



Federal Register

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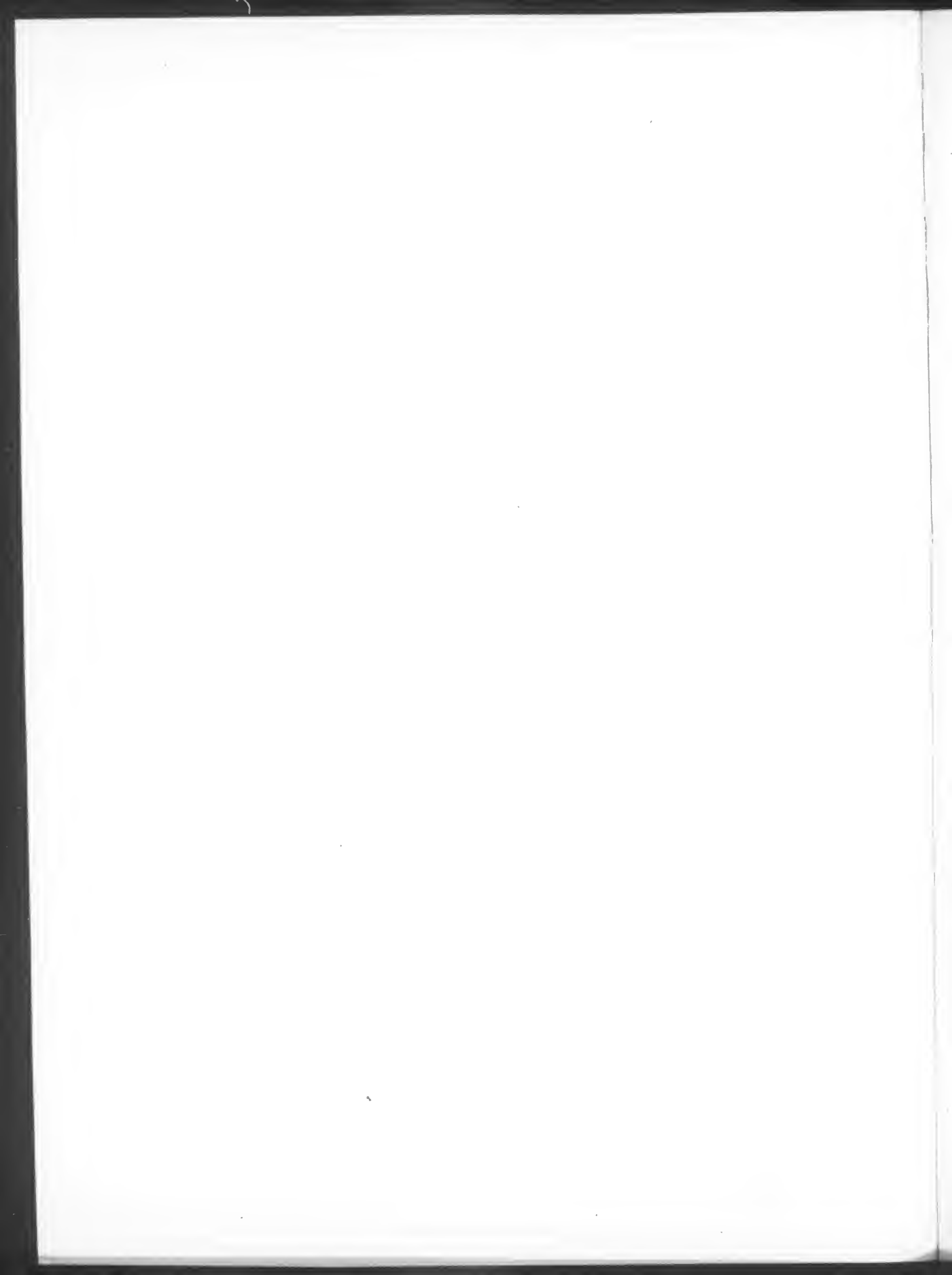
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Nov. 29, 2010

Book 1 of 2 Books



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4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, December 7, 2010
9 a.m.-12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW,
Washington, DC 20002

RESERVATIONS: (202) 741-6008



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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 922

[Doc. No. AMS-FV-10-0062; FV06-922-2 C]

Apricots Grown in Designated Counties in Washington; Temporary Relaxation of the Minimum Grade Requirement; Correction

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Correcting amendment.

SUMMARY: The Agricultural Marketing Service (AMS) is making a correction to the Code of Federal Regulations (CFR) by revising the administrative rules and regulations contained in part 922, Apricots Grown in Designated Counties in Washington. In an interim final rule published in the *Federal Register* on August 2, 2006 (71 FR 43641), and adopted as a final rule on November 13, 2006 (71 FR 66093), changes were made to section 922.321(a)(1) to relax the minimum grade requirements for Washington apricots for the 2006 season. The changes were in effect from August 3, 2006, through March 31, 2007. After the effective dates for the changes, the text of an entire paragraph was inadvertently omitted, by AMS, from subsequent issues of the Code of Federal Regulations (CFR) and the section was reserved. AMS did not intend for the entire paragraph to be removed. This document corrects that error by adding or reinserting the language that was omitted into Title 7 of the CFR, part 922.

DATES: *Effective Date:* November 30, 2010.

FOR FURTHER INFORMATION CONTACT: Robert J. Curry or Gary D. Olson, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs.

AMS, USDA; Telephone: (503) 326-2724, Fax: (503) 326-7440, or E-mail: Robert.Curry@ams.usda.gov or GaryD.Olson@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Antoinette Carter, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: Antoinette.Carter@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This document provides a correcting amendment to Marketing Order 922, found at 7 CFR part 922, so that handlers of fresh apricots from Washington shall continue to adhere to the minimum grade requirements (Washington No. 1) of the Order.

List of Subjects in 7 CFR Part 922

Apricots, Marketing Agreements. Reporting and recordkeeping requirements.

- Accordingly, 7 CFR part 922 is corrected by making the following correcting amendment:
- 1. The authority citation for 7 CFR part 922 continues to read as follows:

Authority: 7 U.S.C. 601-674.

PART 922—APRICOTS GROWN IN DESIGNATED COUNTIES IN WASHINGTON

- 2. In § 922.321, add paragraph (a)(1) to read as follows:

§ 922.321 Apricot Regulation 21.

(a) * * *

(1) *Minimum grade and maturity requirements.* Such apricots that grade not less than Washington No. 1 and are at least reasonably uniform in color: *Provided,* That such apricots of the Moorpark variety in open containers shall be generally well matured.

* * * * *

Dated: November 10, 2010.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. C1-2010-29105 Filed 11-26-10; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 13

[Docket No. FAA-2009-0237; Amendment No. 13-35]

RIN 2120-AJ50

Revisions to the Civil Penalty Inflation Adjustment Tables

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This final rule adjusts for inflation the minimum and maximum civil monetary penalty amounts the FAA may impose for violations of the statutes and regulations it enforces in order to continue the deterrent effect of these penalties. The adjustments are made following a formula provided by Congress.

DATES: This amendment becomes effective December 29, 2010.

FOR FURTHER INFORMATION CONTACT: Cole Milliard, Office of the Chief Counsel, Enforcement Division, AGC-300, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Telephone (202) 267-3452. Facsimile (202) 267-5106. E-mail cole.milliard@faa.gov.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. 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.

This rulemaking is issued under the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law (Pub. L.) 101-410, as amended by the Debt Collection Improvement Act of 1996, Public Law 104-134, codified at 28 U.S.C. 2461 note. These laws authorize the FAA to adjust the minimum and maximum amounts of civil monetary penalties for violations of the statutes it enforces to preserve their deterrent effect.

Good Cause for Immediate Adoption of This Final Rule

The FAA finds that good cause exists under 5 U.S.C. 553(b)(B) for adopting

this final rule without notice and comment. This rule effectuates the intent of the Federal Civil Penalties Inflation Adjustment Act to allow for regular adjustment, for inflation, of civil monetary penalties to preserve the deterrent effect of civil monetary penalties and promote compliance with the law. The inflation adjustments to penalties under this rule apply a formula mandated by Congress. Thus, it is unnecessary to delay these adjustments to receive public comment. Such comments would not allow the FAA to develop any basis to change the method or application of the mandatory inflation adjustments.

Discussion

Background

Under the Debt Collection Improvement Act of 1996, the FAA must adjust all applicable civil monetary penalties at least once every 4 years. In doing so, the FAA must also apply a formula Congress included in the Debt Collection Improvement Act of 1996 to determine the amount of increase to each of its civil monetary penalties. Both of these requirements are included in 28 U.S.C. 2461 note.

Prior FAA Rulemakings

In 1996 (61 FR 67445; December 20, 1996), we added subpart H, Civil

Monetary Penalty Inflation Adjustment, to 14 CFR part 13. Subpart H implements the terms of 28 U.S.C. 2461 note. We also made our initial adjustment to the civil monetary penalties applicable to the FAA's enforcement program in that rulemaking. The current rulemaking is the FAA's third adjustment of its civil monetary penalties since the regulation was adopted. Previous adjustments were made in 2002 (Amendment No. 13-31; 67 FR 6364; February 11, 2002) and 2006 (Amendment No. 13-33; 71 FR 47 28518; May 16, 2006). The 2006 adjustment also incorporated in Subpart H several statutory changes to our authority to impose civil penalties.

This Rulemaking

In this rulemaking, we adjust the civil penalty amounts listed in Tables 2 and 3 of 14 CFR part 13, subpart H, for inflation in accordance with the formula set forth in Subpart H. Under subpart H, we determine the inflation adjustment for each applicable civil penalty by increasing the maximum civil penalty or the range of minimum and maximum civil penalties by the "cost-of-living adjustment" (COLA). The COLA is "the percentage (if any) for each civil monetary penalty by which the Consumer Price Index (CPI) for the month of June of the calendar year preceding the adjustment exceeds the

CPI for the month of June of the calendar year in which the amount of such civil penalty was last set or adjusted pursuant to law." Each increase is rounded off as described in 14 CFR 13.305(a) and the rounded-off increase is added to the existing civil penalty amount. For the initial adjustment of a civil penalty under Subpart H, the increase is limited to ten percent of the civil penalty amount, as stated in 14 CFR 13.305(c).

For this rulemaking, we looked at the increase of the CPI for June 2009 over the CPIs for the years in which each civil penalty amount was last set, reset, or adjusted. The words "set" and "reset" in this context indicate that Congress has added to or changed the FAA's statutory authority to impose civil monetary penalties. The word "adjusted" indicates a change we made under Subpart H.

Civil Penalty Inflation Adjustment

Relevant CPI's

The CPI for June 2009 was 215.693. The CPI for the month of June of the calendar years in which civil monetary penalty amounts were last set, reset, or adjusted are:

- (1) 160.3 for June 1997;
- (2) 183.7 for June 2003;
- (3) 194.5 for June 2005; and
- (4) 202.9 for June 2006.

COLAs

Year	COLA calculation	COLA amount
1997	215.693/160.3	1.346 (134.6%)
2003	215.693/183.7	1.174 (117.4%)
2005	215.693/194.5	1.109 (110.9%)
2006	215.693/202.9	1.063 (106.3%)

Round-off Formula

- (1) Multiple of \$10, in the case of penalties less than or equal to \$100;
- (2) Multiple of \$100, in the case of penalties greater than \$100 but less than or equal to \$1,000;
- (3) Multiple of \$1,000, in the case of penalties greater than \$1,000 but less than or equal to \$10,000;
- (4) Multiple of \$5,000, in the case of penalties greater than \$10,000 but less than \$100,000;
- (5) Multiple of \$10,000, in the case of penalties greater than \$100,000 but less than or equal to \$200,000;
- (6) Multiple of \$25,000, in the case of penalties greater than \$200,000.

Results of Calculations for Inflation Adjustment

Using the methodology outlined in 28 U.S.C. 2461 note and implemented in 14

CFR part 13 subpart H, we have determined that several of our civil monetary penalties should be adjusted. The adjusted civil monetary penalty amounts are set forth in "Table of Minimum and Maximum Civil Monetary Penalty Amounts for Certain Violations Occurring on or After December 29, 2010", which will be located in 14 CFR 13.305(d).

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this final rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency must propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires

agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96-39) forbids agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it is included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

This final rule simply identifies the civil monetary penalties for violations of the statutory and regulatory provisions we enforce. The penalty amounts are those specified by statute or called for under the inflation adjustment statutes, and the information in this rule is required by the Debt Collection Improvement Act of 1996. Its economic impact is minimal.

Also, we determined that this final rule is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866, and is not "significant" as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354) (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals

and to explain the rationale for their actions to assure that such proposals are given serious consideration." The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule simply identifies the civil monetary penalties for violations of the statutory and regulatory provisions we enforce. The penalty amounts are those specified by statute or called for under the inflation adjustment statutes, and the information in this rule is required by the Debt Collection Improvement Act of 1996. Its economic impact is minimal.

Therefore, as the FAA Administrator, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96-39), as amended by the Uruguay Round Agreements Act (Pub. L. 103-465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as the protection of safety, and do not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

This rule only summarizes civil monetary penalties, established by legislation, for violations of statutory and regulatory provisions that apply equally to domestic and foreign entities; therefore, we have determined that this

rule will not result in an impact on international trade by companies doing business in or with the United States.

Unfunded Mandates Reform Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The level equivalent of \$100 million in CY 1995, adjusted for inflation to CY 2007 levels by the Consumer Price Index for all Urban Consumers (CPI-U) as published by the Bureau of Labor Statistics, is \$143.1 million.

This final rule does not contain such a mandate since it only identifies the increase in penalties as required by the Debt Collection Improvement Act of 1996. Therefore, the requirements of Title II of the Act do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the FAA has determined that this final rule does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion and involves no extraordinary circumstances.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a "significant energy action" under the executive order and it is not likely to

have a significant adverse effect on the supply, distribution, or use of energy.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

- (1) Searching the Federal eRulemaking Portal at <http://www.regulations.gov>;
- (2) Visiting the FAA's Regulations and Policies Web page at http://www.faa.gov/regulations_policies/; or
- (3) Accessing the Government Printing Office's Web page at <http://www.gpoaccess.gov/fr/index.html>.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-9680. Make sure to identify the amendment number or docket number of this rulemaking.

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 (Volume 65, Number 70; Pages 19477-78) or you may visit <http://www.regulations.gov>.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact your local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. You can find out more about SBREFA on the Internet at http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects in CFR 14 Part 13

Administrative practice and procedure, Air transportation,

Hazardous materials transportation, Investigations, Law enforcement, Penalties.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of title 14, Code of Federal Regulations as follows:

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

■ 1. The authority citation for part 13 continues to read as follows:

Authority: 18 U.S.C. 6002, 28 U.S.C. 2461 (note); 49 U.S.C. 106(g), 5121-5124, 40113-40114, 44103-44106, 44702-44703, 44709-44710, 44713, 44718, 44725, 46101-46110, 46301-46316, 46318, 46501-46502, 46504-46507, 47106, 47111, 47122, 47306, 47531-47532.

■ 2. Amend § 13.305(d) by removing Tables 1 through 3 and adding a new table in their place to read as follows:

§ 13.305 Cost of living adjustments of civil monetary penalties.

* * * * *
(d) * * *

TABLE OF MINIMUM AND MAXIMUM CIVIL MONETARY PENALTY AMOUNTS FOR CERTAIN VIOLATIONS OCCURRING ON OR AFTER DECEMBER 29, 2010

United States Code cite	Civil monetary penalty description	Minimum penalty amount	New or adjusted minimum penalty amount	Maximum penalty amount when last set or adjusted pursuant to law	New or adjusted maximum penalty amount
49 U.S.C. 5123(a), subparagraph (1).	Violation of hazardous materials transportation law.	\$250 per violation, reset 8/10/2005.	No change	\$50,000 per violation, reset 8/10/2005.	\$55,000 per violation.
49 U.S.C. 5123(a), subparagraph (2).	Violation of hazardous materials transportation law resulting in death, serious illness, severe injury, or substantial property destruction.	\$250 per violation, reset 8/10/2005.	No change	\$100,000 per violation, set 8/10/2005.	\$110,000 per violation.
49 U.S.C. 5123(a), subparagraph (3).	Violation of hazardous materials, transportation law relating to training.	\$450 per violation, set 8/10/2005.	No change	\$50,000 per violation, set 8/10/2005.	\$55,000 per violation.
49 U.S.C. 46301(a)(1)	Violation by a person other than an individual or small business concern under 49 CFR 46301(a)(1)(A) or (B).	N/A	N/A	\$25,000 per violation, reset 12/12/2003.	\$27,500 per violation.
49 U.S.C. 46301(a)(1)	Violation by an airman serving as an airman under 49 U.S.C. 46301(a)(1)(A) or (B) (but not covered by 46301(a)(5)(A) or (B)).	N/A	N/A	\$1,100 per violation, reset 12/12/2003.	No change.
49 U.S.C. 46301(a)(1)	Violation by an individual or small business concern under 49 U.S.C. 46301(a)(1)(A) or (B) (but not covered in 49 U.S.C. 46301(a)(5)).	N/A	N/A	\$1,100 per violation, reset 12/12/2003.	No change.
49 U.S.C. 46301(a)(3)	Violation of 49 U.S.C. 47107(b) (or any assurance made under such section) or 49 U.S.C. 47133.	N/A	N/A	Increase above otherwise applicable maximum amount not to exceed 3 times the amount of revenues that are used in violation of such section.	No change.

TABLE OF MINIMUM AND MAXIMUM CIVIL MONETARY PENALTY AMOUNTS FOR CERTAIN VIOLATIONS OCCURRING ON OR AFTER DECEMBER 29, 2010—Continued

United States Code cite	Civil monetary penalty description	Minimum penalty amount	New or adjusted minimum penalty amount	Maximum penalty amount when last set or adjusted pursuant to law	New or adjusted maximum penalty amount
49 U.S.C. 46301(a)(5)(A)	Violation by an individual or small business concern (except an airman serving as an airman) under 49 U.S.C. 46301(a)(5)(A)(i) or (ii).	N/A	N/A	\$11,000 per violation, adjusted 6/15/2006.	No change.
49 U.S.C. 46301(a)(5)(B)(i).	Violation by an individual or small business concern related to the transportation of hazardous materials.	N/A	N/A	\$11,000 per violation, adjusted 6/15/2006.	No change.
49 U.S.C. 46301(a)(5)(B)(ii).	Violation by an individual or small business concern related to the registration or recordation under 49 U.S.C. chapter 441, of an aircraft not used to provide air transportation.	N/A	N/A	\$11,000 per violation, adjusted 6/16/2006.	No change.
49 U.S.C. 46301(a)(5)(B)(iii).	Violation by an individual or small business concern of 49 U.S.C. 44718(d), relating to limitation on construction or establishment of landfills.	N/A	N/A	\$11,000 per violation, adjusted 6/15/2006.	No change.
49 U.S.C. 46301(a)(5)(B)(iv).	Violation by an individual or small business concern of 49 U.S.C. 44725, relating to the safe disposal of life-limited aircraft parts.	N/A	N/A	\$11,000 per violation, adjusted 6/15/2006.	No change.
49 U.S.C. 46301(b)	Tampering with a smoke alarm device.	N/A	N/A	\$2,200 per violation, adjusted 1/21/1997.	\$3,200 per violation.
49 U.S.C. 46302	Knowingly providing false information about alleged violation involving the special aircraft jurisdiction of the United States.	N/A	N/A	\$11,000 per violation, adjusted 1/21/1997.	\$16,000 per violation.
49 U.S.C. 46318	Interference with cabin or flight crew.	N/A	N/A	\$27,500, adjusted 6/15/2006.	No change.
49 U.S.C. 46319	Permanent closure of an airport without providing sufficient notice.	N/A	N/A	\$11,000 per day, adjusted 6/15/2006.	No change.
49 U.S.C. 47531	Violation of 49 U.S.C. 47528–47530, relating to the prohibition of operating certain aircraft not complying with stage 3 noise levels.	N/A	N/A	See 49 U.S.C. 46301(a)(1)(A) and (a)(5). above.	No change.

