce a GSM–102 program for a specific country or region. The Program Announcement for a country or region will designate specific U.S. Agricultural Commodities or products thereof, or designate that all eligible U.S. Agricultural Commodities are available under the announcement. The Program Announcement will contain any requirements applicable to that country or region as determined by CCC.

§ 1493.20 Definition of terms.

Terms set forth in this subpart, on the USDA Web site (including in Program Announcements and notices to participants), and in any CCC-originated documents pertaining to the GSM–102 Program will have the following meanings:

Affiliate. Entities are affiliates of each other if, directly or indirectly, either one controls or has the power to control the other or a third person controls or has the power to control both. Control may include, but is not limited to: Interlocking management or ownership; identity of interests among family members; shared facilities and equipment; or common use of employees.

Assignee. A U.S. Financial Institution that has obtained the legal right to make a claim and receive the payment of proceeds under the Payment Guarantee.

Business Day. A day during which employees of the U.S. Department of Agriculture in the Washington, DC metropolitan area are on official duty during normal business hours.

CCC. The Commodity Credit Corporation, an agency and instrumentality of the United States within the Department of Agriculture, authorized pursuant to the Commodity Credit Corporation Charter Act (15 U.S.C. 714 *et seq.*).

CCC Late Interest. Interest payable by CCC pursuant to § 1493.180(c).

Cost and Freight (CFR). A customary trade term for sea and inland waterway transport only, as defined by the International Chamber of Commerce, Incoterms 2010 (or as superseded).

Cost Insurance and Freight (CIF). A customary trade term for sea and inland waterway transport only, as defined by the International Chamber of Commerce, Incoterms 2010 (or as superseded).

Date of Export. One of the following dates, depending upon the method of shipment: The on-board date of an ocean bill of lading or the on-board ocean carrier date of an intermodal bill of lading; the on-board date of an airway bill; or, if exported by rail or truck, the date of entry shown on an entry certificate or similar document issued and signed by an official of the government of the importing country.

Date of Sale. The earliest date on which a Firm Export Sales Contract exists between the Exporter, or an Intervening Purchaser, if applicable, and the Importer.

Director. The Director, Credit Programs Division, Office of Trade Programs, Foreign Agricultural Service, or the Director's designee.

Discounts and Allowances. Any consideration provided directly or indirectly, by or on behalf of the Exporter or an Intervening Purchaser, to the Importer in connection with an Eligible Export Sale, above and beyond the commodity's value, stated on the appropriate FOB, FAS, FCA, CFR or CIF basis (or other basis specified in Incoterms 2010, or as superseded), which includes, but is not limited to, the provision of additional goods, services or benefits; the promise to

provide additional goods, services or benefits in the future; financial rebates; the assumption of any financial or contractual obligations; commissions where the buyer requires the Exporter to employ and compensate a specified agent as a condition of concluding the Eligible Export Sale; the whole or partial release of the Importer from any financial or contractual obligations; or settlements made in favor of the Importer for quality or weight.

Eligible Export Sale. An export sale of U.S. Agricultural Commodities in which the obligation of payment for the portion registered under the GSM–102 program arises solely and exclusively from a Foreign Financial Institution Letter of Credit or Terms and Conditions Document issued in connection with a Payment Guarantee.

Eligible Interest. The amount of interest that CCC agrees to pay the Holder of the Payment Guarantee in the event that CCC pays a claim for default of Ordinary Interest. Eligible Interest shall be the lesser of:

(1) The amount calculated using the interest rate specified between the Holder of the Payment Guarantee and the Foreign Financial Institution; or

(2) The amount calculated using the specified percentage of the Treasury bill investment rate set forth on the face of the Payment Guarantee.

Exported Value. (1) Where CCC announces Payment Guarantee coverage on a FAS, FCA, or FOB basis and:

(i) Where the U.S. Agricultural Commodity is sold on a FAS, FCA, or FOB basis, the value, FAS, FCA, or FOB basis, port of shipment, of the export sale, reduced by the value of any Discounts and Allowances granted to the Importer in connection with such sale; or

(ii) Where the U.S. Agricultural Commodity was sold on a CFR or CIF basis, point of entry, the value of the export sale, FAS, FCA or FOB, port of shipment, is measured by the CFR or CIF value of the U.S. Agricultural Commodity less the cost of ocean freight, as determined at the time of application and, in the case of CIF sales, less the cost of marine and war risk insurance, as determined at the time of application, reduced by the value of any Discounts and Allowances granted to the Importer in connection with the sale of the commodity; or

(2) Where CCC announces coverage on a CFR or CIF basis, and where the U.S. Agricultural Commodity is sold on a CFR or CIF basis, port of destination, the total value of the export sale, CFR or CIF basis, port of destination, reduced by the value of any Discounts and Allowances granted to the Importer in connection with the sale of the commodity; or

(3) When a CFR or CIF U.S. Agricultural Commodity export sale involves the performance of non-freight services to be performed outside the United States (e.g., services such as bagging bulk cargo) which are not normally included in ocean freight contracts, the value of such services and any related materials not exported from the U.S. with the commodity must also be deducted from the CFR or CIF sales price in determining the Exported Value.

Exporter. A seller of U.S. Agricultural Commodities that is both qualified in accordance with the provisions of § 1493.30 and the applicant for the Payment Guarantee.

Firm Export Sales Contract. The written sales contract entered into between the Exporter and the Importer (or, if applicable, the written sales contracts between the Exporter and the Intervening Purchaser and the Intervening Purchaser and the Importer) which sets forth the terms and conditions of an Eligible Export Sale of the eligible U.S. Agricultural Commodity from the Exporter to the Importer (or, if applicable, the sale of the eligible U.S. Agricultural Commodity from the Exporter to the Intervening Purchaser and from the Intervening Purchaser to the Importer). Written evidence of a sale may be in the form of a signed sales contract, a written offer and acceptance between parties, or other documentary evidence of sale. The written evidence of sale for the purposes of the GSM–102 program must, at a minimum, document the following information: The eligible U.S. Agricultural Commodity, quantity, quality specifications, delivery terms (FOB, C&F, FCA, etc.) to the eligible country or region, delivery period, unit price, payment terms, Date of Sale, and evidence of agreement between buyer and seller. The Firm Export Sales Contract between the Exporter and the Importer (or, if applicable, between the Exporter and the Intervening Purchaser and between the Intervening Purchaser and the Importer) may be conditioned upon CCC's approval of the Exporter's application for a Payment Guarantee.

Foreign Financial Institution. A financial institution (including foreign branches of U.S. financial institutions):

(1) Organized and licensed under the laws of a jurisdiction outside the United States;

(2) Not domiciled in the United States; and

(3) Subject to the banking or other financial regulatory authority of a foreign jurisdiction (except for multilateral and sovereign institutions).

Foreign Financial Institution Letter of Credit or *Letter of Credit.* An irrevocable documentary letter of credit, subject to the current revision of the Uniform Customs and Practices for Documentary Credits (International Chamber of Commerce Publication No. 600, or latest revision), providing for payment in U.S. dollars against stipulated documents and issued in favor of the Exporter by a CCC-approved Foreign Financial Institution.

Free Alongside Ship (FAS). A customary trade term for sea and inland waterway transport only, as defined by the International Chamber of Commerce, Incoterms 2010 (or as superseded).

Free Carrier (FCA). A customary trade term for all modes of transportation, as defined by the International Chamber of Commerce, Incoterms 2010 (or as superseded).

Free on Board (FOB). A customary trade term for sea and inland waterway transport only, as defined by the International Chamber of Commerce, Incoterms 2010 (or as superseded).

GSM. The General Sales Manager, Foreign Agricultural Service, USDA, acting in his or her capacity as Vice President, CCC, or designee.

Guaranteed Value. The maximum amount indicated on the face of the Payment Guarantee, exclusive of interest, that CCC agrees to pay the Holder of the Payment Guarantee.

Holder of the Payment Guarantee. The Exporter or the Assignee of the Payment Guarantee with the legal right to make a claim and receive the payment of proceeds from CCC under the Payment Guarantee in case of default by the Foreign Financial Institution.

Importer. A foreign buyer that enters into a Firm Export Sales Contract with an Exporter or with an Intervening Purchaser for the sale of U.S. Agricultural Commodities to be shipped from the United States to the foreign buyer.

Importer's Representative. An entity having a physical office and registered to do business in the destination country or region specified in the Payment Guarantee and that is authorized to act on the Importer's behalf with respect to the sale described in the Firm Export Sales Contract.

Incoterms. Trade terms developed by the International Chamber of Commerce in Incoterms 2010 (or latest revision) which define the respective obligations of the buyer and seller in a sales contract.

Intervening Purchaser. A party that is not located in the country or region of

destination specified in the Payment Guarantee and that enters into a Firm Export Sales Contract to purchase U.S. Agricultural Commodities from an Exporter and sell the same U.S. Agricultural Commodities to an Importer.

OFAC. The Office of Foreign Assets Control of the U.S. Department of Treasury, which administers and enforces economic sanctions programs primarily against countries and groups of individuals such as terrorists and narcotics traffickers.

Ordinary Interest. Interest (other than Post Default Interest) charged on the principal amount identified in the Foreign Financial Institution Letter of Credit or, if applicable, the Terms and Conditions Document.