Issued in Washington, DC on November 22, 2010.

J. Randolph Babbitt,
Administrator.

[FR Doc. 2010–29920 Filed 11–26–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2010–0719; Airspace
Docket No. 10–ANM–8]

**Modification of Class E Airspace;
Portland, OR**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action will modify existing Class E airspace at Portland, OR, to accommodate aircraft using the Localizer/Distance Measuring Equipment (LOC/DME) Standard

Instrument Approach Procedures (SIAPs) at Portland International Airport. This will improve the safety and management of Instrument Flight Rules (IFR) operations at the airport. This action also would adjust the geographic coordinates for the airports and the Corvallis VHF Omni-Directional Radio Range/Distance Measuring Equipment (VOR/DME).

DATES: Effective date, 0901 UTC, March 10, 2011. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

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:

History

On September 3, 2010, the FAA published in the *Federal Register* a notice of proposed rulemaking to modify controlled airspace at Portland, OR (75 FR 54057). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, the FAA found the geographic coordinates for the airports and the Corvallis VOR/DME needed to be adjusted. This action makes the adjustment. With the exception of editorial changes, and the changes described above, this rule is the same as that proposed in the NPRM.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9U dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E airspace extending upward from 700 feet above the surface, at Portland International Airport, to accommodate IFR aircraft executing the LOC/DME SIAPs at the airport. This action is necessary for the safety and management of IFR operations. The geographic coordinates for Portland International Airport and McMinnville Municipal Airport, as well as the Corvallis VOR/DME, will be adjusted to coincide with the FAA's National Aeronautical Navigation Services.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this 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 rule, when promulgated, will 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 discusses the authority of 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 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 establishes additional controlled airspace at Portland International Airport, Portland, OR.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 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 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM OR E5 Portland, OR [Modified]

Portland International Airport, OR
(Lat. 45°35'19" N., long. 122°35'49" W.)
Newburg VORTAC

(Lat. 45°21'12" N., long. 122°58'41" W.)
Corvallis VOR/DME

(Lat. 44°29'58" N., long. 123°17'37" W.)
McMinnville Municipal Airport, OR
(Lat. 45°11'40" N., long. 123°08'10" W.)

That airspace extending upward from 700 feet above the surface within a line beginning at lat. 45°59'59" N., long. 123°30'04" W.; to lat. 46°00'00" N., long. 122°13'00" W.; thence via an 8.5-mile radius centered at lat. 45°55'07" N., long. 122°03'02" W. clockwise to lat. 45°46'39" N., long. 122°04'00" W.; thence via a line south along long. 122°04'00"

W. bounded on the south by lat. 45°09'59" N., and on the west by long. 123°30'04" W.; and within a 4.3-mile radius of the McMinnville Municipal Airport; and within 2 miles each side of the Newburg VORTAC 215° radial extending from lat. 45°09'59" N., to 19.8 miles southwest of the Newburg VORTAC; that airspace extending upward from 1,200 feet above the surface bounded on the north by lat. 46°30'29" N., extending from 2.7 miles offshore to V-25, and on the east by V-25, on the south by V-536 to Corvallis VOR/DME; thence via lat. 44°29'59" N., to a point 2.7 miles offshore, and on the west by a line 2.7 miles offshore to the point of beginning.

Issued in Seattle, Washington, on November 17, 2010.

Christine Mellon,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2010-29737 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

14 CFR Part 97

[Docket No. 30755; Amdt. No. 3401]

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 November 29, 2010. 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 November 29, 2010.

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:

Harry J. Hodges, 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 November 12, 2010.

Ray Towles,
Deputy 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.

- 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
16-Dec-10 ...	NC	CHARLOTTE	CHARLOTTE/DOUGLAS INTL	0/3268	11/3/10	ILS OR LOC RWY 23, AMDT 3
16-Dec-10 ...	AL	DOTHAN	DOTHAN RGNL	0/3900	11/3/10	TAKEOFF MINIMUMS AND OBSTACLE DP, ORIG
13-Jan-11 ...	AK	ANCHORAGE	TED STEVENS ANCHORAGE INTL	0/0145	11/9/10	ILS OR LOC/DME RWY 7R, ORIG-A
13-Jan-11 ...	AK	ANCHORAGE	TED STEVENS ANCHORAGE INTL	0/0147	11/9/10	ILS RWY 7L (CAT II), AMDT 1

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
13-Jan-11 ...	AK	ANCHORAGE	TED STEVENS ANCHORAGE INTL.	0/0148	11/9/10	ILS OR LOC/DME RWY 7L, AMDT 1
13-Jan-11 ...	HI	HONOLULU	HONOLULU INTL	0/2462	11/8/10	RNAV (RNP) RWY 26L, ORIG-A
13-Jan-11 ...	CO	ALAMOSA	SAN LUIS VALLEY REGIONAL-BERGMAN FIELD.	0/3489	11/8/10	VOR/DME OR GPS-B, AMDT 4A
13-Jan-11 ...	AR	CONWAY	DENNIS F CANTRELL FIELD	0/4406	11/8/10	TAKEOFF MINIMUMS AND OBSTACLE DP, AMDT 1
13-Jan-11 ...	WY	ROCK SPRINGS ...	ROCK SPRINGS-SWEET-WATER COUNTY.	0/4554	11/8/10	ILS OR LOC/DME RWY 27, AMDT 1
13-Jan-11 ...	AK	GAMBELL	GAMBELL	0/5753	11/9/10	NDB/DME RWY 34, AMDT 2
13-Jan-11 ...	AK	GAMBELL	GAMBELL	0/5754	11/9/10	NDB RWY 16, AMDT 1
13-Jan-11 ...	ID	BOUNDARY COUNTY.	BONNERS FERRY	0/7108	11/9/10	RNAV (GPS) RWY 2, ORIG

(FR Doc. 2010-29410 Filed 11-26-10; 8:45 am)

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30754; Amdt. No. 3400]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This 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 November 29, 2010. 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 November 29, 2010.

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:

Harry J. Hodges, 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 part 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 November 12, 2010.

Ray Towles,

Deputy 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 16 DEC 2010

Fort Lauderdale, FL, Fort Lauderdale/Hollywood Intl, ILS OR LOC RWY 9L, Amdt 21
 Fort Lauderdale, FL, Fort Lauderdale/Hollywood Intl, ILS OR LOC RWY 27R, Amdt 9
 Fort Lauderdale, FL, Fort Lauderdale/Hollywood Intl, LOC RWY 9R, Amdt 5
 Fort Lauderdale, FL, Fort Lauderdale/Hollywood Intl, LOC/DME RWY 13, Amdt 1
 Fort Lauderdale, FL, Fort Lauderdale/Hollywood Intl, VOR RWY 27R, Amdt 12A
 Centerville, IA, Centerville Muni, RNAV (GPS) RWY 34, Orig-A
 Waverly, IA, Waverly Muni, VOR-A, Amdt 3A
 Winfield/Arkansas City, KS, Strother Field, RNAV (GPS) RWY 35, Orig-A
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, ILS OR LOC RWY 10, ILS RWY 10 (CAT II), ILS RWY 10 (CAT III), Amdt 20
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, ILS OR LOC RWY 15L, Amdt 2
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, RNAV (GPS) RWY 15L, Amdt 2
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, RNAV (GPS) RWY 33R, Amdt 2
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, RNAV (GPS) Y RWY 10, Amdt 2
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, RNAV (GPS) Y RWY 33L, Amdt 2
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, RNAV (RNP) Z RWY 10, Amdt 1
 Baltimore, MD, Baltimore/Washington Intl Thurgood Marshall, RNAV (RNP) Z RWY 33L, Amdt 1
 Troy, MI, Oakland/Troy, RNAV (GPS) RWY 9, Orig-B
 Cabool, MO, Cabool Memorial, Takeoff Minimums and Obstacle DP, Amdt 2
 Caruthersville, MO, Caruthersville Memorial, RNAV (GPS) RWY 18, Amdt 1A
 Watford, ND, Watford City Muni, RNAV (GPS) RWY 12, Orig-A
 Glens Falls, NY, Floyd Bennett Memorial, Takeoff Minimums and Obstacle DP, Amdt 1
 Hamilton, NY, Hamilton Muni, VOR-A, Amdt 4
 Newburgh, NY, Stewart Intl, ILS OR LOC RWY 9, ILS RWY 9 (CAT II), Amdt 12
 Willoughby, OH, Willoughby Lost Nations Muni, RNAV (GPS) RWY 23, Orig-A
 Tulsa, OK, Tulsa Intl, ILS OR LOC RWY 18L, Amdt 15A

Klamath Falls, OR, Klamath Falls, VOR/DME OR TACAN RWY 14, Amdt 5B
 Pampa, TX, Perry Lefors Field, NDB RWY 17, Amdt 4B
 Pampa, TX, Perry Lefors Field, VOR/DME-A, Amdt 2B
 Eagle River, WI, Eagle River Union, LOC/DME RWY 4, Orig-A
 Huntington, WV, Tri-State/Milton J. Ferguson Field, ILS OR LOC RWY 12, Amdt 13
 Huntington, WV, Tri-State/Milton J. Ferguson Field, RADAR-1, Amdt 7
 Huntington, WV, Tri-State/Milton J. Ferguson Field, RNAV (GPS) RWY 12, Amdt 2

Effective 13 JAN 2011

Cordova, AK, Merle K (Mudhole) Smith, ILS OR LOC/DME RWY 27, Amdt 10
 Cordova, AK, Merle K (Mudhole) Smith, RNAV (GPS) RWY 27, Amdt 1
 Koyukuk, AK, Dibvy, DIBVY TWO Graphic Obstacle DP
 Platinum, AK, Platinum, RNAV (GPS) RWY 14, Amdt 1A
 Berryville, AR, Carroll County, RNAV (GPS) RWY 7, Orig
 Berryville, AR, Carroll County, RNAV (GPS) RWY 25, Orig
 Berryville, AR, Carroll County, Takeoff Minimums and Obstacle DP, Orig
 Saipan Island, CQ, Francisco C. Ada/Saipan Intl, GPS RWY 7, Orig-B, CANCELLED
 Saipan Island, CQ, Francisco C. Ada/Saipan Intl, GPS RWY 25, Amdt 1C, CANCELLED
 Saipan Island, CQ, Francisco C. Ada/Saipan Intl, RNAV (GPS) RWY 7, Orig
 Saipan Island, CQ, Francisco C. Ada/Saipan Intl, RNAV (GPS) RWY 25, Orig
 Jacksonville, FL, Cecil Field, RNAV (GPS) RWY 9R, Orig
 Jacksonville, FL, Cecil Field, RNAV (GPS) RWY 27L, Orig
 Tampa, FL, Tampa Intl, RNAV (RNP) Y RWY 19L, Amdt 1
 Tampa, FL, Tampa Intl, Takeoff Minimums and Obstacle DP, Amdt 9
 Coeur D'Alene, ID, Coeur D'Alene-Pappy Boyington Field, VOR/DME RWY 1, Amdt 2
 Chicago/Rockford, IL, Chicago/Rockford Intl, ILS OR LOC RWY 7, ILS RWY 7 (SA CAT I), ILS RWY 7 (CAT II), ILS RWY 7 (CAT III), Amdt 1C
 Manito, IL, Manito Mitchell, Takeoff Minimums and Obstacle DP, CANCELLED
 Manito, IL, Manito Mitchell, VOR OR GPS-A, Amdt 3, CANCELLED
 Oberlin, KS, Oberlin Muni, Takeoff Minimums and Obstacle DP, Amdt 1
 Washington, KS, Washington County Memorial, NDB-A, Amdt 1
 Washington, KS, Washington County Memorial, RNAV (GPS) RWY 17, Orig
 Washington, KS, Washington County Memorial, RNAV (GPS) RWY 35, Orig
 Washington, KS, Washington County Memorial, Takeoff Minimums and Obstacles DP, Orig
 New Orleans, LA, Lakefront, Takeoff Minimums and Obstacle DP, Amdt 1
 Salisbury, MD, Salisbury-Ocean City Wicomico Rgnl, RNAV (GPS) RWY 32, Amdt 2
 Salisbury, MD, Salisbury-Ocean City Wicomico Rgnl, VOR RWY 5; Amdt 10
 St Charles, MO, St Charles, VOR OR GPS RWY 9, Amdt 4A, CANCELLED

Meridian, MS, Key Field, ILS OR LOC RWY 19, Orig-A
 Garrison, ND, Garrison Muni, Takeoff Minimums and Obstacle DP, Orig
 Stanley, ND, Stanley Muni, Takeoff Minimums and Obstacle DP, Orig
 Broken Bow, NE, Broken Bow, Muni, Takeoff Minimums and Obstacle DP, Amdt 3
 Harvard, NE, Harvard State, RNAV (GPS) RWY 35, Orig
 Harvard, NE, Harvard State, Takeoff Minimums and Obstacle DP, Orig
 Harvard, NE, Harvard State, VOR/DME RNAV OR GPS RWY 35, Orig, CANCELLED
 Schribner, NE, Schribner State, Takeoff Minimums and Obstacle DP, Orig
 Portland, OR, Portland Intl, VOR-A, Amdt 10
 Beaufort, SC, Beaufort County, RNAV (GPS) RWY 25, Amdt 2
 Rapid City, SD, Rapid City Rgnl, ILS OR LOC RWY 32, Amdt 19
 Newport News, VA, Newport News/Williamsburg Intl, ILS OR LOC RWY 7, Amdt 33
 Newport News, VA, Newport News/Williamsburg Intl, ILS OR LOC RWY 25, Amdt 1
 Newport News, VA, Newport News/Williamsburg Intl, LOC/DME RWY 20, Amdt 1
 Newport News, VA, Newport News/Williamsburg Intl, NDB RWY 2, Amdt 6
 Newport News, VA, Newport News/Williamsburg Intl, NDB RWY 20, Amdt 5
 Newport News, VA, Newport News/Williamsburg Intl, RNAV (GPS) RWY 2, Amdt 1
 Newport News, VA, Newport News/Williamsburg Intl, RNAV (GPS) RWY 7, Amdt 3
 Newport News, VA, Newport News/Williamsburg Intl, RNAV (GPS) RWY 20, Amdt 2
 Newport News, VA, Newport News/Williamsburg Intl, RNAV (GPS) RWY 25, Amdt 2
 Norfolk, VA, Hampton Roads Executive, RNAV (GPS) RWY 10, Amdt 1
 Norfolk, VA, Hampton Roads Executive, RNAV (GPS) RWY 28, Orig, CANCELLED
 Yakima, WA, Yakima Air Terminal/McAllister Field, Takeoff Minimums and Obstacle DP, Amdt 5
 Yakima, WA, Yakima Air Terminal/McAllister Field, ZILLA TWO Graphic Obstacle DP
 Huntington, WV, Tri-State/Milton J. Ferguson Field, Takeoff Minimums and Obstacle DP, Amdt 1
 [FR Doc. 2010-29411 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. CPSC-2010-0085]

16 CFR Parts 1632 and 1633

Third Party Testing for Certain Children's Products; Mattresses, Mattress Pads, and/or Mattress Sets: Revisions to Terms of Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing Prior to Commission's Acceptance of Accreditation

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of requirements; revision of retrospective testing terms.

SUMMARY: The Consumer Product Safety Commission ("CPSC," "Commission," or "we") is issuing a notice amending the terms under which it will accept certifications for children's products based on third party conformity assessment body (laboratory) testing to the flammability regulations at 16 CFR parts 1632 and/or 1633 that occurred before the Commission's acceptance of the accreditation of the third party conformity assessment body. We are taking this action in response to requests from certain mattress manufacturers to reduce unnecessary retesting of mattresses, mattress pads, and/or mattress sets that have already been tested and found to be in compliance with CPSC regulations.

DATES: Effective Date: The revision announced in this notice is effective November 29, 2010.

FOR FURTHER INFORMATION CONTACT: Robert "Jay" Howell, Assistant Executive Director for The Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; e-mail: rhoell@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 14(a)(3)(B)(vi) of the CPSA, as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314, directs the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies to assess children's products for conformity with "other children's product safety rules." Section 14(f)(1) of the CPSA defines "children's product safety rule" as "a consumer product safety rule under [the CPSA] or similar rule, regulation, standard, or ban under any other Act enforced by the

Commission, including a rule declaring a consumer product to be a banned hazardous product or substance." Under section 14(a)(3)(A) of the CPSA, each manufacturer (including the importer) or private labeler of products subject to those regulations must have products that are manufactured more than 90 days after the Commission has established and published notice of the requirements for accreditation tested by a third party conformity assessment body accredited to do so, and must issue a certificate of compliance with the applicable regulations based on that testing. Section 14(a)(2) of the CPSA, as added by section 102(a)(2) of the CPSIA, requires that certification be based on testing of sufficient samples of the product, or samples that are identical in all material respects to the product. The Commission also emphasizes that, irrespective of certification, the product in question must comply with applicable CPSC requirements (see, e.g., section 14(h) of the CPSA, as added by section 102(b) of the CPSIA).

In the **Federal Register** of August 18, 2010 (75 FR 51020), we published a notice of requirements providing the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing pursuant to 16 CFR parts 1632, "Standard for the Flammability of Mattresses and Mattress Pads (FF 4-72, amended)," and/or 1633, "Standard for the Flammability (Open Flame) of Mattress Sets," which set minimum standards for flammability of mattresses, mattress pads, and/or mattress sets under the Flammable Fabrics Act (15 U.S.C. 1191 *et seq.*) (FFA). The notice of requirements stated that the publication had the effect of lifting the stay of enforcement with regard to testing and certification of children's products under 16 CFR parts 1632 and/or 1633, such that each manufacturer of such a product must have any such product manufactured after November 16, 2010, tested by a third party conformity assessment body accredited to do so, and must issue a certificate of compliance based on that testing (75 FR at 51021 through 51022).