Payment Guarantee. An agreement under the GSM–102 program by which CCC, in consideration of a fee paid, and in reliance upon the statements and declarations of the Exporter, subject to the terms set forth in the written guarantee, this subpart, and any applicable Program Announcements, agrees to pay the Holder of the Payment Guarantee in the event of a default by a Foreign Financial Institution on its Repayment Obligation under the Foreign Financial Institution Letter of Credit issued in connection with a guaranteed sale or, if applicable, under the Terms and Conditions Document.

Port Value. (1) Where CCC announces coverage on a FAS, FCA, or FOB basis and:

(i) Where the U.S. Agricultural Commodity is sold on a FAS, FCA, or FOB basis, port of shipment, the value, FAS, FCA, or FOB basis, port of shipment, of the export sale, including the upward loading tolerance, if any, as provided by the Firm Export Sales Contract, reduced by the value of any Discounts and Allowances granted to the Importer in connection with such sale; or

(ii) Where the U.S. Agricultural Commodity was sold on a CFR or CIF basis, port of destination, the value of the export sale, FAS, FCA, or FOB, port of shipment, including the upward loading tolerance, if any, as provided by the Firm Export Sales Contract, is measured by the CFR or CIF value of the U.S. Agricultural Commodity less the value of ocean freight and, in the case of CIF sales, less the value of marine and war risk insurance, reduced by the value of any Discounts and Allowances granted to the Importer in connection with the sale of the commodity.

(2) Where CCC announces coverage on a CFR or CIF basis and where the U.S. Agricultural Commodity was sold on CFR or CIF basis, port of destination, the total value of the export sale, CFR or CIF basis, port of destination, including the upward loading tolerance, if any, as provided by the Firm Export Sales Contract, reduced by the value of any Discounts and Allowances granted to the Importer in connection with the sale of the commodity.

(3) When a CFR or CIF U.S. Agricultural Commodity export sale involves the performance of non-freight services to be performed outside the United States (e.g., services such as bagging bulk cargo), which are not normally included in ocean freight contracts, the value of such services and any related materials not exported from the U.S. with the commodity must also be deducted from the CFR or CIF sales price in determining the Port Value.

Post Default Interest. Interest charged on amounts in default that begins to accrue upon default of payment, as specified in the Foreign Financial Institution Letter of Credit or, if applicable, in the Terms and Conditions Document.

Principal. A principal of a corporation or other legal entity is an individual serving as an officer, director, owner, partner, or other individual with management or supervisory responsibilities for such corporation or legal entity.

Program Announcement. An announcement issued by CCC on the USDA Web site that provides information on specific country and regional programs and may identify eligible U.S. Agricultural Commodities and countries, length of credit periods which may be covered, and other information.

Repayment Obligation. A contractual commitment by the Foreign Financial Institution issuing the Letter of Credit in connection with an Eligible Export Sale to make payment(s) on principal amount(s), plus any Ordinary Interest and Post Default Interest, in U.S. dollars, to an Exporter or U.S. Financial Institution on deferred payment terms consistent with those permitted under CCC's Payment Guarantee. The Repayment Obligation must be documented using one of the methods specified in § 1493.90.

Repurchase Agreement. A written agreement under which the Holder of the Payment Guarantee may from time to time enter into transactions in which the Holder of the Payment Guarantee agrees to sell to another party Foreign Financial Institution Letter(s) of Credit and, if applicable, Terms and Conditions Document(s), secured by the Payment Guarantee, and repurchase the same Foreign Financial Institution Letter(s) of Credit and Terms and Conditions Documents secured by the Payment Guarantee, on demand or date certain at an agreed upon price.

SAM (System for Award Management). A Federal Government owned and operated free Web site that contains information on parties excluded from receiving Federal contracts or certain subcontracts and excluded from certain types of Federal financial and nonfinancial assistance and benefits.

Terms and Conditions Document. A document specifically identified and referred to in the Foreign Financial Institution Letter of Credit which may contain the Repayment Obligation and other special requirements specified in § 1493.90.

United States or *U.S.* Each of the States of the United States, the District of Columbia, Puerto Rico, and the territories and possessions of the United States.

U.S. Agricultural Commodity or *U.S. Agricultural Commodities.* (1)(i) An agricultural commodity or product entirely produced in the United States; or

(ii) A product of an agricultural commodity—

(A) 90 percent or more of the agricultural components of which by weight, excluding packaging and added water, is entirely produced in the United States; and

(B) That the Secretary determines to be a high value agricultural product.

(2) For purposes of this definition, fish entirely produced in the United States include fish harvested by a documented fishing vessel as defined in title 46, United States Code, in waters that are not waters (including the territorial sea) of a foreign country.

USDA. United States Department of Agriculture.

U.S. Financial Institution. A financial institution (including U.S. branches of Foreign Financial Institutions):

(1) Organized and licensed under the laws of a jurisdiction within the United States;

(2) Domiciled in the United States; and

(3) Subject to the banking or other financial regulatory authority jurisdiction within the United States.

Weighted Average Export Date. The mean Date of Export for all exports within a 30 calendar day period, weighted by the guaranteed portion of the Exported Value of each export.

§ 1493.30 Information required for Exporter participation.

Exporters must apply and be approved by CCC to be eligible to participate in the GSM–102 Program.

(a) *Qualification requirements.* To qualify for participation in the GSM–102 program, an applicant must submit the following information to CCC in the manner specified on the USDA Web site:

(1) For the applicant:

(i) The name and full U.S. address (including the full 9-digit zip code) of the applicant's office, along with an indication of whether the address is a business or private residence. A post office box is not an acceptable address. If the applicant has multiple offices, the address included in the information should be that which is pertinent to the GSM–102 export sales contemplated by the applicant;

(ii) Dun and Bradstreet (DUNS) number;

(iii) Employer Identification Number (EIN—also known as a Federal Tax Identification Number);

(iv) Telephone and fax numbers;

(v) Email address (if applicable);

(vi) Business Web site (if applicable);

(vii) Contact name;

(viii) Statement indicating whether the applicant is a U.S. domestic entity or a foreign entity domiciled in the United States; and

(ix) The form of business entity of the applicant (e.g., sole proprietorship, partnership, corporation, etc.) and the U.S. jurisdiction under which such entity is organized and authorized to conduct business. Such jurisdictions are a U.S. State, the District of Columbia, Puerto Rico, and the territories and possessions of the United States. Upon request by CCC, the applicant must provide written evidence that such entity has been organized in a U.S. State, the District of Columbia, Puerto Rico, or a territory or possession of the United States.

(2) For the applicant's headquarters office:

(i) The name and full address of the applicant's headquarters office. A post office box is not an acceptable address; and

(ii) Telephone and fax numbers.

(3) For the applicant's agent for the service of process:

(i) The name and full U.S. address of the applicant's agent's office, along with an indication of whether the address is a business or private residence;

(ii) Telephone and fax numbers;

(iii) Email address (if applicable); and

(iv) Contact name.

(4) A description of the applicant's business. Applicants must provide the following information:

(i) Nature of the applicant's business (e.g., agricultural producer, commodity trader, consulting firm, etc.);

(ii) Explanation of the applicant's experience/history with U.S. Agricultural Commodities for the preceding three years, including a description of such commodities;

(iii) Explanation of the applicant's experience/history exporting U.S. Agricultural Commodities, including number of years involved in exporting, types of products exported, and destination of exports for the preceding three years; and

(iv) Whether or not the applicant is a "small or medium enterprise" (SME) as defined on the USDA Web site;

(5) A listing of any related companies (e.g., Affiliates, subsidiaries, or companies otherwise related through common ownership) currently qualified to participate in CCC export programs;

(6) A statement describing the applicant's participation, if any, during the past three years in U.S. Government programs, contracts or agreements; and

(7) A statement that: "All certifications set forth in 7 CFR 1493.60(a) are hereby made in this application" which, when included in the application, will constitute a certification that the applicant is in compliance with all of the requirements set forth in § 1493.60(a). The applicant will be required to provide further explanation or documentation if not in compliance with these requirements or if the application does not include this statement.

(b) *Qualification notification.* CCC will promptly notify applicants that have submitted information required by this section whether they have qualified to participate in the program or whether further information is required by CCC. Any applicant failing to qualify will be given an opportunity to provide additional information for consideration by the Director.

(c) *Previous qualification.* Any Exporter not submitting an application to CCC for a Payment Guarantee for two consecutive U.S. Government fiscal years must resubmit a qualification application containing the information specified in § 1493.30(a) to CCC to participate in the GSM–102 program. If at any time the information required by paragraph (a) of this section changes, the Exporter must promptly contact CCC to update this information and certify that the remainder of the information previously provided pursuant to paragraph (a) has not changed.

(d) *Ineligibility for program participation.* An applicant may be ineligible to participate in the GSM–102 program if such applicant cannot provide all of the information and certifications required by § 1493.30(a).

§ 1493.40 Information required for U.S. Financial Institution participation.

U.S. Financial Institutions must apply and be approved by CCC to be eligible to participate in the GSM–102 Program.

(a) *Qualification requirements.* To qualify for participation in the GSM–102 Program, a U.S. Financial Institution must submit the following information to CCC in the manner specified on the USDA Web site:

(1) Legal name and address of the applicant;

(2) Dun and Bradstreet (DUNS) number;

(3) Employer Identification Number (EIN—also known as a Federal Tax Identification Number);

(4) Year-end audited financial statements for the applicant's most recent fiscal year;

(5) Breakdown of the applicant's ownership as follows:

(i) Ten largest individual shareholders and ownership percentages;

(ii) Percentage of government ownership, if any; and

(iii) Identity of the legal entity or person with ultimate control or decision making authority, if other than the majority shareholder.