We addressed testing performed by a third party conformity assessment body prior to the Commission's acceptance of its accreditation, or "retrospective" testing, in section IV of the notice of requirements. We stated that we would accept a certificate of compliance with the standard included in 16 CFR parts 1632 and/or 1633, based on testing performed by an accredited third party conformity assessment body (including a government-owned or -controlled conformity assessment body, and a

firewalled conformity assessment body), prior to the Commission's acceptance of its accreditation if:

- At the time of product testing, the product was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an ILAC-MRA member at the time of the test. For firewalled conformity assessment bodies, the firewalled conformity assessment body must be one that the Commission accredited by order at or before the time the product was tested, even though the order will not have included the test methods in the regulations specified in this notice. If the third party conformity assessment body has not been accredited by a Commission order as a firewalled conformity assessment body, the Commission will not accept a certificate of compliance based on testing performed by the third party conformity assessment body before it is accredited, by Commission order, as a firewalled conformity assessment body;
- The third party conformity assessment body's application for testing using the test methods in 16 CFR part 1632 and/or 1633 is accepted by the CPSC on or before October 18, 2010;
- The product was tested under 16 CFR part 1632 and/or 1633 on or after August 18, 2010;
- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to 16 CFR part 1632 and/or 1633;
- The test results show compliance with the applicable current standards and/or regulations; and
- The third party conformity assessment body's accreditation, including inclusion in its scope of 16 CFR part 1632 and/or 1633, remains in effect through the effective date for mandatory third party testing and manufacturer certification for conformity with 16 CFR parts 1632 and/or 1633.

75 FR at 51022.

II. Requests for Revision

In response to the notice of requirements, the International Sleep Products Association (ISPA) submitted a letter to the Commission arguing that the CPSIA's third party testing requirements do not apply to part 1632 or 1633. In the alternative, the ISPA urged that we adopt a longer implementation period for third party testing under 16 CFR part 1632, and to "grandfather in all previously conducted 1632 and 1633 testing performed by third party labs accredited by the CPSC, regardless of whether those tests occurred before or after August 18, 2010." (The ISPA letter may be viewed at <http://www.regulations.gov> in the docket folder for docket number CPSC-2010-0085.) The ISPA met with individual Commissioners and CPSC staff to discuss the requests on September 15, October 22, October 26, and November 9, 2010. Summaries of those meetings may be found at:

<http://www.cpsc.gov/library/foia/meetings/meetings.html>.

With regard to the request for a longer implementation period for third party testing for 16 CFR part 1632, the ISPA requested an additional year "[f]or those prototype and ticking substitutes that were not tested by a third party lab and that are being used in children's mattresses sold today * * * to allow manufacturers of children's mattresses 12 months to retest all of the applicable prototypes and ticking substitutes." The ISPA presented two main arguments in support of this request. First, it noted that "using a third party to perform the required 1632 tests will involve substantial time and costs." Second, it asserted that "changes in how 1632 tests are to be performed make it difficult to conduct those tests at this moment." The standard for the flammability of mattresses and mattress pads at 16 CFR part 1632 sets forth a test to determine the ignition resistance of a mattress or mattress pad when exposed to a smoldering cigarette. Lighted cigarettes are placed at specified locations on the surface of a mattress (or mattress pad). The ignition source is specified in 16 CFR part 1632 by physical properties that were originally selected to represent an unfiltered Pall Mall cigarette, but those cigarettes are no longer available. ISPA stated a concern that there may be substantial confusion about what ignition source will be required for part 1632 tests "[f]or at least the short term."

With regard to the request that we accept, for children's product certification purposes, all tests pursuant to 16 CFR parts 1632 and 1633 previously conducted by accredited third party laboratories, regardless of when the test occurred, the ISPA presented three main arguments, all of which focused on the testing conducted under 16 CFR part 1633. First, the ISPA noted that because the mattress flammability test required by 16 CFR part 1633 since 2007 is a complex, open-flame test that involves the destruction of a mattress, most manufacturers have been using third party laboratories for this testing. According to the ISPA, many of the laboratories that have done the testing since the standard was revised substantially in 2007 meet the baseline requirements for acceptance by the CPSC. Second, there have been no changes to the test method required under 16 CFR part 1633 since 2007. Third, the ISPA notes that testing under 16 CFR part 1633 is expensive and time-consuming. It argued that accepting only those third party tests of children's mattresses under 16 CFR part 1633 that

have occurred since August 18 2010, would be "arbitrary and wasteful" because requiring the mattress industry to retest all mattress prototypes used in making children's mattress sets "would take months to perform and cost the industry hundreds of thousands—if not millions—of dollars and would provide no discernable safety benefit."

Similarly, on November 2, 2010, the Commission received a letter from the Springs Creative Products Group, LLC, claiming that the notice of requirements would "put an extreme burden on mattress manufacturers to complete additional and redundant testing by accredited labs * * * by November 16, 2010," and asking that we:

- "Grandfather in all Part 1633 qualification and confirmation testing performed since 2006 by all test labs that are accredited by the CPSC;"
- "Grandfather in all Part 1632 tests performed by accredited labs since 2006;" and
- Grant a one year compliance period "for all Part 1632 prototypes and ticking substitutes that were not tested by accredited labs."

Letter from Derick S. Close, CEO, Springs Creative Products Group, LLC, to Inez Tenenbaum, Chairman, Consumer Product Safety Commission (October 26, 2010). (The Springs Creative Products Group letter may be viewed at <http://www.regulations.gov> in the docket folder for docket number CPSC-2010-0085). The letter asserted that "[r]equiring manufacturers to have the same labs retest the same Part 1633 prototypes following the same exact test method as was done since 2006 would impose wasted costs on an industry recovering from the worst recession in 70 years" and that "the industry needs more time to retest materials [in] an orderly manner because the CPSC is in the midst of changing the cigarettes used for testing." *Id.* at pages 1 through 2.

III. The Response to the Requests

A. A Brief Description of Testing Under 16 CFR Parts 1632 and 1633

We have considered the requests and, through this notice, are revising our position regarding "Limited Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing Prior to the Commission's Acceptance of Accreditation." To help interested parties understand our reasons for revising our position, we begin by explaining what prototype testing pursuant to 16 CFR parts 1632 and 1633 involves and the relevance of the letters' reference to cigarettes.

The Standard for the Flammability of Mattresses and Mattress Pads, 16 CFR part 1632, sets forth a test to determine the ignition resistance of a mattress or mattress pad when exposed to a lighted cigarette. In brief, the regulations require pre-market prototype testing for each new mattress design and also require prototype testing when there has been a change in materials of an existing prototype design that could influence cigarette ignition resistance. Six mattress surfaces must be tested for each prototype. Lighted cigarettes are placed at specified locations on the surface of a mattress (or mattress pad). The Standard establishes pass/fail criteria for the tests. Currently, the Standard specifies the ignition source for these tests by its physical properties. These properties originally were selected to represent an unfiltered Pall Mall cigarette, which was identified as the most severe smoldering ignition source. Recently, however, the Commission published a proposed rule (75 FR 67047 (Nov. 1, 2010)), to amend the mattress standard to require a standard reference material cigarette, which was developed by the National Institute of Standards and Technology, as the ignition source for testing to the mattress Standard.

The Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR part 1633, is intended to minimize or delay "flashover" when a mattress is ignited in a typical bedroom fire. ("Flashover" is the point at which the entire contents of a room are ignited simultaneously by radiant heat, making conditions in the room untenable and a safe exit from the room impossible. At flashover, room temperatures typically exceed 600–800 degrees Celsius (approximately 1100–1470 degrees Fahrenheit).) In general, the Standard requires manufacturers to test specimens of each of their mattress prototypes (designs) before mattresses of that prototype may be introduced into commerce. The specimen is to be no smaller than twin size, unless the largest size mattress or set produced of that type is smaller than twin size, in which case the largest size must be tested.

The Standard prescribes a full-scale test using a pair of T-shaped gas burners designed to represent burning bedclothes. The mattress set must not exceed a peak heat release rate of 200 kilowatts (kW) at any time during a 30 minute test, and the total heat release for the first 10 minutes of the test must not exceed 15 megajoules ("MJ"). Mattresses that meet the Standard's criteria will make only a limited contribution to a fire, especially in the fire's early stages. This will allow

occupants more time to discover the fire and escape.

Thus, both 16 CFR parts 1632 and 1633 contemplate testing of prototypes rather than testing mattresses, mattress sets, or mattress pads that are already in production. The prototype itself does not have to be a children's mattress, mattress set, or mattress pad for purposes of section 14(a)(2) of the CPSA; however, to support the issuance of a certificate for a children's product, the prototype testing must be conducted by a CPSC-accepted third party conformity assessment body.

B. The Revised "Limited Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing Prior to the Commission's Acceptance of Accreditation"

Given the nature of prototype testing under 16 CFR parts 1632 and 1633, we agree that revising our position on our "Limited Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing Prior to the Commission's Acceptance of Accreditation" is appropriate. The revised position will reduce further the need for redundant testing. We will accept children's product certifications based on third party conformity assessment body testing, prior to our acceptance of accreditation, under two different scenarios.

1. Testing Performed by Certain Accredited Third Party Conformity Assessment Bodies on or After July 1, 2007

The notice of requirements that appeared in the **Federal Register** on August 18, 2010 described the circumstances under which the Commission would accept a certificate of compliance with the standard included in 16 CFR parts 1632 and/or 1633 based on testing performed by an accredited third party conformity assessment body (75 FR at 51023). Due to the nature of prototype testing under 16 CFR parts 1632 and 1633 and the date on which the requirements in 16 CFR part 1633 became effective, we are modifying section IV of the notice of requirements as follows:

- At the time of product testing, the product was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an accreditation body that is a signatory to the ILAC-MRA;
- The third party conformity assessment body's application for testing using the test methods in 16 CFR part 1632 and/or 1633 is accepted by the CPSC on or before November 16, 2010;

- The product was tested under 16 CFR part 1632 and/or 1633 on or after July 1, 2007. The date on which the requirements in 16 CFR part 1633 became effective is July 1, 2007, and, in an "Interim Enforcement Policy for Mattresses Subject to 16 CFR Parts 1632 and 1633," dated May 15, 2006, the CPSC anticipated that 16 CFR part 1633 could prompt manufacturers to redesign mattress prototypes and use new materials to meet the then-new flammability requirements in 16 CFR part 1633, and that the new prototypes also would have to be tested to demonstrate compliance with 16 CFR part 1632. Therefore, provided that the other conditions set forth in part III.B.1 of this document are met, we will accept testing that was done on or after July 1, 2007. We decline to accept results for tests conducted in 2006, because such tests were not equivalent to the tests required in 16 CFR part 1633;

- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to 16 CFR part 1632 and/or 1633;
- The test results show compliance with the applicable current standards and/or regulations; and
- The third party conformity assessment body's accreditation, including inclusion in its scope of 16 CFR part 1632 and/or 1633, remains in effect through the effective date for mandatory third party testing and manufacturer certification for conformity with 16 CFR parts 1632 and/or 1633.

2. Testing Performed by Seven Testing Laboratories

In July 2007, CPSC staff conducted onsite reviews of the facilities that were performing testing to 16 CFR part 1633. During these reviews, we met with laboratory technical staff, toured the laboratory facilities, and observed the laboratory staff performing the test procedures. The purpose of the onsite reviews was to observe and gather information because the CPSC had concerns about test performance. The CPSC staff reviews examined:

- Laboratory staff qualifications;
- Test area and equipment;
- Calibration of equipment;
- Testing, data collection, and storage of samples; and
- Sample handling.

At the time that CPSC staff did the onsite reviews, there were 11 laboratories (nine within the United States and two in foreign countries) with the capability to perform the required test. (Resources limited the CPSC staff's ability to review the

remaining foreign and domestic laboratories prior to the implementation of the Consumer Product Safety Improvement Act.) CPSC staff visited the following laboratories:

- (1) Underwriters Laboratories (UL), in Northbrook, IL;
- (2) Stork Twin City Testing Corporation, in St. Paul, MN;
- (3) Govmark Organization, in Farmingdale, NY;
- (4) SGS US Testing, in Tulsa, OK;
- (5) Southwest Research Institute, in San Antonio, TX;
- (6) Intertek, in Elmendorf, TX; and
- (7) Chilworth, in Kelso, WA.

CPSC staff has confidence that these laboratories can conduct the tests required by the mattress Standard properly because of these field visits and also on the basis of our review of test results submitted to the CPSC since 2007, and, in some instances, verification of the test results by our own independent testing of mattresses built from prototypes tested by these laboratories. Therefore, we will accept children's product certifications based on third party conformity assessment body testing by any of the seven laboratories listed above provided that:

- The laboratory will be ISO/IEC 17025 accredited by an accreditation body that is a signatory to the ILAC-MRA, and the accreditation scope will expressly include testing to 16 CFR part 1632 and/or 1633 by November 16, 2010;
- Testing was conducted on or after July 1, 2007, but not later than November 16, 2010; and
- The test results show compliance with the applicable current standards and/or regulations.

C. The Request for an Extended Compliance Period

Both the ISPA and the Springs Creative Products Group sought an additional one year for manufacturers to comply with the third party testing requirement. Both referred to costs and to the cigarettes to be used in the tests.

We decline to extend the time by which manufacturers must engage in third party testing. We believe that our revised position regarding our "Limited Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing Prior to the Commission's Acceptance of Accreditation" substantially reduces or eliminates the need to retest products. More importantly, however, we note that section 14(a)(3)(F) of the CPSA expressly declares that:

If the Commission determines that an insufficient number of third party conformity assessment bodies have been accredited to

permit certification for a children's product safety rule * * * the Commission may extend the deadline for certification to such rule by not more than 60 days.

Thus, the conditions set forth in section 14(a)(3)(F) of the CPSA have not been met. We do not have information suggesting that there are an insufficient number of third party conformity assessment bodies to conduct tests pursuant to 16 CFR parts 1632 and/or 1633. While we recognize that third party testing may present economic issues for certain manufacturers as described in the ISPA submissions and subsequent meetings, section 14(a)(3)(F) of the CPSA does not authorize us to consider cost or the past or present state of the national economy as reasons for extending the deadline for certification. Additionally, the statute specifically allows for extension "not more than 60 days"; therefore, the one-year extension sought by the ISPA and Springs Creative Product Group would not be possible under section 14(a)(3)(F) of the CPSA.

Dated: November 19, 2010.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

[FR Doc. 2010-29861 Filed 11-26-10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH-253-FOR; Docket ID OSM-2009-0001]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving an amendment to the Ohio regulatory program (the "Ohio program") regulations under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The amendment that we are approving involves changes to Ohio's internal and procedural rules arising from a five-year review of the rules. The changes relate to practice and procedures before the reclamation commission, including definitions, commission meetings, appearance and practice before the commission; appeals to the reclamation commission; filing and service of papers; temporary relief; responsive pleadings; discovery; motions; pre-hearing procedures; notice

of hearings and continuance of hearings; site views and location of hearings; conduct of evidentiary hearings; reports and recommendations of the hearing officer; and decisions of the commission.

DATES: *Effective Date:* This rule is effective November 29, 2010.

FOR FURTHER INFORMATION CONTACT: George Rieger, Chief, Pittsburgh Field Division, Columbus Office, Office of Surface Mining Reclamation and Enforcement, Telephone: (614) 416-2238, e-mail: grieger@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Ohio Program
- II. Description and Submission of the Amendment
- III. OSM's Findings
- IV. Summary and Disposition of Comments
- V. OSM's Decision
- VI. Procedural Determinations

I. Background on the Ohio Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act." See 30 U.S.C. 1253(a)(1) and (7).

You can find background information on the Ohio program, including the Secretary's findings, the disposition of comments, and conditions of approval in the August 16, 1982, *Federal Register* (47 FR 34688). You can also find later actions concerning Ohio's program and program amendments at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Description and Submission of the Amendment

By letter dated January 22, 2009, and received on January 23, 2009, (Administrative Record No. OH-2188-01), Ohio sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). This amendment includes revisions to its regulations (Ohio Administrative Code).

Pursuant to Ohio Revised Code 119.032, all State agencies must review their internal and procedural rules every five years. In response to this requirement, the Ohio Reclamation Commission reviewed its procedural rules. The Commission's procedural rules are found at Ohio Administrative Code 1513-3-01 through 1513-3-22.

This amendment contains the changes made to the Ohio Administrative Code as a result of this review. Changes relate to practice and procedures before the reclamation commission, including definitions; commission meetings; appearance and practice before the commission; appeals to the reclamation commission; filing and service of papers; temporary relief; responsive pleadings; discovery; motions; pre-hearing procedures; notice of hearings and continuance of hearings; site views and location of hearings; conduct of evidentiary hearings; reports and recommendations of the hearing officer; and decisions of the commission. These changes are identified below, with additions italicized and deletions bracketed:

1513-3-01: Definitions.

(N) "*Regular business hours*" for the reclamation commission means 10:00 a.m. to 6:00 p.m. Monday through Friday, except for State holidays or other days in which offices of the government of the State of Ohio are permitted to close due to weather, safety or other unforeseeable events which present a risk to the public or to the commission employees. In the event of the absence of the office staff, contact information for the chairman and vice-chairman of the commission will be prominently posted at the commission offices.

((N))(O) "Rules of the reclamation commission" means rules 1513-3-01 to 1513-3-22 of the Administrative code and shall apply to appeals filed under both Chapters 1513 and 1514. of the Revised code, unless specifically provided otherwise.

1513-3-02: Internal regulations.

(B) Four members constitute a quorum, and no action of the commission shall be valid unless it has the concurrence of at least four members. Where, in rendering a decision, a concurrence of at least four commission members is not obtained, the existing record of proceedings may be submitted to any absent commission member, who will be permitted to participate in the rendering of the decision. [at a subsequent commission meeting.]

1513-3-02: Internal regulations.

(D) Pursuant to section 1513.05 of the Revised code, the reclamation commission shall elect [may appoint] a secretary, who shall perform such duties as the commission prescribes, including:

1513-3-02: Internal regulations.

(D)(4) Providing notice of all public meetings [hearings] of the reclamation commission in accordance with the following procedures:

(a) Any person may determine the time and place of *regularly-scheduled public meetings* [hearings or the time and place of any temporary relief hearings] by contacting the office of the reclamation commission during *regular business hours*;

(b) Upon request, any person may obtain advance notice of all *regularly-scheduled public meetings* [hearings] by supplying the office of the reclamation commission with stamped, self-addressed envelopes. The office will mail to such person a notice of the time and place of *meetings* [hearings] at least four calendar days before the *meeting* [hearing] is scheduled; [unless the hearing is a temporary relief hearing;]

(c) The reclamation commission shall provide the office of the reclamation commission with the time and place of *meetings* [hearings] requiring public notice under the provisions of this rule within sufficient time to enable the office to comply with the provisions of this rule.