(6) Organizational structure (independent, or a subsidiary, Affiliate, or branch of another financial institution);

(7) Documentation from the applicable United States Federal or State agency demonstrating that the applicant is either licensed or chartered to do business in the United States;

(8) Name of the agency that regulates the applicant and the name and telephone number of the primary contact for such regulator; and

(9) A statement that: "All certifications set forth in 7 CFR § 1493.60 are hereby made in this application" which, when included in the application, will constitute a certification that the applicant is in compliance with all of the requirements set forth in § 1493.60. The applicant will be required to provide further explanation or documentation if not in compliance with these requirements or if the application does not include this statement.

(b) *Qualification notification.* CCC will notify applicants that have submitted information required by this section whether they have qualified to participate in the program or whether further information is required by CCC. Any applicant failing to qualify will be given an opportunity to provide additional information for consideration by the Director.

(c) *Previous qualification.* Any U.S. Financial Institution not participating in

the GSM–102 program for two consecutive U.S. Government fiscal years must resubmit a qualification application containing the information specified in § 1493.40(a) to CCC to participate in the GSM–102 program. If at any time the information required by paragraph (a) of this section changes, the U.S. Financial Institution must promptly contact CCC to update this information and certify that the remainder of the information previously provided pursuant to paragraph (a) has not changed.

(d) *Ineligibility for program participation.* A U.S. Financial Institution may be deemed ineligible to participate in the GSM–102 Program if such applicant cannot provide all of the information and certifications required by § 1493.40(a).

§ 1493.50 Information required for Foreign Financial Institution participation.

Foreign Financial Institutions must apply and be approved by CCC to be eligible to participate in the GSM–102 Program.

(a) *Qualification requirements.* To qualify for participation in the GSM–102 program, a Foreign Financial Institution must submit the following information to CCC in the manner specified on the USDA Web site:

(1) Legal name and address of the applicant;

(2) Year end, audited financial statements in accordance with the accounting standards established by the applicant's regulators, in English, for the applicant's three most recent fiscal years. If the applicant is not subject to a banking or other financial regulatory authority, year-end, audited financial statements in accordance with prevailing accounting standards, in English, for the applicant's three most recent fiscal years;

(3) Breakdown of applicant's ownership as follows:

(i) Ten largest individual shareholders and ownership percentages;

(ii) Percentage of government ownership, if any; and

(iii) Identity of the legal entity or person with ultimate control or decision making authority, if other than the majority shareholder.

(4) Organizational structure (independent, or a subsidiary, Affiliate, or branch of another legal entity);

(5) Name of foreign government agency that regulates the applicant; and

(6) A statement that: "All certifications set forth in 7 CFR 1493.60 are hereby made in this application" which, when included in the application, will constitute a certification that the applicant is in compliance with all of the requirements set forth in § 1493.60. The applicant will be required to provide further explanation or documentation if not in compliance with these requirements or if the application does not include this statement.

(b) *Qualification notification.* CCC will notify applicants that have submitted information required by this section whether they have qualified to participate in the program or whether further information is required by CCC. Any applicant failing to qualify will be given an opportunity to provide additional information for consideration by the Director.

(c) *Participation limit.* If, after review of the information submitted and other publicly available information, CCC determines that the Foreign Financial Institution is eligible for participation, CCC will establish a dollar participation limit for the institution. This limit will be the maximum amount of exposure CCC agrees to undertake with respect to this Foreign Financial Institution at any point in time. CCC may change or cancel this dollar participation limit at any time based on any information submitted or any publicly available information.

(d) *Previous qualification and submission of annual financial statements.* Each qualified Foreign Financial Institution shall submit annually to CCC its audited fiscal year-end financial statements in accordance with the accounting standards established by the applicant's regulators, in English, so that CCC may determine the continued ability of the Foreign Financial Institution to adequately service CCC guaranteed debt. If the Foreign Financial Institution is not subject to a banking or other financial regulatory authority, it should submit year-end, audited financial statements in accordance with prevailing accounting standards, in English, for the applicant's most recent fiscal year. Failure to submit this information annually may cause CCC to decrease or cancel the Foreign Financial Institution's dollar participation limit. Any Foreign Financial Institution not participating in the GSM–102 program for two consecutive U.S. Government fiscal years may have its dollar participation limit cancelled. If this participation limit is cancelled, the Foreign Financial Institution must resubmit the information and certifications requested in paragraph (a) of this section to CCC when reapplying for participation. Additionally, if at any time the information required by paragraph (a) of this section changes, the Foreign Financial Institution must promptly contact CCC to update this information and certify that the remainder of the information previously provided under paragraph (a) has not changed.

(e) *Ineligibility for program participation.* A Foreign Financial Institution may be deemed ineligible to participate in the GSM–102 program if:

(1) Such applicant cannot provide all of the information and certifications required in § 1493.50(a); or

(2) Based upon information submitted by the applicant or other publicly available sources, CCC determines that the applicant cannot adequately service the debt associated with the Payment Guarantees issued by CCC.

§ 1493.60 Certifications required for program participation.

(a) When making the statement required by §§ 1493.30(a)(7), 1493.40(a)(9), or 1493.50(a)(6), each Exporter, U.S. Financial Institution and Foreign Financial Institution applicant for program participation is certifying that, to the best of its knowledge and belief:

(1) The applicant and any of its principals (as defined in 2 CFR 180.995) or affiliates (as defined in 2 CFR 180.905) are not presently debarred, suspended, proposed for debarment, declared ineligible, or excluded from covered transactions by any U.S. Federal department or agency;

(2) The applicant and any of its principals (as defined in 2 CFR 180.995) or affiliates (as defined in 2 CFR 180.905) have not within a three-year period preceding this application been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statues or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(3) The applicant and any of its principals (as defined in 2 CFR 180.995) or affiliates (as defined in 2 CFR 180.905) are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (a)(2) of this section;

(4) The applicant and any of its principals (as defined in 2 CFR 180.995) or affiliates (as defined in 2 CFR 180.905) have not within a three-year period preceding this application had

one or more public transactions (Federal, State or local) terminated for cause or default;

(5) The applicant does not have any outstanding nontax debt to the United States that is in delinquent status as provided in 31 CFR 285.13;

(6) The applicant is not controlled by a person owing an outstanding nontax debt to the United States that is in delinquent status as provided in 31 CFR 285.13 (e.g., a corporation is not controlled by an officer, director, or shareholder who owes a debt); and

(7) The applicant does not control a person owing an outstanding nontax debt to the United States that is in delinquent status as provided in 31 CFR 285.13 (e.g., a corporation does not control a wholly-owned or partially-owned subsidiary which owes a debt).

(b) *Additional certifications for U.S. and Foreign Financial Institution applicants.* When making the statement required by § 1493.40(a)(9) or § 1493.50(a)(6), each U.S. and Foreign Financial Institution applicant for program participation is certifying that, to the best of its knowledge and belief:

(1) The applicant and its Principals are in compliance with all requirements, restrictions and guidelines as established by the applicant's regulators; and

(2) All U.S. operations of the applicant and its U.S. Principals are in compliance with U.S. anti-money laundering and terrorist financing statutes including, but not limited to, the USA Patriot Act of 2001, and the Foreign Corrupt Practices Act of 1977.

§ 1493.70 Application for Payment Guarantee.

(a) A Firm Export Sales Contract for an Eligible Export Sale must exist before an Exporter may submit an application for a Payment Guarantee. Upon request by CCC, the Exporter must provide evidence of a Firm Export Sales Contract. An application for a Payment Guarantee must be submitted in writing to CCC in the manner specified on the USDA Web site. An application must identify the name and address of the Exporter and include the following information:

(1) Name of the destination country or region. If the destination is a region, indicate the country or countries within the region to which the U.S. Agricultural Commodity will be exported.

(2) Name and address of the Importer. If the Importer is not physically located in the country or region of destination, it must have an Importer's Representative in the country or region of destination taking receipt of the U.S. Agricultural Commodities exported under the Payment Guarantee. If applicable, provide the name and address of the Importer's Representative.

(3) A statement that the U.S. Agricultural Commodity will be shipped directly to the Importer (or to the Importer's Representative, if applicable) in the destination country or region.

(4) Name and address of the party on whose request the Letter of Credit is issued, if other than the Importer.

(5) Name and address of the Intervening Purchaser, if any.

(6) Date of Sale.

(7) Exporter's sale number.

(8) Delivery period as agreed between the Exporter and the Importer.

(9) A full description of the U.S. Agricultural Commodity (including packaging, if any). The commodity grade and quality specified in the Exporter's application for the Payment Guarantee must be consistent with the commodity grade and quality specified in the Firm Export Sales Contract and the Foreign Financial Institution Letter of Credit.

(10) Mean quantity, contract loading tolerance and, if necessary, a request for CCC to reserve coverage up to the maximum quantity permitted.

(11) Unit sales price of the U.S. Agricultural Commodity, or a mechanism to establish the price, as agreed between the Exporter and the Importer. If the commodity was sold on the basis of CFR or CIF, the actual (if known at the time of application) or estimated value of freight and, in the case of sales made on a CIF basis, the actual (if known at the time of application) or estimated value of marine and war risk insurance, must be specified.

(12) Description and value of Discounts and Allowances, if any.

(13) Port Value (includes upward loading tolerance, if any).

(14) Guaranteed Value.

(15) Guarantee fee, either as announced on the Web site per § 1493.110(a)(1), or the competitive fee bid per § 1493.110(a)(2), depending on the type of fee charged by CCC for the country or region.

(16) Name and location of the Foreign Financial Institution issuing the Letter of Credit and, upon request by CCC, written evidence that the Foreign Financial Institution has agreed to issue the Letter of Credit.

(17) The term length for the credit being extended and the intervals between principal payments for each shipment to be made under the export sale.

(18) A statement indicating whether any portion of the export sale for which the Exporter is applying for a Payment Guarantee is also being used as the basis for an application for participation in USDA's Dairy Export Incentive Program (DEIP). The number of the Agreement assigned by USDA under the DEIP should be included, as applicable.

(19) The Exporter's statement, "All certifications set forth in 7 CFR 1493.80 are hereby being made by the Exporter in this application." which, when included in the application by the Exporter, will constitute a certification that it is in compliance with all the requirements set forth in § 1493.80.

(b) An application for a Payment Guarantee may be approved as submitted, approved with modifications agreed to by the Exporter, or rejected by the Director. In the event that the application is approved, the Director will cause a Payment Guarantee to be issued in favor of the Exporter. Such Payment Guarantee will become effective at the time specified in § 1493.100(b). If, based upon a price review, the unit sales price of the commodity does not fall within the prevailing commercial market level ranges, as determined by CCC, the application will not be approved.

§ 1493.80 Certification requirements for obtaining Payment Guarantee.

By providing the statement in § 1493.70(a)(19), the Exporter is certifying that the information provided in the application is true and correct and, further, that all requirements set forth in this section have been met. The Exporter will be required to provide further explanation or documentation with regard to applications that do not include this statement. If the Exporter makes false certifications with respect to a Payment Guarantee, CCC will have the right, in addition to any other rights provided under this subpart or otherwise as a matter of law, to revoke guarantee coverage for any commodities not yet exported and/or to commence legal action and/or administrative proceedings against the Exporter. The Exporter, in submitting an application for a Payment Guarantee and providing the statement set forth in § 1493.70(a)(19), certifies that:

(a) The commodity or product covered by the Payment Guarantee is a U.S. Agricultural Commodity;

(b) There have not been any corrupt payments or extra sales services or other items extraneous to the transaction provided, financed, or guaranteed in connection with the transaction, and the transaction complies with applicable United States law, including the Foreign

Corrupt Practices Act of 1977 and other anti-bribery measures;

(c) If the U.S. Agricultural Commodity is vegetable oil or a vegetable oil product, that none of the agricultural commodity or product has been or will be used as a basis for a claim of a refund, as drawback, pursuant to section 313 of the Tariff Act of 1930, 19 U.S.C. 1313, of any duty, tax or fee imposed under Federal law on an imported commodity or product;

(d) At the time of submission of the application for Payment Guarantee, neither the Importer nor the Intervening Purchaser, if applicable, is present on either the SAM or the OFAC Specially Designated Nationals (SDN) lists;

(e) The Exporter is fully in compliance with the requirements of § 1493.130(b) for all existing Payment Guarantees issued to the Exporter or has requested and been granted an extension per § 1493.130(b)(3); and

(f) The information provided pursuant to § 1493.30 has not changed and the Exporter still meets all of the qualification requirements of § 1493.30.

§ 1493.90 Special requirements of the Foreign Financial Institution Letter of Credit and the Terms and Conditions Document, if applicable.

(a) *Permitted mechanisms to document special requirements.* (1) A Foreign Financial Institution Letter of Credit is required in connection with the export sale to which CCC's Payment Guarantee pertains. The Letter of Credit must stipulate presentation of at least one original clean on board bill of lading as a required document.

(2) The use of a Terms and Conditions Document is optional. The Terms and Conditions Document, if any, must be specifically identified and referred to in the Foreign Financial Institution Letter of Credit.

(3) The special requirements in paragraph (b) of this section must be documented in one of the two following ways:

(i) The special requirements may be set forth in the Foreign Financial Institution Letter of Credit as a special instruction from the Foreign Financial Institution; or

(ii) The special requirements may be set forth in a separate Terms and Conditions Document.

(b) *Special requirements.* The following provisions are required and must be documented in accordance with paragraph (a) of this section:

(1) The terms of the Repayment Obligation, including a specific promise by the Foreign Financial Institution issuing the Letter of Credit to pay the Repayment Obligation;

(2) The following language: "In the event that the Commodity Credit Corporation ("CCC") is subrogated to the position of the obligee hereunder, this instrument shall be governed by and construed in accordance with the laws of the State of New York, excluding its conflict of laws principles. In such case, any legal action or proceeding arising under this instrument will be brought exclusively in the U.S. District Court for the Southern District of New York or the U.S. District Court for the District of Columbia, as determined by CCC, and such parties hereby irrevocably consent to the personal jurisdiction and venue therein.";

(3) A provision permitting the Holder of the Payment Guarantee to declare all or any part of the Repayment Obligation, including accrued interest, immediately due and payable, in the event a payment default occurs under the Letter of Credit or, if applicable, the Terms and Conditions Document; and

(4) Post Default Interest terms.

§ 1493.100 Terms and requirements of the Payment Guarantee.

(a) *CCC's obligation.* The Payment Guarantee will provide that CCC agrees to pay the Holder of the Payment Guarantee an amount not to exceed the Guaranteed Value, plus Eligible Interest, in the event that the Foreign Financial Institution fails to pay under the Foreign Financial Institution Letter of Credit and, if applicable, the Terms and Conditions Document. Payment by CCC will be in U.S. dollars.

(b) *Period of guarantee coverage.* (1) The Holder of the Payment Guarantee may, with respect to a series of shipments made within a 30 calendar day period, elect to have the Payment Guarantee coverage being on the Weighted Average Export Date for such shipments. The first allowable 30 calendar day period for bundling of shipments to compute the Weighted Average Export Date for such shipments begins on the first Date of Export for transactions covered by the Payment Guarantee. Shipments within each subsequent 30 calendar day period may be bundled with other shipments made within the same 30 calendar period to determine the Weighted Average Export Date for such shipments.

(2)(i) The period of coverage under the Payment Guarantee begins on the earlier of the following dates and will continue during the credit term specified on the Payment Guarantee or any amendments thereto:

(A) the Date(s) of Export or the Weighted Average Export Date(s), as selected by the Holder of the Payment Guarantee consistent with paragraph (b)(1) of this section; or

(B) the date when Ordinary Interest begins to accrue, or the weighted average date when interest begins to accrue.

(ii) However, the Payment Guarantee becomes effective on the Date(s) of Export of the U.S. Agricultural Commodities specified in the Exporter's application for the Payment Guarantee.

(c) *Terms of the CCC Payment Guarantee.* The terms of CCC's coverage will be set forth in the Payment Guarantee, as approved by CCC, and will include the provisions of this subpart, which may be supplemented by any Program Announcements and notices to participants in effect at the time the Payment Guarantee is approved by CCC.

(d) *Final date to export.* The final date to export shown on the Payment Guarantee will be one month, as determined by CCC, after the contractual deadline for shipping.

(e) *Reserve coverage for loading tolerances.* The Exporter may apply for a Payment Guarantee and, if coverage is available, pay the guarantee fee, based on the mean of the lower and upper loading tolerances of the Firm Export Sales Contract; however, the Exporter may also request that CCC reserve additional guarantee coverage to accommodate up to the amount of the upward loading tolerance specified in the Firm Export Sales Contract. The amount of coverage that can be reserved to accommodate the upward loading tolerance is limited to ten (10) percent of the Port Value of the sale. If such additional guarantee coverage is available at the time of application and the Director determines to make such reservation, CCC will so indicate to the Exporter. In the event that the Exporter ships a quantity greater than the amount on which the guarantee fee was paid (i.e., the mean of the upper and lower loading tolerances), it may obtain the additional coverage from CCC, up to the amount of the upward loading tolerance, by filing for an application for amendment to the Payment Guarantee, and by paying the additional amount of fee applicable. If such application for an amendment to the Payment Guarantee is not filed with CCC by the Exporter and the additional fee not received by CCC within 21 calendar days after the date of the last export against the Payment Guarantee, CCC will cancel the reserve coverage originally set aside for the Exporter.

(f) *Certain export sales are ineligible for GSM–102 Payment Guarantees.* (1) An export sale (or any portion thereof) is ineligible for Payment Guarantee

coverage if at any time CCC determines that:

(1) The commodity is not a U.S. Agricultural Commodity;

(2) The export sale includes corrupt payments or extra sales or services or other items extraneous to the transactions provided, financed, or guaranteed in connection with the export sale;

(3) The export sale does not comply with applicable U.S. law, including the Foreign Corrupt Practices Act of 1977 and other anti-bribery measures;

(4) If the U.S. Agricultural Commodity is vegetable oil or a vegetable oil product, any of the agricultural commodity or product has been or will be used as a basis for a claim of a refund, as drawback, pursuant to section 313 of the Tariff Act of 1930, 19 U.S.C. 1313, of any duty, tax or fee imposed under Federal law on an imported commodity or product;

(5) Either the Importer or the Intervening Purchaser, if any, is excluded or disqualified from participation in U.S. government programs;

(6) The export sale has been guaranteed by CCC under another Payment Guarantee; or

(7) The sale is not an Eligible Export Sale.