(d) *The time and location for commission meetings shall be announced in the Hannah Report published by Rotunda, Inc.*

1513-3-02: Internal regulations.

(H) Any [The] transcript [or recording] of a [any] proceeding before the commission, if filed with the commission [shall be the property of the commission and] shall be made available for reproduction upon application to the commission and payment of reproduction costs.

(I) Issuance of subpoenas.

(1) Upon request of a party, or at the initiative of the commission, the commission shall issue subpoenas ad testificandum or duces tecum.

1513-3-03: Appearance and practice before the commission.

(C) *Except as prohibited by section 4705.01 of the Revised code, any party may appear on his own behalf or may be represented by an attorney at law admitted to practice before the Supreme Court of Ohio, or by an attorney admitted to practice by the commission pursuant to a motion to appear pro hac vice.* [In the absence of an attorney, a party may represent itself, a partnership may be represented by any of its members, a corporation or association may be represented by any of its officers and any governmental unit may be represented by an employee offering proof of authority.]

1513-3-04: Appeals to the reclamation commission.

(B) A notice of appeal must:

(7) Pursuant to section 1513.13 of the Revised Code, identify [Identify] the grounds upon which review is being sought, the manner in which appellant

is aggrieved or adversely affected by the action of the chief of the division of mineral resources management and the relief sought on appeal;

1513-3-05: Filing and service of papers.

(H) If papers filed with the commission cite case law as authority in support of argument, the filing must include a copy of the case law cited and must refer to the page number or paragraph on which the relevant language is found.

1513-3-08: Temporary Relief.

(F) The decision of the chairman of the reclamation commission to grant or deny temporary relief may be appealed to the [full] commission, including the chairman who decided temporary relief, within thirty days after the chairman's issuance of the decision in accordance with the provisions of section 1513.13 of the Revised Code. The [full]-commission may confine its review to the record developed at the temporary relief hearing conducted by the chairman. The [full] commission shall affirm the decision of the chairman, unless it determines that the chairman's decision is arbitrary, capricious, or otherwise inconsistent with law.

1513-3-09: Responsive pleadings.

(B) *Unless the commission orders otherwise, the party ordered to file a response pursuant to this rule shall have ten days from the issuance of the commission's order to make such filing.*

[(B)(C) Failure to respond when ordered may be treated as a failure to appear at hearing.]

1513-3-10: Discovery.

(C) Discovery shall be conducted in accordance with the procedural provisions of the "Ohio Rules of Civil Procedure." Discovery may include oral depositions, written interrogatories to parties, inspection of premises, requests for admission, and inspection of documents. [not privileged.]

1513-3-11: Motions.

(A) Except for oral motions which must be made in proceedings on the record, or where the commission otherwise directs, any motion made to the reclamation commission shall:

(4) Be filed with the commission and served upon all parties to the proceeding at least ten [five] days in advance of the hearing, unless the movant demonstrates that unusual circumstances exist justifying an exception to this rule.

1513-3-11: Motions.

(C) Motions for reconsideration of any decision of the commission shall be made in writing within ten [fourteen] days after the issuance of the commission's decision. A motion for reconsideration shall state with

particularity the grounds on which it is based. The filing of a motion for reconsideration does not extend the time for filing a notice of appeal in the appellate court.

1513-3-11: Motions.

(E) In compliance with the requirements of 1513-3-13(C)(2), motions for continuance of a hearing must be filed with the reclamation commission and served upon all parties to a proceeding at least fourteen days in advance of a hearing.

(E)(F) Unless the commission orders otherwise, any party to a proceeding shall have ten days from service of the motion or until hearing, whichever is earlier, to file a response to a motion.

(F)(G) Failure to make a timely motion or to file a statement in response to a motion may be construed as a waiver of objection.

1513-3-12: Pre-hearing procedures.

(A) The reclamation commission, or its hearing officer, may schedule and hold pre-hearing conferences for settlement or simplification of the issues in any appeal.

(B) Whenever a pre-hearing conference is held, the commission, or its hearing officer, may issue an order which recites the matters discussed, the agreements reached, and the rulings made at the pre-hearing conference.

(C) The commission, or its hearing officer, may require the filing of a pre-hearing statement by the parties to an appeal.

1513-3-13: Notice of hearings and continuance of hearings.

(C) Continuance of scheduled hearings.

(2) Motions for continuance of a hearing must be filed with the reclamation commission and served upon all parties to a proceeding at least fourteen [five] days in advance of a hearing.

(3) Motions for continuance made less than fourteen [five] days before hearing or at hearing shall be granted only upon demonstration that an extraordinary situation exists which could not have been anticipated and which would justify the granting of a continuance.

1513-3-14: Site views and location of hearings.

(A) Site views.

(2) Subject to any applicable safety requirements, the [The] commission may, upon reasonable notice and at reasonable times, inspect any site or other premises when the commission is of the opinion that such a viewing would have a beneficial value in any matter pending before the commission.

(3) [Unless the right to a site view is statutorily prescribed, a] A quorum of commission members need not attend a site view.

(4) All parties shall have prior notice of a site view and shall have the right to be present. Parties shall be informed of any safety requirements prior to the site view. The commission may limit the number of persons, which may accompany a party at a site view.

1513-3-16: Conduct of evidentiary hearings.

(E) Written testimony.

(2) The use of a deposition in lieu of the [dependent's] deponent's oral testimony at hearing shall be allowed under the same provisions as are articulated in rule 32 of the "Ohio Rules of Civil Procedure." A party desiring to use a deposition, or any designated part thereof, at hearing shall file the deposition with the commission and serve written notice to every other party at least five days prior to hearing.

(F) Witnesses.

(2) The commission may require each party in an appeal to identify prior to the commencement of a hearing each person who is or may be present and [in] his interest or who will or may be a witness for his cause in the appeal.

(G) If the appellant fails to appear personally or by counsel or other authorized representative at a hearing scheduled after being duly notified of the hearing by the mailing of a notice of hearing to such party's last known address, and if good cause for such failure to appear [appeal] is not shown, the commission shall dismiss the appeal.

(I) The reclamation commission may order the parties to a proceeding to submit post-hearing briefs or proposed findings of fact and conclusions of law at a time designated by the commission, on issues raised on the appeal or upon possible errors or omissions in the record or on any issues as the commission in its discretion shall determine. The commission may also order the parties to submit written closing arguments or proposed findings of fact and conclusions of law at the conclusion of hearing.

1513-3-18: Reports and recommendations of the hearing officer.

(F) Any party to a proceeding may have [seven] fourteen days from service of the objections to the report and recommendation of the hearing officer to file a response.

1513-3-19: Decisions of the commission.

(A) All decisions of the commission shall [incorporate] set forth:

- (1) Findings of fact;
- (2) Conclusions of law; and
- (3) An order granting or denying relief.

1513-3-19: Decisions of the commission.

(F) Remission of prepaid civil penalty assessments.

(1) If a review of a civil penalty assessment results in an order reducing or eliminating a civil penalty, the reclamation commission shall remit the funds to the appellant in accordance with division [(F)](E) of section 1513.02 of the Revised Code.

III. OSM's Findings

We are approving the amendment request under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. Changes for which no findings are made below involve clarifications and non-substantive corrections of punctuation, typos, and errors in references.

1513-3-01: Definitions. These changes involve the addition of a description of regular business hours for the reclamation commission and subsequent paragraph renumbering. While this provision has no Federal counterpart, we find that it is not inconsistent with the Federal regulations at 43 CFR part 4, pertaining to the Office of Hearings and Appeals, and is therefore approved.

1513-3-02: Internal regulations. The changes to 1513-3-02(B) and (D) pertain to the Commission's procedural rules regarding quorums and the election of the secretary. While these provisions have no Federal counterpart, we find that they are not inconsistent with the Federal regulations at 43 CFR part 4, and are therefore approved.

1513-3-02: Internal regulations. The changes to 1513-3-02(D)(4) pertain to the notice of public meetings of the reclamation commission. These section changes replace references to public "hearings" to public "meetings" to reflect the same language that is included under Ohio's Sunshine Law. They clarify that a person may obtain advance notice of "regularly" scheduled public meetings, and provide the medium in which the time and location of such meetings are made available. Ohio explained that adjudicatory "hearings" are a subset of the term "meetings" (Administrative Record No. OH-2188-05). While these provisions have no Federal counterpart, we find that they are not inconsistent with the Federal regulations at 43 CFR part 4, and are therefore approved.

1513-3-02: Internal regulations. The change to 1513-3-02(H) regarding the availability of transcripts of commission proceedings is consistent with 43 CFR 4.23, Transcript of hearings, and is therefore approved.

1513-3-02: Internal regulations. The change to 1513-3-02(I) regarding the issuance of subpoenas is consistent with

43 CFR 4.26, Subpoena power and witness provisions generally, and is therefore approved.

1513-3-03: Appearance and practice before the commission. The changes to 1513-3-03(C) regarding representation when appearing before the commission are not inconsistent with 43 CFR 4.3, Representation before appeals boards, and are therefore approved.

1513-3-04: Appeals to the reclamation commission. The changes to 1513-3-04(B)(7) involve referencing pertinent regulations of the Revised Code and clarifying who may appeal. These changes are consistent with 43 CFR 4.1281, Who may appeal, and 43 CFR 4.1282, Appeals; how taken, and are therefore approved.

1513-3-05: Filing and service of papers. The change to 1513-3-05(H) involves the documentation required for a filing of an appeal. This change is not inconsistent with 43 CFR 4.1107, Filing of documents, and is therefore approved.

1513-3-08: Temporary Relief. The change to 1513-3-08(F) provides that the chairman who decided temporary relief will be involved in the final decision of the full commission with respect to an appeal of the temporary relief ruling. This change is not inconsistent with 43 CFR 4.1267, Appeals (of decisions on temporary relief) and 4.1367(f), Request for temporary relief, and is therefore approved.

1513-3-09: Responsive pleadings. The change to 1513-3-09(B) adds a time frame for responding to the commission. While this provision has no direct Federal counterpart, we find that it is not inconsistent with the Federal regulations at 43 CFR part 4, and is therefore approved.

1513-3-10: Discovery. The change to 1513-3-10(C) deletes the phrase "not privileged." Read by itself, this amendment could be construed to allow discovery of privileged information, without the permission of the person or agency in possession of the information. However, existing language also states that "[d]iscovery shall be conducted in accordance with the procedural provisions of the Ohio Rules of Civil Procedure." Rule 26 of Ohio's Rules of Civil Procedure provides "[p]arties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action. Therefore, the change proposed here is non-substantive, does not render the State provision inconsistent with 43 CFR 4.1130 and 4.1132(a), and is approved.

1513-3-11: Motions. The changes to 1513-3-11(A)(4); 1513-3-11(C) and (E)

amend the deadlines for filing responses to written motions, for filing motions for reconsideration, and for filing motions for continuance before the reclamation commission. Other changes in this section involve paragraph renumbering. While these amended time limitations have no direct Federal counterparts, we find that they are not inconsistent with 43 CFR 4.22(d) and 43 CFR 4.1112, and they are therefore approved.

1513-3-12: Pre-hearing procedures. The changes to 1513-3-12(A) through (C) provide that a hearings officer may schedule and hold pre-hearing conferences, issue orders involving such conferences, and require filing of pre-hearing statements. Under the current program, only the full reclamation commission may take these actions. While these changes have no Federal counterparts, we find that they are not inconsistent with 43 CFR 4.1121(b), and are therefore approved.

1513-3-13: Notice of hearings and continuance of hearings. Changes to 1513-3-13(C) require that motions be filed at least fourteen days prior to the hearing. Motions for continuance made after this deadline will be granted only upon a demonstration of a need based upon an extraordinary situation. Under the current regulation, such a motion could be filed as late as five days prior to the hearing and granted without a demonstration that an extraordinary situation exists. While this provision has no Federal counterpart, we find that it is not inconsistent with the Federal regulations at 43 CFR part 4, and is therefore approved.

1513-3-14: Site views and location of hearings. The changes to 1513-3-14(A) involving site inspections require that safety requirements be met; clarify that a quorum of commission members need not attend a site view; and add that the commission may limit the number of individuals that may accompany a party to a site view. While these provisions have no Federal counterpart, we find that they are not inconsistent with the Federal regulations at 43 CFR part 4, and are therefore approved.

1513-3-16: Conduct of evidentiary hearings. The change to 1513-16(I) allows the commission to order the parties to file proposed findings of fact and conclusions of law at the conclusion of a hearing. We find that this change is consistent with 43 CFR 4.1126, Proposed findings of fact and conclusions of law, and is therefore approved.

1513-3-18: Reports and recommendations of the hearing officer. The change to 1513-3-18(F) increases the time in which a party may file a response to objections to a hearing

officer's report and recommendations from seven to fourteen days. While this provision has no Federal counterpart, we find that it is not inconsistent with the Federal regulations at 43 CFR part 4, and is therefore approved.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment (Administrative Record No. OH-2188-04) 74 FR 17802. We did not receive any public comments or a request to hold a public meeting.

Federal Agency Comments

Under Federal regulations at 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Ohio program (Administrative Record No. OH-2188-02). The Mine Safety and Health Administration (MSHA), District 1, responded (Administrative Record No. OH-2188-03) that it did not find any changes or issues that would impact upon coal miners' health and safety.

Environmental Protection Agency (EPA) Concurrence and Comments

Under Federal regulations at 30 CFR 732.17(h)(11)(ii), we are required to get a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

None of the revisions that Ohio proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment.

V. OSM's Decision

Based on the above findings, we approve the amendment Ohio sent to us on January 22, 2009, pertaining to Ohio's Administrative code.

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by Section 3 of Executive Order 12988 and has determined that, to the extent allowable by law, this rule meets the applicable standards of Subsections (a) and (b) of that Section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under Sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of SMCRA, and Section 503(a)(7) requires that State programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Government

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian Tribes and have determined that the rule does not have substantial direct effects 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. The basis for this determination is that

our decision is on a State regulatory program and does not involve a Federal program involving Indian lands.

Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of Section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon data and assumptions for the Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business

Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, geographic regions, or Federal, State, or local government agencies; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or Tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 1, 2010.

Thomas D. Shope,
Regional Director, Appalachian Region.

■ For the reasons set out in the preamble, 30 CFR part 935 is amended as set forth below:

PART 935—OHIO

■ 1. The authority citation for part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 935.15 is amended in the table by adding a new entry in chronological order by "Date of Final Publication" to read as follows:

§ 935.15 Approval of Ohio regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
January 22, 2009.	November 29, 2010.	OAC 1513-3-01; 3-02(B); 3-02(D)(4); 3-02(H)-(I)(1); 3-03(C); 3-04(B)(7); 3-04(H); 3-08(F); 3-09(B)-(C); 3-10(C); 3-11(A)(4); 3-11(C); 3-11(E)-(G); 3-12(A)-(C); 3-13(C)(2)-(3); 3-14(A)(2)-(4); 3-16(E)(2); 3-16(F)(2); 3-16(G); 3-16(I); 3-18(F); 3-19(A); 3-19(F); 3-19(I).

[FR Doc. 2010-29916 Filed 11-26-10; 8:45 am]
BILLING CODE 4310-05-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0979]

RIN 1625-AA00

Safety Zone; 1000-yard radius from position 29°48.77' N 091°33.02' W, Charenton Drainage and Navigation Canal, St. Mary Parish, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone extending to a 1000-yard radius from position 29°48.77' N 091°33.02' W, Charenton Drainage and Navigation Canal, St. Mary Parish, LA. This Safety Zone is needed to protect the general public, vessels and tows from destruction, loss or injury due to a sunken vessel and associated hazards.

DATES: This rule is effective in the CFR on November 29, 2010 through December 31, 2010. This rule is effective with actual notice for purposes of enforcement on October 20, 2010. This rule will remain in effect until December 31, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0979 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0979 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary

rule, call or e-mail Lieutenant (LT) Russel Pickering, Coast Guard; telephone 985-380-5320, e-mail russel.t.pickering@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing an NPRM would be impracticable, as immediate action is needed to protect the general public, vessel and tows from a sunken vessel and associated hazards in position 29°48.77' N 091°33.02' W, in the Charenton Drainage and Navigation Canal.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Publishing an NPRM and delaying its effective date would be contrary to public interest since immediate action is needed to protect the general public, vessel and tows from destruction, loss or injury due to sunken vessel and associated hazards in position 29°48.77' N 091°33.02' W.

Background and Purpose

A Mobile Inshore Drilling Rig (Hercules Rig 61) scheduled for scrap sank in the Charenton Navigation and Drainage Canal. The Charenton Navigation and Drainage Canal will be closed to all marine traffic within a

1000-yard radius of position 29°48.77' N 091°33.02' W from 20 OCT, 2010 through 31 DEC, 2010. This Safety Zone is needed to protect the general public, vessels and tows from destruction, loss or injury from a sunken vessel and associated hazards.

Discussion of Rule

The Coast Guard is establishing a temporary Safety Zone in a 1000-yard radius of position 29°48.77' N 091°33.02' W within the Charenton Drainage and Navigation Canal. The temporary Safety Zone will continue from October 20, 2010 through December 31, 2010. Vessels and tows may not enter this zone unless authorized by the Captain of the Port Morgan City.

Regulatory Analyses

We developed this 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.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This rule will only be in effect for a short period of time and notifications to the marine community will be made through broadcast notice to mariners and Local Notice to Mariners. The impacts on routine navigation are expected to be minimal.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule 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.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit through the Safety Zone from October 20, 2010 through December 31, 2010. This Safety Zone will not have a significant economic impact on a substantial number of small entities because this rule will be in effect for only a short period of time.

If you are a small business entity and are significantly affected by this regulation, please contact LT Russel Pickering, Marine Safety Unit Morgan City, at 985-380-5320.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

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 rule under that Order and have determined that it does not have implications for federalism

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 or more (adjusted for inflation) in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This 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.

Civil Justice Reform

This 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.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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.

Energy Effects

We have analyzed this 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.

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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves an emergency situation and will be in effect for over one week, but is not expected to result in any significant adverse environmental impact as described in NEPA.

An environmental analysis checklist and a categorical exclusion determination will be provided and made available at the docket as indicated in the ADDRESSES section.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08-0979 to read as follows:

§ 165.T08-0979 Safety Zone; 1000 yard radius from position 29°48.77' N 091°33.02' W, Charenton Drainage and Navigation Canal, St. Mary Parish, LA.

(a) *Enforcement Areas.* The safety zone exists in an area comprising a 1000 yard radius from position 29°48.77' N 091°33.02' W, Charenton Drainage and Navigation Canal.