(g) *Certain exports of U.S. Agricultural Commodities are ineligible for Payment Guarantee coverage.* The following exports are ineligible for coverage under a GSM–102 Payment Guarantee except where it is determined by the Director to be in the best interest of CCC to provide guarantee coverage on such exports:

(1) Exports of U.S. Agricultural Commodities with a Date of Export prior to the date of receipt by CCC of the Exporter's written application for a Payment Guarantee;

(2) Exports of U.S. Agricultural Commodities with a Date of Export later than the final date to export shown on the Payment Guarantee or any amendments thereof; or

(3) Exports of U.S. Agricultural Commodities where the date of issuance of a Foreign Financial Institution Letter of Credit is later than 30 calendar days after:

(i) The Date of Export, or

(ii) The Weighted Average Export Date, if the Holder of the Payment Guarantee has elected to have the Payment Guarantee coverage begin on the Weighted Average Export Date.

(h) *Additional requirements.* The Payment Guarantee may contain such additional terms, conditions, and limitations as deemed necessary or desirable by the Director. Such additional terms, conditions or qualifications as stated in the Payment Guarantee are binding on the Exporter and the Assignee.

(i) *Amendments.* A request for an amendment of a Payment Guarantee may be submitted only by the Exporter, with the written concurrence of the Assignee, if any. The Director will consider such a request only if the amendment sought is consistent with this subpart and any applicable Program Announcements and sufficient budget authority exists. Any amendment to the Payment Guarantee, particularly those that result in an increase in CCC's liability under the Payment Guarantee, may result in an increase in the guarantee fee. CCC reserves the right to request additional information from the Exporter to justify the request and to charge a fee for amendments. Such fees will be announced and available on the USDA Web site. Any request to amend the Foreign Financial Institution on the Payment Guarantee will require that the Holder of the Payment Guarantee resubmit to CCC the certifications in § 1493.120(c)(1)(i) or § 1493.140(d).

§ 1493.110 Guarantee fees.

(a) *Guarantee fee rates.* Payment Guarantee fee rates charged may be one of the following two types:

(1) Those that are announced on the USDA Web site and are based upon the length of the payment terms provided for in the Firm Export Sales Contract, the degree of risk that CCC assumes, as determined by CCC, and any other factors which CCC determines appropriate for consideration.

(2) Those where Exporters are invited to submit a competitive bid for coverage. If CCC determines to offer coverage on a competitive fee bid basis, instructions for bidding, and minimum fee rates, if applicable, will be made available on the USDA Web site. Under a competitive bidding process, the final guarantee fee rate will be determined by CCC and will be advised to the Exporter.

(b) *Calculation of fee.* The guarantee fee will be computed by multiplying the Guaranteed Value by the guarantee fee rate.

(c) *Payment of fee.* The Exporter shall remit, with his application, the full amount of the guarantee fee. Applications will not be accepted until the guarantee fee has been received by CCC. The Exporter's wire transfer or check for the guarantee fee shall be made payable to CCC and be submitted in the manner specified on the USDA Web site.

(d) *Refunds of fee.* Guarantee fees paid in connection with applications that are accepted by CCC will ordinarily not be refundable. Once CCC notifies an Exporter of acceptance of an application, the fee for that application will not be refunded unless the Director determines that such refund will be in the best interest of CCC, even if the Exporter withdraws the application prior to CCC's issuance of the Payment Guarantee. If CCC does not accept an application for a Payment Guarantee or accepts only part of the guarantee coverage requested, a full or pro rata refund of the fee will be made.

§ 1493.120 Assignment of the Payment Guarantee.

(a) *Requirements for assignment.* The Exporter may assign the Payment Guarantee only to a U.S. Financial Institution approved for participation by CCC. The assignment must cover all amounts payable under the Payment Guarantee not already paid, may not be made to more than one party, and may not, unless approved in advance by CCC, be:

(1) Made to one party acting for two or more parties, or

(2) Subject to further assignment.

(b) *CCC to receive notice of assignment of payment guarantee.* A notice of assignment signed by the parties thereto must be filed with CCC by the Assignee in the manner specified on the USDA Web site. The name and address of the Assignee must be included on the written notice of assignment. The notice of assignment should be received by CCC within 30 calendar days of the date of assignment.

(c) *Required certifications.* (1) The U.S. Financial Institution must include the following certification on the notice of assignment: "I certify that:

(i) [Name of Assignee] has verified that the Foreign Financial Institution, at the time of submission of the notice of assignment, is not present on either the SAM or OFAC Specially Designated Nationals (SDN) lists; and

(ii) To the best of my knowledge and belief, the information provided pursuant to § 1493.40 has not changed and [name of Assignee] still meets all of the qualification requirements of § 1493.40."

(2) If the Assignee makes a false certification with respect to a Payment Guarantee, CCC may, in its sole discretion, in addition to any other action available as a matter of law, rescind and cancel the Payment Guarantee, reject the assignment of the Payment Guarantee, and/or commence legal action and/or administrative proceedings against the Assignee.

(d) *Notice of eligibility to receive assignment.* In cases where a U.S. Financial Institution is determined to be

ineligible to receive an assignment, in accordance with paragraph (e) of this section, CCC will provide notice thereof to the U.S. Financial Institution and to the Exporter issued the Payment Guarantee.

(e) *Ineligibility of U.S. Financial Institutions to receive an assignment and proceeds.* A U.S. Financial Institution will be ineligible to receive an assignment of a Payment Guarantee or the proceeds payable under a Payment Guarantee if such U.S. Financial Institution:

(1) At the time of assignment of a Payment Guarantee, is not in compliance with all requirements of 1493.40(a); or

(2) Is the branch, agency, or subsidiary of the Foreign Financial Institution issuing the Letter of Credit; or

(3) Is owned or controlled by an entity that owns or controls the Foreign Financial Institution issuing the Letter of Credit; or

(4) Is the U.S. parent of the Foreign Financial Institution issuing the Foreign Financial Institution Letter of Credit; or

(5) Is owned or controlled by the government of a foreign country and the Payment Guarantee has been issued in connection with export sales of U.S. Agricultural Commodities to Importers located in such foreign country.

(f) *Repurchase agreements.* (1) The Holder of the Payment Guarantee may enter into a Repurchase Agreement, to which the following requirements apply:

(i) Any repurchase under a Repurchase Agreement by the Holder of the Payment Guarantee must be for the entirety of the outstanding balance under the associated Repayment Obligation;

(ii) In the event of a default with respect to the Repayment Obligation subject to a Repurchase Agreement, the Holder of the Payment Guarantee must immediately effect such repurchase; and

(iii) The Holder of the Payment Guarantee must file all documentation required by §§ 1493.160 and 1493.170 in case of a default by the Foreign Financial Institution under the Payment Guarantee.

(2) The Holder of the Payment Guarantee shall, within five Business Days of execution of a transaction under the Repurchase Agreement, notify CCC of the transaction in writing in the manner specified on the USDA Web site. Such notification must include the following information:

(i) Name and address of the other party to the Repurchase Agreement;

(ii) A statement indicating whether the transaction executed under the Repurchase Agreement is for a fixed term or if it is terminable upon demand by either party. If fixed, provide the purchase date and the agreed upon date for repurchase. If terminable on demand, provide the purchase date only; and

(iii) The following written certification: "[Name of Holder of the Payment Guarantee] has entered into a Repurchase Agreement that meets the provisions of 7 CFR 1493.120(f)(1) and, prior to entering into this agreement, verified that [name of other party to the Repurchase Agreement] is not present on either the SAM or OFAC Specially Designated Nationals (SDN) lists."

(3) Failure of the Holder of the Payment Guarantee to comply with any of the provisions of § 1493.120(f) will result in CCC annulling coverage on the Foreign Financial Institution Letter of Credit and Terms and Conditions Document, if applicable, covered by the Payment Guarantee.

§ 1493.130 Evidence of export.

(a) *Report of export.* The Exporter is required to provide CCC an evidence of export report for each shipment made under the Payment Guarantee. This report must include the following information:

(1) Payment Guarantee number;

(2) Evidence of export report number (e.g., Report 1, Report 2) reflecting the report's chronological order of submission under the particular Payment Guarantee;

(3) Date of Export;

(4) Destination country or region. If the sale was registered under a regional program, the Exporter must indicate the specific country or countries within the region to which the goods were shipped;

(5) Exporter's sale number;

(6) Exported Value;

(7) Quantity;

(8) A full description of the commodity exported;

(9) Unit sales price received for the commodity exported and the Incoterms 2010 basis (e.g., FOB, CFR, CIF). Where the unit sales price at export differs from the unit sales price indicated in the Exporter's application for a Payment Guarantee, the Exporter is also required to submit a statement explaining the reason for the difference;

(10) Description and value of Discounts and Allowances, if any;

(11) Number of the agreement assigned by USDA under the Dairy Export Incentive Program (DEIP) if any portion of the export sale was also approved for participation in the DEIP;

(12) The Exporter's statement, "All certifications set forth in 7 CFR 1493.140 are hereby being made by the Exporter in this Evidence of Export." which, when included in the evidence of export by the Exporter, will constitute a certification that it is in compliance with all the requirements set forth in § 1493.140; and

(13) In addition to all of the above information, the final evidence of export report for the Payment Guarantee must include the following:

(i) The statement "Exports under the Payment Guarantee have been completed."

(ii) A statement summarizing the total quantity and value of the commodity exported under the Payment Guarantee (i.e., the cumulative totals on all numbered evidence of export reports).

(b) *Time limit for submission of evidence of export.* (1) The Exporter must provide a written report to the CCC in the manner specified on the USDA Web site within 21 calendar days of the Date of Export.

(2) If at any time the Exporter determines that no shipments are to be made under a Payment Guarantee, the Exporter is required to notify CCC in writing no later than the final date to export specified on the Payment Guarantee by furnishing the Payment Guarantee number and stating "no exports will be made under the Payment Guarantee."

(3) Requests for an extension of the time limit for submitting an evidence of export report must be submitted in writing by the Exporter to the Director and must include an explanation of why the extension is needed. An extension of the time limit may be granted only if such extension is requested prior to the expiration of the time limit for filing and is determined by the Director to be in the best interests of CCC.

(c) *Failure to comply with time limits for submission.* CCC will not accept any new applications for Payment Guarantees from an Exporter under § 1493.70 until the Exporter is fully in compliance with the requirements of § 1493.130(b) for all existing Payment Guarantees issued to the Exporter or has requested and been granted an extension per § 1493.130(b)(3).

(d) *Export sales reporting.* Exporters have a mandatory reporting responsibility under Section 602 of the Agricultural Trade Act of 1978 (7 U.S.C. 5712), for exports of certain agricultural commodities and products thereof.

§ 1493.140 Certification requirements for the evidence of export.

By providing the statement contained in § 1493.130(a)(12), the Exporter is certifying that the information provided in the evidence of export report is true and correct and, further, that all

requirements set forth in this section have been met. The Exporter will be required to provide further explanation or documentation with regard to reports that do not include this statement. If the Exporter makes false certifications with respect to a Payment Guarantee, CCC, will have the right, in addition to any other rights provided under this subpart or otherwise as a matter of law, to annul guarantee coverage for any commodities not yet exported and/or to commence legal action and/or administrative proceedings against the Exporter. The Exporter, in submitting the evidence of export and providing the statement set forth in § 1493.130(a)(12), certifies that:

(a) The agricultural commodity or product exported under the Payment Guarantee is a U.S. Agricultural Commodity;

(b) The U.S. Agricultural Commodity was shipped to the Importer (or to the Importer's Representative, if applicable) in the country or region specified on the Payment Guarantee;

(c) There have not been any corrupt payments or extra sales services or other items extraneous to the transaction provided, financed, or guaranteed in connection with the export sale, and that the export sale complies with applicable United States law, including the Foreign Corrupt Practices Act of 1977 and other anti-bribery measures;

(d) If the Exporter has not assigned the Payment Guarantee to a U.S. Financial Institution, the Exporter has verified that the Foreign Financial Institution, at the time of submission of the evidence of export report, is not present on either the SAM or OFAC Specially Designated Nationals (SDN) lists;

(e) The transaction is an Eligible Export Sale; and

(f) The information provided pursuant to §§ 1493.30 and 1493.70 has not changed (except as agreed to and amended by CCC) and the Exporter still meets all of the qualification requirements of § 1493.30.

§ 1493.150 Proof of entry.

(a) *Diversion.* The diversion of U.S. Agricultural Commodities covered by a Payment Guarantee to a country or region other than that shown on the Payment Guarantee is prohibited, unless expressly authorized in writing by the Director.

(b) *Records of proof of entry.* (1) Exporters must obtain and maintain records of an official or customary commercial nature that demonstrate the arrival of the U.S. Agricultural Commodities exported in connection with the GSM–102 program in the country or region that was the intended country or region of destination of such commodities. At the Director's request, the Exporter must submit to CCC records demonstrating proof of entry. Records demonstrating proof of entry must be in English or be accompanied by a certified or other translation acceptable to CCC. Records acceptable to meet this requirement include an original certification of entry signed by a duly authorized customs or port official of the importing country, by an agent or representative of the vessel or shipline that delivered the U.S. Agricultural Commodity to the importing country, or by a private surveyor in the importing country, or other documentation deemed acceptable by the Director showing:

(i) That the U.S. Agricultural Commodity entered the importing country or region;

(ii) The identification of the export carrier;

(iii) The quantity of the U.S. Agricultural Commodity;

(iv) The kind, type, grade and/or class of the U.S. Agricultural Commodity; and

(v) The date(s) and place(s) of unloading of the U.S. Agricultural Commodity in the importing country or region.

(2) Where shipping documents (e.g., bills of lading) clearly demonstrate that the U.S. Agricultural Commodities were shipped to the destination country or region, proof of entry verification may be provided by the Importer.

§ 1493.160 Notice of default.

(a) *Notice of default.* If the Foreign Financial Institution issuing the Letter of Credit fails to make payment pursuant to the terms of the Letter of Credit or the Terms and Conditions Document, the Holder of the Payment Guarantee must submit a notice of default to CCC as soon as possible, but not later than 5 Business Days after the date that payment was due from the Foreign Financial Institution (the due date). A notice of default must be submitted in writing to CCC in the manner specified on the USDA Web site and must include the following information:

(1) Payment Guarantee number;

(2) Name of the country or region as shown on the Payment Guarantee;

(3) Name of the defaulting Foreign Financial Institution;

(4) Payment due date;

(5) Total amount of the defaulted payment due, indicating separately the amounts for principal and Ordinary Interest, and including a copy of the repayment schedule with due dates, principal amounts and Ordinary Interest rates for each installment;

(6) Date of the Foreign Financial Institution's refusal to pay, if applicable;

(7) Reason for the Foreign Financial Institution's refusal to pay. if known, and copies of any correspondence with the Foreign Financial Institution regarding the default.

(b) *Failure to comply with time limit for submission.* If the Holder of the Payment Guarantee fails to notify CCC of a default within 5 Business Days, CCC may deny the claim for that default.

(c) *Impact of a default on other existing Payment Guarantees.* (1) In the event that a Foreign Financial Institution defaults under a Repayment Obligation, CCC may declare that such Foreign Financial Institution is no longer eligible to provide additional Letters of Credit under the GSM–102 Program. If CCC determines that such defaulting Foreign Financial Institution is no longer eligible for the GSM–102 Program, CCC shall provide written notice of such ineligibility to all Exporters and Assignees, if any, having Payment Guarantees covering transactions with respect to which the defaulting Foreign Financial Institution is expected to issue a Letter of Credit. Receipt of written notice from CCC that a defaulting Foreign Financial Institution is no longer eligible to provide additional Letters of Credit under the GSM–102 Program shall constitute withdrawal of coverage of that Foreign Financial Institution under all Payment Guarantees with respect to any Letter of Credit issued on or after the date of receipt of such written notice. CCC will not withdraw coverage of the defaulting Foreign Financial Institution under any Payment Guarantee with respect to any Letter of Credit issued before the date of receipt of such written notice.

(2) If CCC withdraws coverage of the defaulting Foreign Financial Institution, CCC will permit the Exporter (with concurrence of the Assignee, if any) to utilize another approved Foreign Financial Institution, and will consider other requested amendments to the Payment Guarantee, for the balance of the export sale covered by the Payment Guarantee. If no alternate Foreign Financial Institution is identified to issue the Letter of Credit within 30 calendar days, CCC will cancel the Payment Guarantee and refund the Exporter's guarantee fees corresponding to any unutilized portion of the Payment Guarantee.

§ 1493.170 Claims for default.

(a) *Filing a claim.* A claim by the Holder of the Payment Guarantee for a defaulted payment will not be paid if it

is made later than 180 calendar days from the due date of the defaulted payment. A claim must be submitted in writing to CCC in the manner specified on the USDA Web site. The claim must include the following documents and information:

(1) An original cover document signed by the Holder of the Payment Guarantee and containing the following information:

(i) Payment Guarantee number;

(ii) A description of:

(A) Any payments from or on behalf of the defaulting party or otherwise related to the defaulted payment that were received by the Exporter or the Assignee prior to submission of the claim; and

(B) Any security, insurance, or collateral arrangements, whether or not any payment has been realized from such security, insurance, or collateral arrangement as of the time of claim, from or on behalf of the defaulting party or otherwise related to the defaulted payment.

(iii) The following certifications:

(A) A certification that the scheduled payment has not been received, listing separately scheduled principal and Ordinary Interest;

(B) A certification of the amount of the defaulted payment, indicating separately the amounts for defaulted principal and Ordinary Interest;

(C) A certification that all documents submitted under paragraph (3) of this section are true and correct copies; and

(D) A certification that all documents conforming with the requirements for payment under the Foreign Financial Institution Letter of Credit have been submitted to the negotiating bank or directly to the Foreign Financial Institution under such Letter of Credit.

(2) An original instrument, in form and substance satisfactory to CCC, subrogating to CCC the respective rights of the Holder of the Payment Guarantee to the amount of payment in default under the applicable export sale. The instrument must reference the applicable Foreign Financial Institution Letter of Credit and, if applicable, the Terms and Conditions Document; and

(3) A copy of each of the following documents:

(i) The repayment schedule with due dates, principal amounts and Ordinary Interest rates for each installment (if the Ordinary Interest rates for future payments are unknown at the time the claim for default is submitted, provide estimates of such rates);

(ii)(A) The Foreign Financial Institution Letter of Credit securing the export sale; and

(B) if applicable, the Terms and Conditions Document;

(iii) Depending upon the method of shipment, the negotiable ocean carrier or intermodal bill(s) of lading signed by the shipping company with the onboard ocean carrier date for each shipment, the airway bill, or, if shipped by rail or truck, the bill of lading and the entry certificate or similar document signed by an official of the importing country;

(iv)(A) The Exporter's invoice showing, as applicable, the FAS, FCA, FOB, CFR or CIF values; or

(B) If there was an Intervening Purchaser, both the Exporter's invoice to the Intervening Purchaser and the Intervening Purchaser's invoice to the Importer;

(v) The evidence of export report(s) previously submitted by the Exporter to CCC in conformity with the requirements of § 1493.130(a); and

(vi) If the defaulted payment was part of a transaction executed under a Repurchase Agreement, written evidence that the repurchase occurred as required under § 1493.120(f)(1)(ii).