(b) *Effective date.* This rule is effective on October 20, 2010 through December 31, 2010.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Morgan City.

(2) Vessels requiring entry into or passage through the Safety Zone must request permission from the Captain of the Port Morgan City, or a designated representative. They may be contacted on VHF Channel 13 or 16, or by telephone at (985) 380-5320.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Morgan City and designated on-scene patrol personnel. On-scene patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

Dated: October 20, 2010.

Blake E. Welborn.

Commander, U.S. Coast Guard, Acting Captain of the Port Morgan City, Louisiana.

[FR Doc. 2010-29878 Filed 11-26-10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2010-0656; FRL-9232-2]

Approval and Promulgation of Air Quality Implementation Plans; Ohio; Ohio Portion of the Cincinnati-Hamilton Area; 8-Hour Ozone Maintenance Plan

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: EPA is approving a revision to the maintenance plan for the Ohio portion of the Cincinnati-Hamilton, OH-KY-IN 8-hour ozone area. The Cincinnati-Hamilton area includes Butler, Clermont, Clinton, Hamilton,

and Warren Counties in Ohio, Lawrenceburg Township in Dearborn County, Indiana, and Boone, Campbell, and Kenton Counties in Kentucky. The Ohio Environmental Protection Agency (Ohio EPA) submitted a maintenance plan revision on July 6, 2010. The submittal contained revisions to 2015 and 2020 NO_x point source emissions projections for Butler County to reflect modifications at a major source that will occur during the maintenance period.

DATES: This direct final rule will be effective January 28, 2011, unless EPA receives adverse comments by December 29, 2010. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2010-0656, by one of the following methods:

1. <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

2. *E-mail:* mooney.john@epa.gov.

3. *Fax:* (312) 692-2551.

4. *Mail:* John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R05-OAR-2010-0656. 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 e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which

means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov> your e-mail 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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.

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 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 Kathleen D'Agostino, Environmental Engineer, at (312) 886-1767 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-1767, dagostino.kathleen@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?
- II. What revisions are being made to the maintenance plan?
- III. What action is EPA taking?
- IV. Statutory and Executive Order Reviews

I. What is the background for this action?

On May 11, 2010 (75 FR 26118), EPA redesignated the Ohio and Indiana portions of the Cincinnati-Hamilton area to attainment for the 1997 8-hour ozone National Ambient Air Quality Standard (NAAQS). At that time, EPA also approved, as a revision to the Ohio and Indiana State Implementation Plans (SIP), the States' plans for maintaining the 8-hour ozone NAAQS through 2020 in the area.

The Ohio and Indiana plans demonstrated maintenance of the 8-hour ozone standard through 2020 by showing that current and future emissions of VOC and NO_x for the Cincinnati-Hamilton area remain at or below attainment year emission levels. The Cincinnati-Hamilton area attained the 8-hour ozone NAAQS during the 2007–2009 time period. For attainment emission levels, Ohio and Indiana used 2008 inventories. Emissions inventory projections for the years 2015 and 2020 were used to demonstrate maintenance.

As part of their maintenance plans, the States elected to include a "safety margin" for the area. A "safety margin" is the difference between the attainment level of emissions (from all sources) and

the projected level of emissions (from all sources) in the maintenance plan which continues to demonstrate attainment of the standard. For the Ohio and Indiana portion of the Cincinnati-Hamilton area, the emissions from point, area, nonroad, and mobile sources in 2008 equaled 144.22 tons per day (tpd) and 230.28 tpd of VOC and NO_x, respectively. In the maintenance plans, Ohio and Indiana projected VOC and NO_x emission levels for 2020 to be 117.70 tpd and 197.75 tpd, respectively. The SIP submissions demonstrated that the Cincinnati-Hamilton area will continue to maintain the standard with emissions at this level. The safety margin was calculated to be the difference between 2008 and 2020 emissions levels. The 2020 safety margin for VOC was 26.52 tpd (*i.e.*, 144.22 tpd less 117.70). For NO_x, the 2020 safety margin was 32.53 tpd. Using the same method of calculation, the 2015 safety margins for VOC and NO_x were 23.40 tpd and 17.50 tpd, respectively. The safety margin, or a portion thereof, can be allocated to any of the source categories, as long as the total attainment level of emissions is maintained.

At the time the maintenance plan was approved, EPA also approved VOC and

NO_x Motor Vehicle Emissions Budgets (MVEBs) for 2015 and 2020 for the Ohio and Indiana portions of the Cincinnati-Hamilton area. The MVEBs requested by Ohio EPA and the Indiana Department of Environmental Management (IDEM) contained safety margins for mobile sources smaller than the allowable safety margins reflected in the total emissions for the Ohio and Indiana portions of the Cincinnati-Hamilton area. For VOC, mobile safety margins of 4.14 tpd and 3.76 tpd were included for 2015 and 2020, respectively. For NO_x, mobile safety margins of 6.39 tpd and 4.49 tpd were included for 2015 and 2020, respectively.

II. What revisions are being made to the maintenance plan?

Ohio submitted revisions to 2015 and 2020 NO_x point source emissions projections for Butler County to reflect modifications at a major source which will occur during the maintenance period. These revised projections show an increase of 1.31 tons per day (tpd) of NO_x in both 2015 and 2020. As shown in Table 1, for the Ohio and Indiana portions of the Cincinnati-Hamilton area, 2015 and 2020 emissions remain below attainment levels.

TABLE 1—COMPARISON OF 2008, 2015 AND 2020 VOC AND NO_x EMISSIONS FOR THE OHIO AND INDIANA PORTION OF THE CINCINNATI-HAMILTON AREA (TPD)

	VOC					NO _x				
	2008	2015	2020	Net change (2008–2015)	Net change (2008–2020)	2008	2015	2020	Net change (2008–2015)	Net change (2008–2020)
Point	10.65	12.85	13.53	2.20	2.88	88.97	135.21	138.43	46.24	49.46
Area	57.73	54.33	54.33	–3.40	–3.40	10.98	11.03	11.03	0.05	0.05
Onroad	30.51	27.59	25.06	–2.92	–5.45	91.67	42.61	29.90	–49.06	–61.77
Nonroad	45.33	26.05	24.78	–19.28	–20.55	38.66	25.24	19.70	–13.42	–18.96
Total	144.22	120.82	117.70	–23.40	–26.52	230.28	214.09	199.06	–16.19	–31.22

For the Ohio and Indiana portion of the Cincinnati-Hamilton area, the NO_x emissions from point, area, nonroad, and mobile sources in 2008 equaled 230.28 tpd. For 2015, projected NO_x emission levels equal 214.09 tpd. The safety margin for NO_x is calculated to be the difference between these amounts or, in this case, 16.19 tpd for 2015. For 2020, the NO_x safety margin is 31.22 tpd. The portion of the NO_x safety margins allocated to the onroad mobile source sector when the MVEBs were approved remains smaller than the revised allowable safety margins reflected in the total emissions for the Ohio and Indiana portion of the Cincinnati-Hamilton area. Because no changes were made to the VOC

inventories, the safety margins remain unchanged.

III. What action is EPA taking?

EPA is approving a revision to the maintenance plan for the Ohio portion of the Cincinnati-Hamilton 8-hour ozone area. Changes were made to the 2015 and 2020 NO_x point source emissions projections for Butler County to reflect modifications at a major source that will occur during the maintenance period.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we

are publishing a separate document that will serve as the proposal to approve the State plan if relevant adverse written comments are filed. This rule will be effective January 28, 2011 without further notice unless we receive relevant adverse written comments by December 29, 2010. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA

receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective January 28, 2011.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act (CAA), the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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. 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 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 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 28, 2011. 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. 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: November 15, 2010.

Susan Hedman,

Regional Administrator, Region 5.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart KK—Ohio

2. Section 52.1885 is amended by adding paragraph (ff)(11) to read as follows:

§ 52.1885 Control strategy: Ozone.

* * * * *

(ff) * * *

(11) Approval—On July 6, 2010, the Ohio Environmental Protection Agency submitted a request to revise the maintenance plan for the Ohio portion of the Cincinnati-Hamilton, OH-KY-IN 8-hour ozone area. The submittal revises 2015 and 2020 NO_x point source emissions projections for Butler County.

* * * * *

[FR Doc. 2010-29784 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2009-0515; FRL-9232-3]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Clean Air Interstate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a request submitted by the Indiana Department of Environmental Management (IDEM) on June 29, 2009, to revise the Indiana State Implementation Plan (SIP) under the Clean Air Act (CAA). The State has submitted amendments to the Indiana Administrative Code (IAC), which supplement Indiana's Clean Air Interstate Rule (CAIR), for which EPA granted limited approval as an abbreviated SIP on October 22, 2007. The abbreviated SIP was to be implemented in conjunction with a Federal Implementation Plan (FIP) that specified requirements for emissions monitoring, permit provisions, and other elements of CAIR programs. The State's June 29, 2009, submittal includes elements that EPA deems necessary in order for EPA to fully approve Indiana's CAIR SIP. This will allow a transition from an abbreviated SIP with limited approval to a full SIP with full approval under which the various CAIR implementation provisions would be governed by State rules rather than FIP

rules. This action results in the withdrawal of the Indiana CAIR FIP concerning sulfur dioxide (SO₂), nitrogen oxides (NO_x) annual, and NO_x ozone season emissions.

DATES: This direct final will be effective January 28, 2011, unless EPA receives adverse comments by December 29, 2010. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2009-0515, by one of the following methods:

1. *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *E-mail*: mooney.john@epa.gov.

3. *Fax*: (312) 692-2551.

4. *Mail*: John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery*: John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R05-OAR-2009-0515. 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 e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov> your e-mail 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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.

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 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 Andy Chang, Environmental Engineer, at (312) 886-0258 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Andy Chang, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-0258, chang.andy@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 action is EPA taking?
- II. What is the regulatory history of CAIR and CAIR FIPs?
- III. What are the general requirements of CAIR and CAIR FIPs?
- IV. What are the types of CAIR SIP submittals?
- V. Analysis of Indiana's CAIR SIP submittals
 - A. What is the history of the State's submittals?
 - B. State Budgets for Allowance Allocations
 - C. CAIR Cap-and-Trade Programs
 - D. Applicability Provisions
 - E. Individual Opt-in Units
 - F. Deficiencies in the State's February 28, 2007, Submittal and the State's Subsequent Responses
 - G. Federal Definition of "Biomass" in Reference to "Cogeneration Unit"

- H. The State's Complete CAIR Regulations
- I. NO_x Reduction Program for Specific Source Categories—Applicability
- J. Sunset Provision
- VI. Final Action
- VII. Statutory and Executive Order Reviews

I. What action is EPA taking?

In this rulemaking EPA is fully approving Indiana's CAIR SIP, including the State's June 29, 2009, submittal. This will allow a transition from an abbreviated SIP with limited approval to a full SIP with full approval under which the various CAIR implementation provisions would be governed by State rules rather than FIP rules. This action causes the CAIR FIPs concerning SO₂, NO_x annual, and NO_x ozone season emissions by Indiana sources to be automatically withdrawn.

II. What is the regulatory history of CAIR and CAIR FIPs?

EPA published CAIR on May 12, 2005 (70 FR 25162). In that rule, EPA determined that 28 States and the District of Columbia contribute significantly to nonattainment and interfere with maintenance of the National Ambient Air Quality Standards (NAAQS) for fine particles (PM_{2.5}) and/or 8-hour ozone in downwind States in the eastern part of the country. As a result, EPA required those upwind States to revise their SIPs to include control measures that reduce emissions of SO₂, which is a precursor to PM_{2.5} formation, and/or NO_x, which is a precursor to both ozone and PM_{2.5} formation. For jurisdictions that contribute significantly to downwind PM_{2.5} nonattainment, CAIR sets annual State-wide emission reduction requirements (*i.e.*, budgets) for SO₂ and NO_x. Similarly, for jurisdictions that contribute significantly to 8-hour ozone nonattainment, CAIR sets State-wide emission budgets for NO_x for the ozone season (May 1st to September 30th). Under CAIR, States may implement these reduction requirements by participating in the EPA-administered cap-and-trade programs or by adopting any other control measures.

CAIR establishes requirements that must be included in SIPs to address the requirements of section 110(a)(2)(D) of the CAA with regard to interstate transport for ozone and PM_{2.5}. On April 25, 2005 (70 FR 21147), EPA made national findings that the States had failed to submit SIPs meeting the requirements of section 110(a)(2)(D). The SIPs were due in July 2000, 3 years after the promulgation of the 8-hour ozone and PM_{2.5} NAAQS. These findings started a 2-year clock for EPA to promulgate a FIP to address the

requirements of section 110(a)(2)(D). Under section 110(c)(1) of the CAA, EPA may issue a FIP anytime after such findings are made, and must do so within two years unless EPA has approved a SIP revision correcting the deficiency before the FIP is promulgated.

On April 28, 2006, EPA promulgated FIPs for all States covered by CAIR to ensure that the emissions reductions required by CAIR would be achieved on schedule. The CAIR FIPs required electric generating units (EGUs) to participate in the EPA-administered CAIR SO₂, NO_x annual, and NO_x ozone season trading programs, as appropriate. The CAIR FIP trading programs impose essentially the same requirements as, and are integrated with, the respective CAIR SIP trading programs. The integration of the FIP and SIP trading programs was meant to create a single trading program for each regulated pollutant (SO₂, NO_x annual, and NO_x ozone season) in all States covered by CAIR FIP or SIP trading programs for that pollutant. Further, as provided in a rule published by EPA on November 2, 2007 (72 FR 62338), a State's CAIR FIP is automatically withdrawn when EPA approves a SIP revision as fully meeting the requirements of CAIR. Where only portions of the SIP revision are approved, the corresponding portions of the FIPs are automatically withdrawn and the remaining portions of the FIP stay in place. Finally, the CAIR FIPs also allow States to submit abbreviated SIP revisions that, if approved by EPA, automatically replace or supplement certain CAIR FIP provisions (e.g., the methodology for allocating NO_x allowances to sources in the State), while the CAIR FIP remains in place for all other provisions. Therefore, because Indiana only had an abbreviated CAIR SIP in place prior to today's rulemaking, there were also elements of CAIR FIPs in effect.

On October 19, 2007 (72 FR 59190), EPA amended CAIR and CAIR FIPs to clarify the definition of "cogeneration unit" and, thus, the applicability of the CAIR trading program to cogeneration units.

EPA was sued by a number of parties on various aspects of CAIR, and on July 11, 2008, the U.S. Court of Appeals for the District of Columbia Circuit issued its decision to vacate and remand both CAIR and the associated CAIR FIPs in their entirety. *North Carolina v. EPA*, 531 F.3d 836 (DC Cir. 2008). However, in response to EPA's petition for rehearing, the Court issued an order remanding CAIR to EPA without vacating either CAIR or the CAIR FIPs. *North Carolina v. EPA*, 550 F.3d 1176

(DC Cir. 2008). The Court thereby left CAIR in place in order to "temporarily preserve the environmental values covered by CAIR" until EPA replaces it with a rule consistent with the Court's opinion. *Id.* at 1178. The Court directed EPA to "remedy CAIR's flaws" consistent with its July 11, 2008, opinion, but declined to impose a schedule on EPA for completing that action. *Id.*

III. What are the general requirements of CAIR and CAIR FIPs?

CAIR, which establishes statewide emission budgets for SO₂ and NO_x, is to be implemented in two phases. The first phase of NO_x reductions starts in 2009 and continues through 2014, while the first phase of SO₂ reductions starts in 2010 and continues through 2014. The second phase of reductions for both NO_x and SO₂ starts in 2015 and continues thereafter. CAIR requires States to implement the budgets by either: (1) Requiring EGUs to participate in the EPA-administered cap-and-trade programs; or (2) adopting other control measures of the States' choosing and demonstrating that such control measures will result in compliance with the applicable State SO₂ and NO_x budgets. The May 12, 2005, and April 28, 2006, CAIR provides model rules that States must adopt (with certain limited changes, if desired) if they want to participate in the EPA-administered trading programs. With two exceptions, only States that choose to meet the requirements of CAIR through methods that exclusively regulate EGUs are allowed to participate in the EPA-administered trading programs. One exception is for States that adopt the opt-in provisions of the model rules to allow non-EGUs individually to opt into the EPA-administered trading programs. The other exception is for each State to include all non-EGUs from its respective NO_x Budget Trading Program into its respective CAIR NO_x Ozone Season Trading Program.

IV. What are the types of CAIR SIP submittals?

States have the flexibility to choose the type of control measures they will use to meet the requirements of CAIR. As EPA anticipated, most States have chosen to meet the CAIR requirements by selecting an option that requires EGUs to participate in the EPA-administered CAIR cap-and-trade programs. For such States, EPA has provided two approaches for submitting and obtaining approval for CAIR SIP revisions. States may submit full SIP revisions that adopt the model CAIR cap-and-trade rules. If approved, these

SIP revisions will fully replace the CAIR FIPs. Alternatively, States may submit abbreviated SIP revisions. These SIP revisions will not replace the CAIR FIPs; however, the CAIR FIPs provide that, when approved, the provisions in these abbreviated SIP revisions will be used instead of or in conjunction with, as appropriate, the corresponding provisions of the CAIR FIPs (e.g., the NO_x allowance allocation methodology).

A State submitting a full SIP revision may either adopt regulations that are substantively identical to the model rules or incorporate by reference the model rules. CAIR provides that States may only make limited changes to the model rules if the States want to participate in the EPA-administered trading programs. A full SIP revision may change the model rules only by altering their applicability and allowance allocation provisions to:

1. Include all NO_x Budget trading sources that are not EGUs under CAIR in the CAIR NO_x Ozone Season Trading Program;
2. Provide for State allocation of NO_x annual or ozone season allowances using a methodology chosen by the State;
3. Provide for State allocation of NO_x annual allowances from the compliance supplement pool (CSP) using the State's choice of allowed, alternative methodologies; or
4. Allow units that are not otherwise CAIR units to opt individually into the CAIR SO₂, NO_x Annual, or NO_x Ozone Season Trading Programs under the opt-in provisions in the model rules.

An approved CAIR SIP revision addressing EGUs' SO₂, NO_x annual, or NO_x ozone season emissions will replace the CAIR FIP for that State for the respective EGU emissions. As discussed above, once EPA has approved a CAIR SIP submission in full, without any conditions, the CAIR FIP is automatically withdrawn. See 72 FR 62338.

V. Analysis of Indiana's CAIR SIP submittals

A. What is the history of the State's submittals?

IDEM submitted the State's rules to address CAIR requirements on February 28, 2007, for incorporation into the SIP. On September 20, 2007, Indiana submitted a letter to EPA requesting that EPA act only on a portion of the February 28, 2007 submittal. Consequently, on October 22, 2007 (72 FR 59480) EPA gave a limited approval to portions of the February 28, 2007 submittal as an abbreviated SIP revision

which addressed the applicability provisions for the NO_x ozone season trading program and supporting definitions and terms, the methodology to be used to allocate annual and ozone season NO_x allowances and supporting definitions and terms, the CSP provisions for the NO_x annual trading program, and provisions for SO₂ and NO_x opt-in units, all under the CAIR FIP. EPA found several minor deficiencies in the February 28, 2007, submittal, as identified in a technical support document that accompanied the October 22, 2007, limited approval. The State's June 29, 2009, submittal sufficiently addresses these deficiencies.

On October 19, 2007, EPA revised the definition of "cogeneration unit" (72 FR 59190). Particularly of note, the term "biomass" was added so that cogeneration units could exclude biomass energy input in efficiency calculations. IDEM has made corresponding and appropriate changes that adopt the Federal definition of "cogeneration unit" and "biomass" in its June 29, 2009, submittal. Indiana's budget and allowance allocation methodologies for CAIR trading programs were also included in the June 29, 2009, submittal. The amended rules became effective State-wide on June 11, 2009, and an in-depth analysis of the June 29, 2009, submittal follows below.

B. State Budgets for Allowance Allocations

In today's action, EPA is reaffirming its approval of Indiana's SIP revision adopting the budgets established for the State (by EPA) in CAIR in its October 22, 2007 limited approval.

In *North Carolina*, the Court determined, among other things, that the State SO₂ and NO_x budgets established in CAIR were arbitrary and capricious.¹ However, as discussed above, the Court also decided to remand CAIR but to leave the rule in place in order to "temporarily preserve the environmental values covered by CAIR" pending EPA's development and promulgation of a replacement rule that "remedies CAIR's flaws." *North Carolina*, at 1178. EPA had indicated to the Court that development and promulgation of a replacement rule would take about two years. *Reply in*

Support of Petition for Rehearing or Rehearing en Banc at 5 (filed Nov. 17, 2008 in *North Carolina v. EPA*, Case No. 05-1224, DC Cir.). On August 2, 2010 (75 FR 45210), EPA proposed FIPs to Reduce Interstate Transport of Fine Particulate Matter and Ozone to replace CAIR; however, that rule is not yet final. In the meantime, consistent with the Court's orders, EPA is implementing CAIR by approving State SIP revisions that are consistent with CAIR (such as the provisions setting State SO₂ and NO_x budgets for the CAIR trading programs) in order to "temporarily preserve" the environmental benefits achievable under the CAIR trading programs.

C. CAIR Cap-and-Trade Programs

The CAIR NO_x annual and ozone season model trading rules both largely mirror the structure of the NO_x Budget model trading rule in 40 CFR Part 96, subparts A through I. While the provisions of the NO_x annual and ozone season model rules are similar, there are some differences. For example, the NO_x annual model rule (but not the NO_x ozone season model rule) provides for a CSP, which is discussed below and under which allowances may be awarded for early reductions of NO_x annual emissions. As a further example, the NO_x ozone season model rule reflects the fact that the CAIR NO_x Ozone Season Trading Program replaces the NO_x Budget Trading Program after the 2008 ozone season and is coordinated with the NO_x SIP Call program. The NO_x ozone season model rule provides incentives for early emissions reductions by allowing banked, pre-2009 NO_x Budget Trading Program allowances to be used for compliance in the CAIR NO_x ozone season trading program. In addition, States have the option of continuing to meet their NO_x SIP Call requirements by participating in the CAIR NO_x Ozone Season Trading Program and including all their NO_x Budget trading sources in that program.

The provisions of the CAIR SO₂ model rule are also similar to the provisions of the NO_x annual and ozone season model rules. However, since CAA title IV establishes an ongoing Acid Rain cap-and-trade program for SO₂ and not for NO_x, the model rule for SO₂ must additionally be coordinated with the Acid Rain Program. The SO₂ model rule uses the title IV allowances for compliance, with each allowance allocated for 2010-2014 authorizing only 0.50 ton of emissions and each allowance allocated for 2015 and thereafter authorizing only 0.35 ton of emissions. Banked title IV allowances

allocated for years before 2010 can be used at any time in the CAIR SO₂ cap-and-trade program, with each such allowance authorizing one ton of emissions. Title IV allowances are to be freely transferable among sources covered by the Acid Rain Program and sources covered by the CAIR SO₂ cap-and-trade program.

EPA used the CAIR model trading rules as the basis for the trading programs in the CAIR FIPs. The CAIR FIP trading rules are virtually identical to the CAIR model trading rules, with changes made to account for Federal rather than State implementation. The CAIR model SO₂, NO_x annual, and NO_x ozone season trading rules and the respective CAIR FIP trading rules are designed to work together as integrated SO₂, NO_x annual, and NO_x ozone season trading programs.

In the SIP revision EPA is approving, Indiana has chosen to implement its CAIR budgets by requiring EGUs to participate in EPA-administered cap-and-trade programs for SO₂, NO_x annual, and NO_x ozone season emissions. Indiana has adopted State rules for a full SIP revision that adopts, with certain allowed changes discussed below, the CAIR model cap-and-trade rules for SO₂, NO_x annual, and NO_x ozone season emissions. Finally, Indiana's rules provide that non-EGUs that were required to participate in the NO_x Budget Trading Program must participate in the CAIR NO_x Ozone Season Trading Program.

D. Applicability Provisions

In general, the CAIR model trading rules apply to any stationary, fossil-fuel-fired boiler or stationary, fossil-fuel-fired combustion turbine serving at any time, since the later of November 15, 1990, or the start-up of the unit's combustion chamber, a generator with nameplate capacity of more than 25 megawatts producing electricity for sale.

States have the option of bringing in, for the CAIR NO_x Ozone Season Trading Program only, those units in the State's NO_x Budget Trading Program that are not EGUs as defined under CAIR. EPA advises States exercising this option to add the applicability provisions in the State's NO_x Budget trading rule for non-EGUs to the applicability provisions in 40 CFR 96.304 in order to include in the CAIR NO_x Ozone Season Trading Program all units required to be in the State's NO_x Budget Trading Program that are not already included under 40 CFR 96.304. Under this option, the CAIR NO_x Ozone Season Trading Program must cover all large industrial boilers and combustion turbines, as well as any small EGUs (*i.e.*,

¹ The Court also determined that the CAIR trading programs were unlawful (*id.* at 906-8) and that the treatment of title IV allowances in CAIR was unlawful (*id.* at 921-23). For the same reason that EPA is approving the provisions of Indiana's SIP revision that use the SO₂ and NO_x budgets set in CAIR, EPA is also approving, as discussed below, Indiana's SIP revision to the extend the SIP revision adopts the CAIR trading programs, including the provisions addressing applicability, allowance allocations, and the use of title IV allowances.

units serving a generator with a nameplate capacity of 25 megawatts or less) that the State previously required to be in the NO_x Budget Trading Program. Indiana has chosen to expand the applicability provisions of the CAIR NO_x Ozone Season Trading Program to include all non-EGUs that were subject to the State's NO_x Budget Trading Program. Indiana's February 28, 2007, abbreviated SIP submittal did not include (or modify) certain definitions that are necessary in order to expand the CAIR NO_x Ozone applicability to all NO_x Budget Trading units. Indiana's June 29, 2009, submittal includes these definitions and modifications. These definitions are part of today's approval and are discussed in more detail under Section H. (Deficiencies in the State's submittal and the State's subsequent responses).

E. Individual Opt-in Units

The opt-in provisions of the CAIR SIP model trading rules allow certain non-EGUs (*i.e.*, boilers, combustion turbines, and other stationary fossil-fuel-fired devices) that do not meet the applicability criteria for a CAIR trading program to participate voluntarily in (*i.e.*, opt into) the CAIR trading program. A non-EGU may opt into one or more of the CAIR trading programs. In order to qualify to opt into a CAIR trading program, a unit must vent all emissions through a stack and be able to meet monitoring, recordkeeping, and recording requirements of 40 CFR part 75. The owners and operators seeking to include such a unit in a CAIR trading program must apply for a CAIR opt-in permit. If the unit is issued a CAIR opt-in permit, the unit becomes a CAIR unit, is allocated allowances, and must meet the same allowance-holding and emissions monitoring and reporting requirements as other units subject to the CAIR trading program. The opt-in provisions provide for two methodologies for allocating allowances for opt-in units, one methodology that applies to opt-in units in general and a second methodology that allocates allowances only to opt-in units that the owners and operators intend to repower before January 1, 2015.

States have several options concerning the opt-in provisions. States may adopt the CAIR opt-in provisions entirely or may adopt them but exclude one of the methodologies for allocating allowances. States may also decline to adopt the opt-in provisions at all.

Consistent with this flexibility, Indiana has chosen to allow non-EGUs meeting certain requirements to participate in the CAIR NO_x Annual Trading Program, the CAIR NO_x Ozone

Season Trading Program, and the CAIR SO₂ Trading Program. EPA approved Indiana's earlier version of rules authorizing these opt-ins (72 FR 59480). The complete set of rules governing CAIR NO_x annual, CAIR SO₂, and CAIR NO_x ozone season opt-in units in Indiana are contained in 326 IAC 24-1-12, 326 IAC 24-2-11, and 326 IAC 24-3-12, respectively. Indiana's June 29, 2009, submittal includes some modifications to these parts. These modifications are part of today's approval.

F. Deficiencies in the State's February 28, 2007, Submittal and the State's Subsequent Responses

EPA found several deficiencies in Indiana's February 28, 2007, submittal and communicated these deficiencies to IDEM staff in August and September of 2007. The deficiencies and the State's subsequent responses to correct them are discussed in detail below. All responses to the deficiencies were provided in the State's June 29, 2009, submittal.

EPA found that Indiana needed to revise 326 IAC 24-3-1 in the following manner:

"Indiana needs to revise, in subsection (b), 'CAIR NO_x ozone season units as follows:' to read 'CAIR NO_x ozone season units under subsection 1(a)(1) or (3)' and revise, in subsections (b)(1), (2), and (3), 'under subsection (a)' to read 'under subsection (a)(1) or (3).';"

Indiana has made these changes verbatim; therefore, these deficiencies have been addressed and EPA concludes that the revisions to 326 IAC 24-3-1 are approvable.

EPA also found that Indiana needed to amend 326 IAC 24-3-2 by revising the definitions of "commence operation," "fossil-fuel-fired," and "unit."

IDEM addressed all of the deficiencies that EPA identified regarding the terms "commence operation," "fossil-fuel-fired," and "unit" at 326 IAC 24-3-2 (33), (44), and (80). EPA finds these revisions approvable.

EPA found that Indiana needed to add the definition of "electricity for firm sale to the electric grid." to read as follows:

"Electricity for firm sale to the electric grid means electricity for sale where the capacity involved is intended to be available at all times during the period covered by a guaranteed commitment to deliver, even under adverse conditions."

The State has added the following definition at 326 IAC 24-3-2 (38):

"'Electricity for sale under a firm contract to the electric grid' means electricity for sale where the capacity involved is intended to be

available at all times during the period covered by the guaranteed commitment to deliver, even under adverse conditions."

EPA asked IDEM for clarification concerning the phrase "for sale under a firm contract" as opposed to the model language "for firm sale." On September 25, 2009, IDEM responded that the language originated in Indiana's NO_x SIP Call; therefore, all sources subject to the applicability of the NO_x Budget Trading Program would also be subject to the applicability of the CAIR NO_x Ozone Season Trading Program. Because there is no applicability gap for affected sources, IDEM has addressed this deficiency. EPA therefore finds that the addition of the term "electricity for sale under a firm contract to the electric grid" to 326 IAC 24-3-2 is approvable.

EPA found that Indiana needed to revise the definition of "large affected unit" to add, after clause (B):

"(C) For units other than cogeneration units commencing operation: (i) Before January 1, 1997, a unit serving a generator during 1995 or 1996 that had a nameplate capacity greater than twenty-five (25) megawatts and produced electricity for sale under a firm contract to the electric grid; (ii) on or after January 1, 1997, and before January 1, 1999, a unit serving a generator during 1997 or 1998 that had a nameplate capacity greater than twenty-five (25) megawatts and producing electricity for sale under a firm contract to the electric grid; or (iii) on or after January 1, 1999, a unit serving a generator at any time that has a nameplate capacity greater than twenty-five (25) megawatts and produces electricity for sale. (D) For cogeneration units commencing operation: (i) Before January 1, 1997, a unit serving a generator during 1995 or 1996 that had a nameplate capacity greater than twenty-five (25) megawatts and failing to qualify as an unaffected unit for 1995 or 1996 under the acid rain program; (ii) in 1997 or 1998, a unit serving a generator during 1997 or 1998 with a nameplate capacity greater than twenty-five (25) megawatts and failing to qualify as an unaffected unit for 1997 or 1998 under the acid rain program; or (iii) on or after January 1, 1999, a unit serving at any time as a generator with a nameplate capacity greater than twenty-five (25) megawatts and failing to qualify as an unaffected unit under the acid rain program for any year."

IDEM has made all the appropriate changes at 326 IAC 24-3-2 (51) with minor wording changes, which include the clarification of the phrase, "(C) For units other than cogeneration units that are not already subject to this rule under section 1(a)(1) or 1(a)(3) of this rule commencing operation * * *" and a phrase at the end of the rule that reads, "The term does not include a unit subject to 326 IAC 10-3." At 326 IAC 24-3-2 (51)(C)(iii), Indiana's rule ends with, "for sale under a firm contract to the electric grid," which differs from the

model rule which ends with, "for sale." EPA asked for clarification of the phrase, "for sale under a firm contract to the electric grid." On September 25, 2009, IDEM stated that, although the language differs slightly, all sources subject to the NO_x Budget Trading Program would also be subject to the CAIR NO_x Ozone season Trading Program. Because there is no applicability gap for affected sources, and because other revisions Indiana has made serve to clarify the existing rule, EPA finds that the revision of the term, "large affected unit" in 326 IAC 24-3-2 is approvable.

G. Federal Definition of "Biomass" in Reference to "Cogeneration Unit"

EPA changed the definition of "cogeneration unit" as it applies to CAIR, CAIR FIPs, and the CAIR model cap-and-trade rules in 72 FR 59190. Specifically, EPA revised the calculation methodology for the efficiency standard in the cogeneration unit definition to exclude energy input from biomass. At 326 IAC 24-1-2 (8), 326 IAC 24-2-2 (8), and 326 IAC 24-3-2 (8), Indiana has made this change verbatim. EPA finds the addition of the term "biomass" to the SIP approvable.

H. The State's Complete CAIR Regulations

As discussed previously, EPA granted a limited approval to Indiana's abbreviated SIP on October 22, 2007. This action was a result of the State's request on September 20, 2007, that EPA act on a portion of its February 28, 2007, submittal. Consequently, EPA approved an abbreviated SIP revision for Indiana which addressed the applicability provisions for the NO_x ozone season trading programs and supporting definitions of terms, the methodology to be used to allocate NO_x annual and ozone season NO_x allowances and supporting definitions of terms, the CSP provisions for the NO_x annual trading program, and provisions for SO₂ and NO_x opt-in units, all under the CAIR FIP.

The State's June 29, 2009, submittal was intended to satisfy requirements that would allow us to approve Indiana's CAIR regulations so as to transition from an abbreviated SIP with limited approval to a full SIP with full approval. Indiana addressed the deficiencies that EPA found with its existing CAIR regulations and also adopted the Federal definition of "biomass" as it pertains to "cogeneration unit."

However, it was not clear in the June 29, 2009, submittal that IDEM was requesting full approval of the CAIR

rules contained in 326 IAC 24-1, 326 IAC 24-2, and 326 IAC 24-3. On December 9, 2009, IDEM sent a letter to EPA clarifying that such was its intent. Therefore, inasmuch as the State has cured the identified deficiencies and as such is the State's intent, we are approving Indiana's CAIR regulations in their entirety for incorporation into the SIP.

I. NO_x Reduction Program for Specific Source Categories—Applicability

On February 28, 2007, Indiana also submitted minor revisions to 326 IAC 10-3, "NO_x Reduction Program for Specific Source Categories." Namely, the revisions pertain to the "Applicability" portion of this rule. The revisions refer to 326 IAC 24 and 326 IAC 24-3. The reference to 326 IAC 24-3 clarifies that 326 IAC 10-3-1 applies to any other blast furnace gas fired boilers with a heat input greater than 250,000,000 Btu per hour that is not subject to 326 IAC 10-4 or 326 IAC 24-3. As this revision ensures that all applicable sources are covered, EPA finds it approvable. The reference to 326 IAC 24 clarifies that the monitoring, recordkeeping, and reporting requirements under section 4 and 5 of 326 IAC 10-3-1 does not apply to a unit that opts into the NO_x Budget Trading Program under 326 IAC 10-4 or 326 IAC 24. As the State's CAIR has its own set of monitoring, recordkeeping, and reporting requirements, EPA finds this revision to be approvable.

J. Sunset Provision

EPA did not act on 326 IAC 10-4-16, "Sunset," when Indiana submitted the rule as part of its original CAIR package on February 28, 2007. We are approving this rule into the Indiana SIP today, and it reads:

"Sec. 16. (a) Sections 1 through 15 of this rule shall not apply to any control period in 2009 or thereafter. The 2009 NO_x allowances allocated under section 9 of this rule remain in effect for purposes of the Clean Air Interstate Rule (CAIR) NO_x ozone season trading program in 326 IAC 24-3.

(b) By December 31, 2008, the department shall allocate any remaining allowances for the years 2004 through 2008 in the EGU or large affected unit new unit set-aside or the energy efficiency and renewable energy set-aside to the relevant existing NO_x budget units on a pro rata basis. The allowances from the energy efficiency and renewable energy set-aside shall be allocated to existing large affected units."

Approval of the termination of the NO_x Budget Trading Program provision ensures that there are no conflicts between allocations made under the NO_x Budget Trading Program and allocations made under the CAIR NO_x Ozone Season Trading Program. The

NO_x SIP Call requirements will now be met through the implementation of CAIR.

VI. Final Action

EPA is approving revisions to Indiana's CAIR, which the State submitted on June 29, 2009. The rules supplement the State's original CAIR, for which EPA promulgated limited approval on October 22, 2007 (72 FR 59480). The State has corrected deficiencies in its original CAIR submittal, and has made appropriate revisions that align State and Federal definitions for "cogeneration unit" and "biomass," as contained in 72 FR 59190. In addition, EPA is approving into the Indiana SIP the remainder of Indiana's CAIR regulations upon which we did not previously act. EPA is also approving the applicability provisions of Indiana's NO_x Reduction Program for Specific Source Categories, as well as the sunset provision from Indiana's NO_x Budget Trading Program. Lastly, EPA is approving minor wording, formatting, and typographical changes contained in the State's submittal; since these changes serve to clarify the existing rules or to correct minor errors, EPA finds them approvable. With this approval, Indiana has transitioned from an abbreviated CAIR SIP with limited approval to a full SIP with full approval. After the effective date of this direct final rule, Indiana will no longer be subject to elements of CAIR FIPs. This action causes the CAIR FIPs with regard to sulfur dioxide (SO₂), NO_x annual, and NO_x ozone season emissions by Indiana sources to be automatically withdrawn.