(b) *Additional documents.* If a claim is denied by CCC, the Holder of the Payment Guarantee may provide further documentation to CCC to establish that the claim is in good order.

(c) *Subsequent claims for defaults on installments.* If the initial claim is found in good order, the Holder of the Payment Guarantee need only provide all of the required claims documents with the initial claim relating to a covered transaction. For subsequent claims relating to failure of the Foreign Financial Institution to make scheduled installments on the same export shipment, the Holder of the Payment Guarantee need only submit to CCC a notice of such failure containing the information stated in paragraph (a)(1)(i) and (ii) and (a)(1)(iii)(A) and (B) of this section; an instrument of subrogation as per paragraph (a)(2) of this section; and the date the original claim was filed with CCC.

(d) *Alternative satisfaction of Payment Guarantees.* CCC may establish procedures, terms and/or conditions for the satisfaction of CCC's obligations under a Payment Guarantee other than those provided for in this subpart if CCC determines that those alternative procedures, terms, and/or conditions are appropriate in rescheduling the debts arising out of any transaction covered by the Payment Guarantee and would not result in CCC paying more than the amount of CCC's obligation.

§ 1493.180 Payment for default.

(a) *Determination of CCC's liability.* Upon receipt in good order of the information and documents required under § 1493.170, CCC will determine whether or not a default has occurred for which CCC is liable under the applicable Payment Guarantee. Such determination shall include, but not be limited to, CCC's determination that all documentation conforms to the specific requirements contained in this subpart, and that all documents submitted for payment conform to the requirements of the Letter of Credit and, if applicable, the Terms and Conditions Document. If CCC determines that it is liable to the Holder of the Payment Guarantee, CCC will pay the Holder of the Payment Guarantee in accordance with paragraphs (b) and (c) of this section.

(b) *Amount of CCC's liability.* CCC's maximum liability for any claims submitted with respect to any Payment Guarantee, not including any CCC Late Interest payments due in accordance with paragraph (c) of this section, will be limited to the lesser of:

(1) The Guaranteed Value as stated in the Payment Guarantee, plus Eligible Interest, less any payments received or funds realized from insurance, security or collateral arrangements prior to claim by the Exporter or the Assignee from or on behalf of the defaulting party or otherwise related to the obligation in default (other than payments between CCC, the Exporter or the Assignee); or

(2) The guaranteed percentage (as indicated in the Payment Guarantee) of the Exported Value indicated in the evidence of export, plus Eligible Interest, less any payments received or funds realized from insurance, security or collateral arrangements prior to claim by the Exporter or the Assignee from or on behalf of the defaulting party or otherwise related to the obligation in default (other than payments between CCC, the Exporter or the Assignee).

(c) *CCC Late Interest.* If CCC does not pay a claim within 15 Business Days of receiving the claim in good order, CCC Late Interest will accrue in favor of the Holder of the Payment Guarantee beginning with the sixteenth Business Day after the day of receipt of a complete and valid claim found by CCC to be in good order and continuing until and including the date that payment is made by CCC. CCC Late Interest will be paid on the guaranteed amount, as determined by paragraphs (b)(1) and (2) of this section, and will be calculated at a rate equal to the average investment rate of the most recent Treasury 91-day bill auction as announced by the Department of Treasury as of the due date. If there has been no 91-day auction within 90 calendar days of the date CCC Late Interest begins to accrue, CCC will

apply an alternative rate in a manner to be described on the USDA Web site.

(d) *Accelerated payments.* CCC will pay claims only on amounts not paid as scheduled. CCC will not pay claims for amounts due under an accelerated payment clause in the Firm Export Sales Contract, the Foreign Financial Institution Letter of Credit, the Terms and Conditions Document (if applicable), or any obligation owed by the Foreign Financial Institution to the Holder of the Payment Guarantee that is related to the Letter of Credit issued in favor of the Exporter, unless it is determined to be in the best interests of CCC. Notwithstanding the foregoing, CCC at its option may declare up to the entire amount of the unpaid balance, plus accrued Ordinary Interest, in default, require the Holder of the Payment Guarantee to invoke the acceleration provision in the Foreign Financial Institution Letter of Credit or, if applicable, in the Terms and Conditions Document, require submission of all claims documents specified in § 1493.170, and make payment to the Holder of the Payment Guarantee in addition to such other claimed amount as may be due from CCC.

(e) *Action against the Assignee.* If an Assignee submits a claim for default pursuant to Section 1493.170 and all documents submitted appear on their face to conform with the requirements of such section, CCC will not hold the Assignee responsible or take any action or raise any defense against the Assignee for any action, omission, or statement by the Exporter of which the Assignee has no knowledge.

§ 1493.190 Recovery of defaulted payments.

(a) *Notification.* Upon claim payment to the Holder of the Payment Guarantee, CCC will notify the Foreign Financial Institution of CCC's rights under the subrogation agreement to recover all monies in default.

(b) *Receipt of monies.* (1) In the event that monies related to the obligation in default are recovered by the Exporter or the Assignee from or on behalf of the defaulting party, the Importer, or any source whatsoever (excluding payments among CCC, the Exporter, and the Assignee), such monies shall be immediately paid to CCC. Any monies derived from insurance or through the liquidation of any security or collateral after the claim is filed with CCC shall be deemed recoveries that must be paid to CCC. If such monies are not received by CCC within 15 Business Days from the date of recovery by the Exporter or the Assignee, such party will owe to CCC interest from the date of recovery to the date of receipt by CCC. This interest will be calculated at a rate equal to the latest average investment rate of the most recent Treasury 91-day bill auction, as announced by the Department of Treasury, in effect on the date of recovery and will accrue from such date to the date of payment by the Exporter or the Assignee to CCC. Such interest will be charged only on CCC's share of the recovery. If there has been no 91-day auction within 90 calendar days of the date interest begins to accrue, CCC will apply an alternative rate in a manner to be described on the USDA Web site.

(2) If CCC recovers monies that should be applied to a Payment Guarantee for which a claim has been paid by CCC, CCC will pay the Holder of the Payment Guarantee its pro rata share, if any, provided that the required information necessary for determining pro rata distribution has been furnished. If a required payment is not made by CCC within 15 Business Days from the date of recovery or 15 business days from receiving the required information for determining pro rata distribution, whichever is later, CCC will pay interest calculated at a rate equal to the latest average investment rate of the most recent Treasury 91-day bill auction, as announced by the Department of Treasury, in effect on the date of recovery and interest will accrue from such date to the date of payment by CCC. The interest will apply only to the portion of the recovery payable to the Holder of the Payment Guarantee.

(c) *Allocation of recoveries.* Recoveries received by CCC from any source whatsoever that are related to the obligation in default will be allocated by CCC to the Holder of the Payment Guarantee and to CCC on a pro rata basis determined by their respective interests in such recoveries. The respective interest of each party will be determined on a pro rata basis, based on the combined amount of principal and interest in default on the date the claim is paid by CCC. Once CCC has paid a particular claim under a Payment Guarantee, CCC pro-rates any collections it receives and shares these collections proportionately with the Holder of the Payment Guarantee until both CCC and the Holder of the Payment Guarantee have been reimbursed in full.

(d) *Liabilities to CCC.* Notwithstanding any other terms of the Payment Guarantee, under the following circumstances the Exporter or the Assignee will be liable to CCC for any amounts paid by CCC under the Payment Guarantee:

(1) The Exporter will be liable to CCC when and if it is determined by CCC that the Exporter has engaged in fraud, or has been or is in material breach of any contractual obligation, certification or warranty made by the Exporter for the purpose of obtaining the Payment Guarantee or for fulfilling obligations under the GSM–102 program; and

(2) The Assignee will be liable to CCC when and if it is determined by CCC that the Assignee has engaged in fraud or otherwise violated program requirements.

(e) *Cooperation in recoveries.* Upon payment by CCC of a claim to the Holder of the Payment Guarantee, the Holder of the Payment Guarantee and the Exporter will cooperate with CCC to effect recoveries from the Foreign Financial Institution and/or the Importer. Cooperation may include, but is not limited to, submission of documents to the Foreign Financial Institution (or its representative) to establish a claim; participation in discussions with CCC regarding the appropriate course of action with respect to a default; actions related to accelerated payments as specified in § 1493.180(d); and other actions that do not increase the obligation of the Holder of the Payment Guarantee or the Exporter under the Payment Guarantee.

§ 1493.191 Additional obligations and requirements.

(a) *Maintenance of records, access to premises, and responding to CCC inquiries.* For a period of five years after the date of expiration of the coverage of a Payment Guarantee, the Exporter and the Assignee, if applicable, must maintain and make available all records and respond completely to all inquiries pertaining to sales and deliveries of and extension of credit for U.S. Agricultural Commodities exported in connection with a Payment Guarantee, including those records generated and maintained by agents, Intervening Purchasers, and related companies involved in special arrangements with the Exporter. The Secretary of Agriculture and the Comptroller General of the United States, through their authorized representatives, must be given full and complete access to the premises of the Exporter and the Assignee, as applicable, during regular business hours from the effective date of the Payment Guarantee until the expiration of such five-year period to inspect, examine, audit, and make copies of the Exporter's, Assignee's, agent's, Intervening Purchaser's or related company's books, records and accounts concerning transactions relating to the Payment Guarantee, including, but not

limited to, financial records and accounts pertaining to sales, inventory, processing, and administrative and incidental costs, both normal and unforeseen. During such period, the Exporter and the Assignee may be required to make available to the Secretary of Agriculture or the Comptroller General of the United States, through their authorized representatives, records that pertain to transactions conducted outside the program, if, in the opinion of the Director, such records would pertain directly to the review of transactions undertaken by the Exporter in connection with the Payment Guarantee.