Specifically, EPA is approving the following rules, which were submitted on June 29, 2009: 326 IAC 24-1-2, 326 IAC 24-1-7, 326 IAC 24-1-8, 326 IAC 24-1-9, 326 IAC 24-1-12, 326 IAC 24-2-2, 326 IAC 24-2-7, IAC 24-2-8, IAC 24-2-11, IAC 24-3-1, IAC 24-3-2, IAC 24-3-7, IAC 24-3-8, IAC 24-3-9, IAC 24-3-12. The rules became effective State-wide on June 11, 2009.

EPA is also approving the remainder of the State's CAIR regulations, which were submitted on February 28, 2007. These rules include: 326 IAC 24-1-1, 326 IAC 24-1-3, 326 IAC 24-1-4, 326 IAC 24-1-5, 326 IAC 24-1-6, 326 IAC 24-1-10, 326 IAC 24-1-11, 326 IAC 24-2-1, 326 IAC 24-2-3, 326 IAC 24-2-4, 326 IAC 24-2-5, 326 IAC 24-2-6, 326 IAC 24-2-9, 326 IAC 24-2-10, 326 IAC 24-3-3, 326 IAC 24-3-4, 326 IAC 24-3-5, 326 IAC 24-3-6, 326 IAC 24-3-10, and 326 IAC 24-3-11. These rules became effective State-wide on February 25, 2007.

As previously mentioned, EPA is further approving revisions submitted on February 28, 2007, pertaining to the State's Nitrogen Oxide Reduction Program for Specific Source Categories, Applicability provisions as contained in 326 IAC 10-3-1. This revision was effective State-wide on February 25, 2007. Lastly, EPA is approving the sunset provision in their NO_x Budget Trading Program; this specific provision is contained in 326 IAC 10-4-16. This rule was submitted on February 28, 2007, and became effective State-wide on February 25, 2007.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the Proposed Rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the State plan if relevant adverse written comments are filed. This rule will be effective January 28, 2011 without further notice unless we receive relevant adverse written comments by December 29, 2010. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. The EPA will not institute a second comment period; therefore, any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective January 28, 2011.

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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. 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 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 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 28, 2011. 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. 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, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: November 15, 2010.

Susan Hedman,

Regional Administrator, Region 5.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart P—Indiana

§ 52.35 [Amended]

- 2. Section 52.35 is amended by:
 - a. In paragraph (d)(1), by adding, after the word "are:", the words "Indiana, and"; and
 - b. In paragraph (d)(2), by adding, after the words "chapter, are:", the words "Indiana, and".

§ 52.36 [Amended]

- 3. Section 52.36 is amended in paragraph (c) by adding, after the word "are:", the words "Indiana, and".
- 4. In § 52.770, the table in paragraph (c) is amended by:

- a. Revising the entries for Article 10, sections 10-3 and 10-4.
- b. Revising the entries for Article 24, sections 24-1, 24-2 and 24-3.
- The revisions read as follows:

§ 52.770 Identification of plan.

* * * * *
(c) * * *

EPA-APPROVED INDIANA REGULATIONS

Indiana citation	Title	Indiana effective date	EPA approval date	Notes
Article 10. Nitrogen Oxides Rules				
10-3	Nitrogen Oxide Reduction Program for Specific Source Categories.	02/25/2007	11/29/2010, [Insert page number where the document begins].	Sec. 1.
10-4	Nitrogen Oxides Budget Trading Program ..	02/25/2007	11/29/2010, [Insert page number where the document begins].	Sec. 16.
Article 24. Trading Programs: Nitrogen Oxides (NO_x) and Sulfur Dioxide (SO₂)				
24-1	Clean Air Interstate Rule Nitrogen Oxides Annual Trading Program.	02/25/2007	11/29/2010, [Insert page number where the document begins].	Sec. 1, 3, 4, 5, 6, 10, 11.
		06/11/2009	11/29/2010, [Insert page number where the document begins].	Sec. 2, 7, 8, 9, 12.
24-2	Clean Air Interstate Rule (CAIR) Sulfur Dioxide Trading Program.	02/25/2007	11/29/2010, [Insert page number where the document begins].	Sec. 1, 3, 4, 5, 6, 9, 10.
		06/11/2009	11/29/2010, [Insert page number where the document begins].	Sec. 2, 7, 8, 11.
24-3	Clean Air Interstate Rule (CAIR) NO _x Ozone Season Trading Program.	02/25/2007	11/29/2010, [Insert page number where the document begins].	Sec. 3, 4, 5, 6, 10, 11.
		06/11/2009	11/29/2010, [Insert page number where the document begins].	Sec. 1, 2, 7, 8, 9, 12.

§ 52.789 [Removed]

- 5. Section 52.789 is removed.

§ 52.790 [Removed]

- 6. Section 52.790 is removed.

[FR Doc. 2010-29788 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R03-OAR-2010-0594; FRL-9231-9]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of Volatile Organic Compound Emissions From Industrial Solvent Cleaning Operations; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, EPA is withdrawing the direct final rule to approve revisions to Maryland's State

Implementation Plan (SIP). This SIP revision consists of an addition to Maryland's Volatile Organic Compounds from Specific Processes Regulation. Maryland Department of the Environment (MDE) adopted standards for industrial solvent cleaning operations that satisfy the reasonably available control technology (RACT) requirements for sources of volatile organic compounds (VOCs) covered by control techniques guidelines (CTG). In the direct final rule published on September 29, 2010 (75 FR 59973), we stated that if we received any adverse comments by October 29, 2010, the rule would be withdrawn and would not take effect. EPA received an adverse comment within the comment period. EPA will address the comment received in a subsequent final action based upon the proposed action also published on September 29, 2010 (75 FR 60013). EPA will not institute a second comment period on this action.

DATES: The direct final rule published at 75 FR 59973, September 29, 2010, is withdrawn as of November 29, 2010.

ADDRESSES: EPA has established docket number EPA-R03-OAR-2010-0594 for

this action. The index to the docket is available electronically at <http://www.regulations.gov> and in hard copy at Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

FOR FURTHER INFORMATION CONTACT: Jacqueline Lewis, (215) 814-2037, or by e-mail at lewis.jacqueline@epa.gov.

List of Subjects in 40 CFR Part 52

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

Dated: November 16, 2010.

W.C. Early,

Acting, Regional Administrator, Region III.

■ Accordingly, the amendment to the table in 40 CFR 52.1070(c), published on September 29, 2010 (75 FR 59973) on page 59975 is withdrawn as of November 29, 2010.

[FR Doc. 2010-29815 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[R09-OAR-2010-0718; FRL-9233-1]

Determinations of Attainment by the Applicable Attainment Date for the Hayden, Nogales, Paul Spur/Douglas PM₁₀ Nonattainment Areas, Arizona; Withdrawal of Direct Final Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Withdrawal of direct final rule.

SUMMARY: Due to the receipt of an adverse comment, EPA is withdrawing the November 2, 2010 (75 FR 67220), direct final rule determining that the Hayden, Nogales, and Paul Spur/Douglas areas in Arizona had attained the national ambient air quality standard (NAAQS) for particulate matter with an aerodynamic diameter of less than or equal to ten microns for the applicable attainment date. On the basis of this determination, EPA concluded that these three "moderate" nonattainment areas were not subject to reclassification. In the direct final rule, EPA stated that if adverse comments were submitted by December 2, 2010, the rule would be withdrawn and not take effect. On November 3, 2010, EPA received a comment. EPA believes this comment is adverse and, therefore, EPA is withdrawing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed action also published on November 2, 2010 (75 FR 67303). EPA will not institute a second comment period on this action.

DATES: The direct final rule published at 75 FR 67220 on November 2, 2010, is withdrawn as of November 29, 2010.

FOR FURTHER INFORMATION CONTACT: Wienke Tax, Air Planning Office, Air Division (AIR-2), Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 947-4192, tax.wienke@epa.gov.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, National Parks, Particulate matter, Wilderness Areas.

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

Dated: November 19, 2010.

Keith Takata,
Acting Regional Administrator, Region IX.
[FR Doc. 2010-29937 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R05-OAR-2007-0642; FRL-9231-8]

Disapproval and Promulgation of Air Quality Implementation Plans; Indiana; Addition of Incentive for Regulatory Flexibility for Its Environmental Stewardship Program**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: On July 6, 2007, the Indiana Department of Environmental Management (IDEM) submitted a request to EPA to amend its State Implementation Plan (SIP) to add incentives for regulatory flexibility for participants in its Environmental Stewardship Program (ESP) and Comprehensive Local Environmental Action Network (CLEAN) Community Challenge Program. Indiana requested that EPA approve the following for ESP and CLEAN members: The incorporation by reference of certain incentives under the National Environmental Performance Track (NEPT) Program, monthly averaging of volatile organic compound (VOC) coating limits, and the processing of pollution prevention projects as minor permit revisions. EPA proposed to disapprove these three incentives on August 19, 2010, and received no comments.

DATES: This final rule is effective on December 29, 2010.

ADDRESSES: EPA has established a docket for this action under Docket ID Nos. EPA-R05-OAR-2007-0642. All documents in the docket are listed on the <http://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 <http://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 Steven Rosenthal,

Environmental Engineer, at (312) 886-6052 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Steven Rosenthal, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6052.

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 public comments were received on the proposed approval and what is EPA's response?
- II. What action is EPA taking today and what is the reason for this action?
- III. Statutory and Executive Order Reviews

I. What public comments were received on the proposed approval and what is EPA's response?

EPA's August 19, 2010, proposed action at 75 FR 51188 provided a 30-day public comment period. We did not receive any comments on the proposed action.

II. What action is EPA taking today and what is the reason for this action?

EPA is disapproving IDEM's request for an amendment to the Indiana SIP for incentives for regulatory flexibility for its ESP and CLEAN Community Challenge Program. EPA is disapproving the incorporation by reference of Federal incentives for NEPT members because EPA has discontinued its NEPT program. EPA is disapproving monthly averaging of VOC coating limits because this would constitute a relaxation that could exacerbate high ozone levels and contribute to violations of the ozone standard. EPA is disapproving the third incentive, which affects public notice requirements for pollution prevention projects, because it relaxes the existing SIP-approved public notice requirements and is inconsistent with EPA minor new source rule requirements.

III. Statutory and Executive Order Reviews*Executive Order 12866: Regulatory Planning and Review*

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and, therefore, is not subject to review by the Office of Management and Budget.

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).

Regulatory Flexibility Act

This action merely approves State law as meeting Federal requirements and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies 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 approves pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it 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).

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 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 approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act (CAA).

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

This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it approves a State rule implementing a Federal Standard.

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.

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.*).

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. 804(2).

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 January 28, 2011. 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, Ozone, Reporting and recordkeeping requirements.

Dated: November 15, 2010.

Susan Hedman,

Regional Administrator, Region 5.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart P—Indiana

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

§ 52.781 Rules and regulations.

* * * * *

(g) *Disapproval*. EPA is disapproving 326 IAC 25-2-1, 326 IAC 25-2-3 and 326 IAC 25-2-4 as revisions to the Indiana SIP.

[FR Doc. 2010-29817 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

GENERAL SERVICES ADMINISTRATION

41 CFR Parts 300-3, 301-10, 301-12, 301-30, 301-70, Chapter 301, Parts 302-1, 302-2, 302-3, 302-7, 302-11, and 303-70

[FTR Amendment 2010-07; FTR Case 2010-307; Docket 2010-0020, Sequence 1]

RIN 3090-AJ09

Federal Travel Regulation; Removal of Privately Owned Vehicle Rates; Privately Owned Automobile Mileage Reimbursement When Government Owned Automobiles Are Authorized; Miscellaneous Amendments

AGENCY: Office of Governmentwide Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: GSA is amending the Federal Travel Regulation (FTR) by removing the Privately Owned Vehicle (POV) rates from Section 301-10.303. These rates will be published on a periodic basis as FTR Bulletins by the Office of

Governmentwide Policy, Office of Travel, Transportation and Asset Management, and will be posted on the Internet at <http://www.gsa.gov/ftr>. This amendment also revises the reimbursement amount for travelers who are authorized to use a Government Owned Automobile (GOA) for temporary duty travel (TDY) and choose to use their privately owned automobile (POA) instead; updates the definition of "official station"; clarifies various provisions of Chapters 301, 302, and 303 regarding TDY and relocation travel; and makes certain grammatical corrections, where applicable.

DATES: Effective Date: This final rule is effective November 29, 2010.

Applicability Date: This final rule is applicable for official travel performed on or after December 29, 2010.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat (MVCB), 1275 First Street, NE., Washington, DC, 20417, (202) 501-4755, for information pertaining to status or publication schedules. For clarification of content, contact Mr. Cy Greenidge, Program Analyst, Office of Governmentwide Policy, at (202) 219-2349. Please cite FTR Amendment 2010-07; FTR case 2010-307.

SUPPLEMENTARY INFORMATION:

A. Background

Pursuant to 5 U.S.C. 5704(c), the Administrator of General Services has the responsibility to establish a mileage reimbursement rate based on the cost of travel by a Government vehicle when an employee on official business for the Government chooses to use a privately owned vehicle when a Government vehicle is authorized. This amendment, therefore, revises the reimbursement amount when travelers who are authorized to use a GOA choose to use their POA instead. This amendment also serves as notification to the public that all POV rates will be removed from the FTR and periodically published in FTR Bulletins; updates the definition of "official station"; clarifies what baggage expenses an agency may pay; clarifies that the employee is responsible for all additional expenses "that exceed the cost of the authorized method of transportation" when the employee chooses to travel via a different method of transportation than that which is authorized; requires agencies to establish policies regarding Seating Upgrade Programs in coach-class; and corrects grammatical errors.

Accordingly, this final rule amends the FTR by:

1. *Section 300-3.1*—Revising the term "official station".

2. *Section 301-10.6*—Clarifying that the employee will be responsible for all additional expenses that exceed the cost of the authorized method of transportation when the employee chooses to travel by a method of transportation other than that authorized by the agency.

3. *Section 301-10.124*—Correcting a grammatical error by removing the comma after "seat choice fee" in the last sentence and adding a regulatory citation.

4. *Section 301-10.301*—Clarifying how to compute mileage reimbursement.

5. *Section 301-10.303*—Revising the information pertaining to mileage reimbursement when the use of POV is determined to be advantageous to the Government.

6. *Section 301-10.304*—Revising the information in the heading pertaining to allowable expenses.

7. *Section 301-10.309*—Removing the reference to another chapter in this section.

8. *Section 301-10.310*—Revising the information pertaining to reimbursement for the use of a POA when a GOA is authorized and by removing all language pertaining to being committed to using a GOA.

9. *Section 301-12.1*—Revising reference to "official duty station" to read "official station."

10. *Section 301-12.2*—Revising subparagraph (d) in regard to checked baggage fee reimbursement.

11. *Section 301-30.5*—Revising reference to "official duty station" to read "official station."

12. *Section 301-70.102*—Adding paragraph (k) requiring agencies to establish policies regarding Seating Upgrade Programs in coach-class.

13. *Section 301-70.200*—Removing paragraph (g) requiring agencies to develop policy in regard to defining a broader radius than the official station in which per diem or actual expenses will not be authorized.

14. *Section 301-70.502*—Revising reference to "official duty station" to read "official station."

15. *Appendix C to Chapter 301*—Revising reference to "official duty station" to read "official station," and updating the definition of official station.

16. *Appendix E to Chapter 301, Sections 302-1.1, 302-2.2, 302-2.6, 302-3.312, 302-7.1, 302-11.1, and 303-70.300*—Revising references to "official duty station" to read "official station."

B. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to

review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This final rule is not a major rule under 5 U.S.C. 804.

C. Regulatory Flexibility Act

This final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* This final rule is also exempt from the Regulatory Flexibility Act per 5 U.S.C. 553 (a)(2) because it applies to agency management. However, this final rule is being published to provide transparency in the promulgation of Federal policies.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FTR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Parts 300-3, 301-10, 301-12, 301-30, 301-70, Chapter 301, Parts 302-1, 302-2, 302-3, 302-7, 302-11, and 303-70

Government employees, Travel and transportation expenses, Administrative practices and procedures.

Dated: October 21, 2010.

Martha Johnson,

Administrator of General Services.

■ For the reasons set forth in the preamble, under 5 U.S.C. chapter 57, subchapters I, II, and III, GSA amends 41 CFR parts 300-3, 301-10, 301-12, 301-30, 301-70, Appendices C and E to Chapter 301, 302-1, 302-2, 302-3, 302-7, 302-11, and 303-70 as set forth below:

PART 300-3—GLOSSARY OF TERMS

■ 1. The authority citation for 41 CFR part 300-3 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); 49 U.S.C. 40118; 5 U.S.C. 5738; 5 U.S.C. 5741-5742; 20 U.S.C. 905(a); 31 U.S.C. 1353; E.O. 11609, as amended; 3 CFR, 1971-1975 Comp., p. 586, OMB Circular No. A-126, revised May 22, 1992.

■ 2. Amend § 300-3.1 by revising the definition of "official station" to read as follows:

§ 300-3.1 What do the following terms mean?

* * * * *

Official station—An area defined by the agency that includes the location where the employee regularly performs his or her duties or an invitational traveler's home or regular place of business (see § 301-1.2). The area may be a mileage radius around a particular point, a geographic boundary, or any other definite domain, provided no part of the area is more than 50 miles from where the employee regularly performs his or her duties or from an invitational traveler's home or regular place of business. If the employee's work involves recurring travel or varies on a recurring basis, the location where the work activities of the employee's position of record are based is considered the regular place of work.

* * * * *

PART 301-10—TRANSPORTATION EXPENSES

■ 3. The authority citation for 41 CFR part 301-10 continues to read as follows:

Authority: 5 U.S.C. 5707, 40 U.S.C. 121(c); 49 U.S.C. 40118, OMB Circular No. A-126, revised May 22, 1992.

§ 301-10.6 [Amended]

■ 4. Amend § 301-10.6 by removing the word "selected" and adding the word "authorized" in its place whenever it appears in the section heading and the text, and by adding the words "which exceed the cost of the authorized method of transportation" after the word "incur".

§ 301-10.124 [Amended]

■ 5. Amend § 301-10.124 in the last sentence, by removing the comma after "seat choice fee"; and adding "(see 301-70.102(k))" after the word "policy".

§ 301-10.301 [Amended]

■ 6. Amend § 301-10.301 by removing the words "prescribed in § 301-10.303 of this subpart".