(b) *Responsibility of program participants.* It is the responsibility of all Exporters and U.S. and Foreign Financial Institutions to review, and fully acquaint themselves with, all regulations, Program Announcements, and notices to participants relating to the GSM–102 program, as applicable. All Exporters and U.S. and Foreign Financial Institutions participating in the GSM–102 program are hereby on notice that they will be bound by this subpart and any terms contained in the Payment Guarantee and in applicable Program Announcements.

(c) *Submission of documents by Principals.* All required submissions, including certifications, applications, reports, or requests (i.e., requests for amendments) by Exporters or Assignees under this subpart must be signed by a Principal of the Exporter or Assignee or their authorized designee(s). In cases where the designee is acting on behalf of the Principal, the signature must be accompanied by: wording indicating the delegation of authority or, in the alternative, by a certified copy of the delegation of authority; and the name and title of the authorized person or officer. Further, the Exporter or Assignee must ensure that all information and reports required under these regulations are timely submitted.

(d) *Misstatements or noncompliance by Exporter may lead to rescission of Payment Guarantee.* CCC may cancel a Payment Guarantee in the event that an Exporter makes a willful misstatement in the certifications in §§ 1493.80(b) and 1493.140(c) or if the Exporter fails to comply with the provisions of § 1493.150 or § 1493.191(a). However, notwithstanding the foregoing, CCC will not cancel its Payment Guarantee, if it determines, in its sole discretion, that an Assignee had no knowledge of the Exporter's misstatement or noncompliance at the time of assignment of the Payment Guarantee.

§ 1493.192 Dispute resolution and appeals.

(a) *Dispute resolution.* (1) The Director and the Exporter or the Assignee will attempt to resolve any disputes, including any adverse determinations made by CCC, arising under the GSM–102 program, this subpart, the applicable Program Announcements and notices to participants, or the Payment Guarantee.

(2) The Exporter or the Assignee may seek reconsideration of a determination made by the Director by submitting a letter requesting reconsideration to the Director within 30 calendar days of the date of the determination. For the purposes of this section, the date of a determination will be the date of the letter or other means of notification to the Exporter or the Assignee of the determination. The Exporter or the Assignee may include with the letter requesting reconsideration any additional information that it wishes the Director to consider in reviewing its request. The Director will respond to the request for reconsideration within 30 calendar days of the date on which the request or the final documentary evidence submitted by the Exporter or the Assignee is received by the Director, whichever is later, unless the Director extends the time permitted for response. If the Exporter or the Assignee fails to request reconsideration of a determination by the Director, then the determination of the Director will be deemed final.

(3) If the Exporter or the Assignee requests reconsideration of a determination by the Director pursuant to subparagraph (a)(2) of this section, and the Director upholds the original determination, then the Exporter or the Assignee may appeal the Director's final determination to the GSM in accordance with the procedures set forth in paragraph (b) of this section. If the Exporter or the Assignee fails to appeal the Director's final determination within 30 calendar days as provided in section 1493.192(b)(1), then the Director's decision becomes the final determination of CCC.

(b) *Appeal procedures.* (1) An Exporter or Assignee that has exhausted the procedures set forth in paragraph (a) of this section may appeal to the GSM for a determination of the Director. An appeal to the GSM must be made in writing and filed with the office of the GSM no later than 30 calendar days following the date of the final determination by the Director. If the Exporter or Assignee requests an administrative hearing in its appeal letter, it shall be entitled to a hearing before the GSM or the GSM's designee.

(2) If the Exporter or Assignee does not request an administrative hearing, the Exporter or Assignee must indicate in its appeal letter whether or not it will submit any additional written information or documentation for the GSM to consider in acting upon its appeal. This information or documentation must be submitted to the GSM within 30 calendar days of the date of the appeal letter to the GSM. The GSM will make a decision regarding the appeal based upon the information contained in the administrative record. The GSM will issue his or her written decision within 60 calendar days of the latter of the date on which the GSM receives the appeal or the date that final documentary evidence is submitted by the Exporter or Assignee to the GSM.

(3) If the Exporter or the Assignee has requested an administrative hearing, the GSM will set a date and time for the hearing that is mutually convenient for the GSM and the Exporter or Assignee. This date will ordinarily be within 60 calendar days of the date on which the GSM receives the request for a hearing. The hearing will be an informal procedure. The Exporter or Assignee and/or its counsel may present any relevant testimony or documentary evidence to the GSM. A transcript of the hearing will not ordinarily be prepared unless the Exporter or Assignee bears the costs involved in preparing the transcript, although the GSM may decide to have a transcript prepared at the expense of the Government. The GSM will make a decision regarding the appeal based upon the information contained in the administrative record. The GSM will issue his or her written decision within 60 calendar days of the latter of the date of the hearing or the date of receipt of the transcript, if one is to be prepared.

(4) The decision of the GSM will be the final determination of CCC. The Exporter or Assignee will be entitled to no further administrative appellate rights.

(c) *Failure to comply with determination.* If the Exporter or Assignee has violated the terms of this subpart or the Payment Guarantee by failing to comply with a determination made under this section, and the Exporter or Assignee has exhausted its rights under this section or has failed to exercise such rights, then CCC will have the right to take any measures available to CCC under applicable law.

(d) *Exporter's obligation to perform.* The Exporter will continue to have an obligation to perform pursuant to the provisions of these regulations and the terms of the Payment Guarantee

pending the conclusion of all procedures under this section.

§ 1493.195 Miscellaneous provisions.

(a) *Officials not to benefit.* No member of or delegate to Congress, or Resident Commissioner, shall be admitted to any share or part of the Payment Guarantee or to any benefit that may arise therefrom, but this provision shall not be construed to extend to the Payment Guarantee if made with a corporation for its general benefit.

(b) *OMB control number assigned pursuant to the Paperwork Reduction Act.* The information collection requirements contained in this part (7 CFR part 1493) have been approved by the Office of Management and Budget (OMB) in accordance with the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0551–0004.

Dated: October 22, 2013.

Philip C. Karsting,

Administrator, Foreign Agricultural Service, and Vice President, Commodity Credit Corporation.

[FR Doc. 2013–29439 Filed 12–26–13; 8:45 am]

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Federal Register

Vol. 78, No. 249

Friday, December 27, 2013

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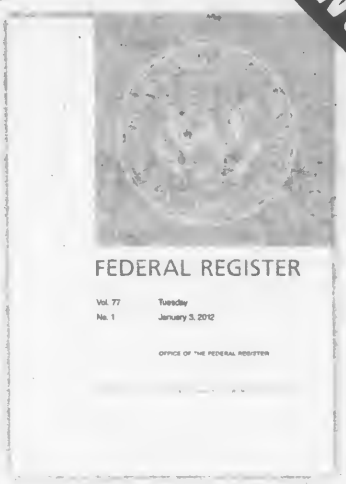

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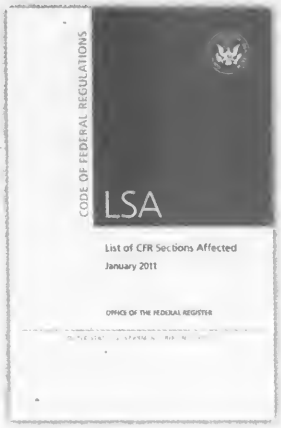

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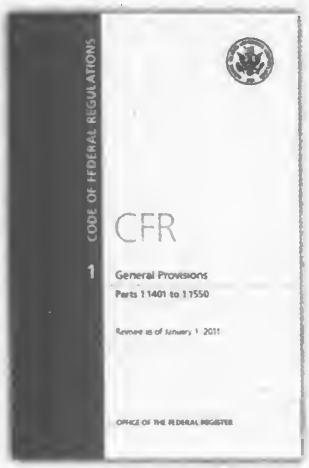

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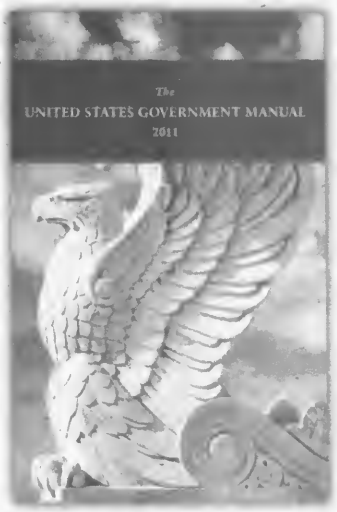

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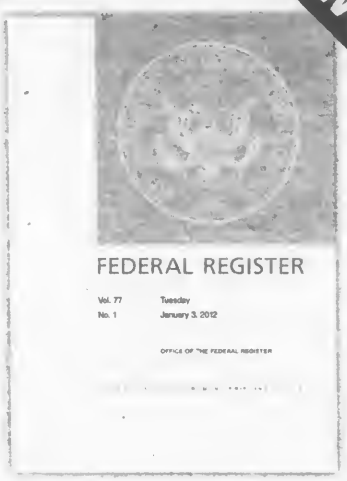

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