■ 7. Revise § 301-10.303 to read as follows:

§ 301-10.303 What am I reimbursed when use of POV is determined by my agency to be advantageous to the Government?

You will be reimbursed an applicable mileage rate based on the type of POV you actually use (privately owned airplane, privately owned automobile, privately owned motorcycle). These rates will be published in an FTR bulletin and are also displayed on

GSA's Web site (<http://www.gsa.gov/mileage>).

■ 8. Amend § 301-10.304 by revising the section heading to read as follows:

§ 301-10.304 What expenses are allowable in addition to the POV mileage rate allowances?

* * * * *

§ 301-10.309 [Amended]

■ 9. Amend § 301-10.309 in the first sentence by removing "(see § 301-10.303)".

■ 10. Revise § 301-10.310 to read as follows:

§ 301-10.310 What will I be reimbursed if I am authorized to use a Government owned automobile and I use a privately owned automobile instead?

You will be reimbursed based on a constructive mileage rate limited to the cost that would be incurred for use of a Government automobile. This rate will be published in an FTR bulletin available at <http://www.gsa.gov/fttr>. If your agency determines the cost of providing a GOA would be higher because of unusual circumstances, it may allow reimbursement not to exceed the mileage rate for a POA. In addition, you may be reimbursed other allowable expenses as provided in § 301-10.304.

PART 301-12—MISCELLANEOUS EXPENSES

■ 11. The authority citation for 41 CFR part 301-12 continues to read as follows:

Authority: 5 U.S.C. 5707.

§ 301-12.1 [Amended]

■ 12. Amend § 301-12.1, in the third column of the table, in the second entry under the heading "Special expenses of foreign travel" by removing the words "official duty station" and adding the words "official station" in its place.

■ 13. Revise § 301-12.2(d) to read as follows:

§ 301-12.2 What baggage expenses may my agency pay?

* * * * *

(d) All fees pertaining to the first checked bag. In addition, charges relating to the second and subsequent bags may be reimbursed when the agency determines those expenses necessary and in the interest of the Government (see §§ 301-70.300, 301-70.301). Travelers should verify their agency's current policies and procedures regarding excess baggage prior to traveling; and

* * * * *

PART 301-30—EMERGENCY TRAVEL

■ 14. The authority citation for 41 CFR part 301-30 continues to read as follows:

Authority: 5 U.S.C. 5707.

§ 301-30.5 [Amended]

■ 15. Amend § 301-30.5(a)(1) by removing the word "duty".

PART 301-70—INTERNAL POLICY AND PROCEDURE REQUIREMENTS

■ 16. The authority citation for 41 CFR part 301-70 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); Sec 2, Pub. L. 105-264, 112 Stat. 2350 (5 U.S.C. 5701, note), OMB Circular No. A-126, revised May 22, 1992, and OMB Circular No. A-123, Appendix B, revised January 15, 2009.

■ 17. Amend § 301-70.102 by removing the word "and" at the end of paragraph (i); removing the period at the end of paragraph (j) and adding "; and" in its place; and adding paragraph (k) to read as follows:

§ 301-70.102 What governing policies must we establish for authorization and payment of transportation expenses?

* * * * *

(k) Develop and publish internal guidance regarding Seating Upgrade Programs in coach-class (see § 301-10.124).

§ 301-70.200 [Amended]

■ 18. Amend § 301-70.200—

■ a. In paragraph (f) by adding the word "and" after "case";

■ b. By removing paragraph (g); and

■ c. By redesignating paragraph (h) as paragraph (g).

§ 301-70.502 [Amended]

■ 19. Amend § 301-70.502(a) by replacing the words "official duty station" with the words "official station" wherever it appears.

Appendix C to Chapter 301 [Amended]

■ 20. Amend Appendix C to Chapter 301, in the first table, under the heading "Traveler Identification"—

■ a. By removing the entry "Official Duty Station" and adding the entry "Official Station" in its place in the first column under the heading "Group name", and in the third column under the heading "Description" wherever it appears.

■ b. In the third column of the table under the heading "Description", by removing the entry "Either the corporate

limits of city/town or the reservation, station, established area where stationed" and adding "The location where the employee regularly performs his or her duties or an invitational traveler's home or regular place of business. If the employee's work involves recurring travel or varies on a recurring basis, the location where the work activities of the employee's position of record are based is considered the employee's official station" in its place.

Appendix E to Chapter 301 [Amended]

- 21. Amend Appendix E to Chapter 301, under the heading "Food and Drink", in the first bulleted entry, by removing the words "official duty stations" and adding the words "official stations" in its place.

PART 302-1—GENERAL RULES

- 22. The authority citation for 41 CFR part 302-1 continues to read as follows:
Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a).

§ 302-1.1 [Amended]

- 23. Amend § 302-1.1(a) by removing the words "official duty station" and adding the words "official station" in its place.

PART 302-2—EMPLOYEES ELIGIBILITY REQUIREMENTS

- 24. The authority citation for 41 CFR part 302-2 continues to read as follows:
Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a).

§ 302-2.2 [Amended]

- 25. Amend § 302-2.2 by removing the words "official duty station" and adding the words "official station" in its place wherever it appears in the section heading and the text.

§ 302-2.6 [Amended]

- 26. Amend § 302-2.6 by removing from the section heading the words "official duty station" and adding the words "official station" in its place.

PART 302-3—RELOCATION ALLOWANCE BY SPECIFIC TYPE

- 27. The authority citation for 41 CFR part 302-3 continues to read as follows:
Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a).

§ 302-3.312 [Amended]

- 28. Amend § 302-3.312 by removing from the section heading the words "official duty station" and adding the words "official station" in its place.

PART 302-7—TRANSPORTATION AND TEMPORARY STORAGE OF HOUSEHOLD GOODS AND PROFESSIONAL BOOKS, PAPERS, AND EQUIPMENT (PBP&E)

- 29. The authority citation for 41 CFR part 302-7 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, 36 FR 13747, 3 CFR, 1971-1973 Comp. p. 586.

§ 302-7.1 [Amended]

- 30. Amend § 302-7.1—
 - a. In paragraph (a) by removing the words "official duty stations" and adding the words "official stations" in its place.
 - b. In paragraph (b) by removing the words "official duty station" and adding the words "official station" in its place.

PART 302-11—ALLOWANCES FOR EXPENSES INCURRED IN CONNECTION WITH RESIDENCE TRANSACTIONS

- 31. The authority citation for 41 CFR part 302-11 continues to read as follows:

Authority: 5 U.S.C. 5738 and 20 U.S.C. 905(c).

§ 302-11.1 [Amended]

- 32. Amend § 302-11.1(a) by removing the words "official duty station" and adding the words "official station" in its place wherever it appears.

PART 303-70—AGENCY REQUIREMENTS FOR PAYMENT OF EXPENSES CONNECTED WITH THE DEATH OF CERTAIN EMPLOYEES

- 33. The authority citation for 41 CFR part 303-70 continues to read as follows:

Authority: 5 U.S.C. 5721-5738; 5741-5742; E.O. 11609, 3 CFR, 1971-1975 Comp., p. 586.

§ 303-70.300 [Amended]

- 34. Amend § 303-70.300 by removing the words "official duty station" and adding the words "official station" in its place.

[FR Doc. 2010-29730 Filed 11-26-10; 8:45 am]

BILLING CODE 6820-14-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 10-148; FCC 10-193]

Implementation of Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA); Amendments to Section 340 of the Communications Act

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission modifies its satellite television "significantly viewed" rules to implement Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA). Section 203 of the STELA amends Section 340 of the Communications Act, which gives satellite carriers the authority to offer out-of-market but "significantly viewed" broadcast television network stations as part of their local service to subscribers. The STELA requires the Commission to promulgate final rules in this proceeding on or before November 24, 2010.

DATES: Effective December 29, 2010.

FOR FURTHER INFORMATION CONTACT: Evan Baranoff, *Evan.Baranoff@fcc.gov*, of the Media Bureau, Policy Division, (202) 418-2120.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order and Order on Reconsideration* (Order), FCC 10-193, adopted on Nov. 22, 2010, and released on Nov. 23, 2010. The full text of this document is available electronically via ECFS at <http://fjallfoss.fcc.gov/ecfs/> or may be downloaded at <http://hraunfoss.fcc.gov/edocs-public/attachmatch/FCC-10-130.pdf>. (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document is also available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY-A257, Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY-B402, Washington, DC 20554. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an e-mail to fcc504@fcc.gov or calling the Commission's Consumer and Governmental Affairs Bureau at (202)

418-0530 (voice), (202) 418-0432 (TTY).

Summary of the Report and Order and Order on Reconsideration

I. Introduction

1. With this *Report and Order* ("R&O"), we modify our satellite television "significantly viewed" rules to implement Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA).¹ Section 203 of the STELA amends Section 340 of the Communications Act of 1934 ("Communications Act" or "Act"), which gives satellite carriers the authority to offer out-of-market but "significantly viewed" broadcast television stations as part of their local service to subscribers.² We initiated this proceeding on July 23, 2010 by issuing a Notice of Proposed Rulemaking ("NPRM").³ We received 20 comments and reply comments (from 17 parties) in response to our NPRM.⁴ With this R&O, we satisfy the STELA's mandate that the Commission promulgate final rules in this proceeding on or before November 24, 2010.⁵ In addition, in this *Order on Reconsideration*, we dispose of the pending petition for reconsideration of

¹ The Satellite Television Extension and Localism Act of 2010 (STELA) sec. 203, Public Law 111-175, 124 Stat. 1218, 1245 (2010) (sec. 203 codified as amended at 47 U.S.C. 340, other STELA amendments codified in scattered sections of 17 and 47 U.S.C.). The STELA was enacted on May 27, 2010 (S. 3333, 111th Cong.). This proceeding to implement STELA sec. 203 (titled "Significantly Viewed Stations"), 124 Stat. at 1245, and the related statutory copyright license provisions in STELA sec. 103 (titled "Modifications to Statutory License for Satellite Carriers in Local Markets"), 124 Stat. at 1227-28, is one of a number of Commission proceedings that are required to implement the STELA.

² 47 U.S.C. 340. We note that the nature of SV carriage under Section 340 is permissive (and not mandatory), meaning a satellite carrier may choose to carry an SV station. The statute also requires that the SV station grant consent in order for its signal to be carried. *Id.* 340(d).

³ STELA—Significantly Viewed NPRM, FCC 10-130, 75 FR 44198, July 28, 2010 (NPRM).

⁴ We identify the list of commenters and reply commenters to this docket in Appendix. We also received *ex parte* submissions in this docket. All of the filings made in this docket are available to the public both online via the Commission's Electronic Comment Filing System ("ECFS") at <http://www.fcc.gov/ecfb/ecsfs/> and during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY-A257, Washington, DC 20554.

⁵ The STELA requires the Commission to implement the amendments within 270 days after the date of the enactment. STELA sec. 203(b). The STELA establishes February 27, 2010 as its effective date or "date of enactment," even though the law was enacted by Presidential signature on May 27, 2010. STELA sec. 307. Congress passed four short-term extensions of the distant signal statutory copyright license (December 19, 2009, March 2, March 25 and April 15, 2010) before passing STELA to reauthorize the compulsory license for distant signal carriage for five years. STELA sec. 107(a).

the 2005 *SHVERA Significantly Viewed Report and Order*.⁶

2. Significantly viewed ("SV") stations are television broadcast stations that the Commission has determined have sufficient over-the-air (*i.e.*, non-cable or non-satellite) viewing⁷ to be considered local for certain purposes and so are not constrained by the boundary of the stations' local market or Designated Market Area ("DMA").⁸ The individual TV station, or cable operator or satellite carrier that seeks to carry the station, may petition the Commission to obtain "significantly viewed" status for the station,⁹ and placement on the SV List.¹⁰ The designation of "significantly viewed" status allows a station assigned

⁶ *SHVERA Significantly Viewed Report and Order*, FCC 05-187, 70 FR 76504, December 27, 2005. See DIRECTV and EchoStar Satellite L.L.C. (now Dish) Joint Petition for Reconsideration in MB Docket No. 05-49 (filed Jan. 26, 2006) ("2006 DIRECTV-EchoStar Joint Petition").

⁷ To qualify for significantly viewed status (*i.e.*, for placement on the significantly viewed list or "SV List," see note 10, *infra*), an SV station can be either a "network" station or an "independent" station, with network stations requiring a higher share of viewing hours. 47 CFR 76.5(i)(1) and (2). The Commission's rules define network station as one of the "three major national television networks" (*i.e.*, ABC, CBS or NBC). 47 CFR 76.5(j) and (k). Parties may demonstrate that stations are significantly viewed either on a community basis or on a county-wide basis. 47 CFR 76.54(b), (d).

⁸ See 17 U.S.C. 122(j)(2)(A) (defining "local market").

⁹ See 47 CFR 76.5, 76.7, 76.54. A TV station, cable operator or satellite carrier that wishes to have a station designated significantly viewed must file a petition pursuant to the pleading requirements in 47 CFR 76.7(a)(1) and use the method described in 47 CFR 76.54 to demonstrate that the station is significantly viewed as defined in 47 CFR 76.5(i).

¹⁰ The significantly viewed list or "SV List" identifies the list of stations the Commission has determined to be significantly viewed in specified counties and communities. The list applies to both cable and satellite providers. The Commission updates this list as necessary upon the appropriate demonstrations by stations or cable or satellite providers. A station, satellite carrier or cable operator may petition the Commission, either to add eligible stations or communities pursuant to 47 CFR 76.54, or to restrict carriage of eligible stations through application of the Commission's network non-duplication or syndicated exclusivity rules in 47 CFR 76.122(a), (j) and 76.123(a), (k). Generally, a station's SV status is only challenged when another station seeks to exercise its rights under the network non-duplication or syndicated program exclusivity rules, and the SV station asserts its SV status, which is an exception to both requirements. See 47 CFR 76.92(f) (SV exception in cable network non-duplication rules); 47 CFR 76.106(a) (SV exception in cable syndicated program exclusivity rules); 47 CFR 76.122(j) (SV exception in satellite network non-duplication rules); and 47 CFR 76.123(k) (SV exception to satellite syndicated program exclusivity rules). If a station's SV status is challenged, and it is demonstrated that the station is no longer significantly viewed in a particular community or county, the station's listing is modified to indicate that it is subject to programming deletions in those communities or counties. See *SHVERA Significantly Viewed Report and Order* at para. 14. The current SV List is available on the Media Bureau's Web site at <http://www.fcc.gov/mb/>.

to one market to be treated as a "local" station with respect to a particular cable or satellite community¹¹ in another market, and, thus, enables it to be carried by cable or satellite in that community in the other market.¹² In general, SV status applies to only some communities or counties in a DMA and does not apply throughout an entire DMA. In contrast, the "local" station designation based on Nielsen's assignment to a particular DMA applies to the entire market.¹³ Whereas cable operators have had carriage rights for SV stations since 1972,¹⁴ satellite carriers have had such authority only since 2004¹⁵ and may only retransmit SV network stations to "eligible" satellite subscribers.¹⁶ These satellite subscriber eligibility restrictions are intended to prevent satellite carriers from favoring an SV network station over the in-market (local) station affiliated with the same network.¹⁷

3. Section 203 of the STELA changes the restrictions on subscriber eligibility to receive SV network stations from

¹¹ See 47 CFR 76.5(dd) (defining cable "community unit") and 76.5(gg) (defining a "satellite community").

¹² For copyright purposes, significantly viewed status means that cable and satellite providers may carry the out-of-market but SV station with the reduced copyright payment obligations applicable to local (in-market) stations. See 17 U.S.C. 111(a), (c), (d), and (f), as amended by STELA sec. 104 (relating to cable statutory copyright license) and 122(a)(2), as amended by STELA sec. 103 (relating to satellite statutory copyright license).

¹³ 17 U.S.C. 122(j)(2)(C) (defining DMA as "a designated market area, as determined by Nielsen Media Research and published in the 1999-2000 Nielsen Station Index Directory and Nielsen Station Index United States Television Household Estimates or any successor publication").

¹⁴ See *Cable Television Report and Order*, FCC 72-108 at para. 83, 37 FR 3252, February 3, 1972 (adopting the concept of "significantly viewed" signals to differentiate between otherwise out-of-market television stations "that have sufficient audience to be considered local and those that do not").

¹⁵ Section 202 of the Satellite Home Viewer Extension and Reauthorization Act of 2004 (SHVERA) created Section 340 of the Communications Act, which authorized satellite carriage of Commission-determined SV stations. See SHVERA sec. 202, Public Law 108-447, 118 Stat 2809, 3393 (2004) (codified in 47 U.S.C. 340). See also *SHVERA Significantly Viewed Report and Order*.

¹⁶ See 47 U.S.C. 340(b) and 47 CFR 76.54(g) and (h). See also *infra* para. 8 (for background).

¹⁷ 47 U.S.C. 340(b)(1) and (2). See *SHVERA Significantly Viewed Report and Order* at para. 94. The Copyright Act's definitions of "network station" and "non-network station" will apply for purposes of determining subscriber eligibility to receive an SV network station. See 47 U.S.C. 330(d) and 47 U.S.C. 122(j)(4), as amended, applying the definitions of such terms in 47 U.S.C. 119(d)(2) and (9). Unlike the definition in the Commission's rules, which specifically include only ABC, CBS and NBC (see *supra* note 7), the Copyright Act definition of "network station" may include other stations. See *SHVERA Significantly Viewed Report and Order* at paras. 35-36 and n. 102.

satellite carriers.¹⁸ To implement the STELA, we revise our satellite subscriber eligibility rules as follows:

- We find that the local service requirement in amended Section 340(b)(1) requires only that a satellite subscriber receive local-into-local satellite service as a precondition for that subscriber to receive SV stations. We find that the statute no longer requires a satellite subscriber to receive the specific local network station as a precondition for that subscriber to receive an SV station affiliated with the same network.

- We find that amended Section 340(b)(2) no longer requires that a satellite carrier offer "equivalent bandwidth" to the local and SV network station pair and instead imposes an "HD format" requirement. We find that the HD format requirement in amended Section 340(b)(2) requires that, in order to carry an SV station in high definition (HD) format, a satellite carrier must carry the local station affiliated with the same network in HD whenever such format is available from the local station.

The HD format requirement applies only where a satellite carrier retransmits to a subscriber the SV station in HD format. This requirement does not restrict a satellite carrier from retransmitting to a subscriber the SV station in standard definition (SD) format.

For purposes of the HD format requirement, the corresponding local (in-market) station will be considered "available" to the satellite carrier when the station: (1) Elects mandatory carriage or grants retransmission consent; (2) provides a good quality signal to the satellite carrier as required by Section 76.66(g) of the rules; and (3) is otherwise in compliance with the "good faith negotiation" and carriage provisions set forth in Sections 76.65 and 76.66 of the rules. However, the HD signal of the corresponding local station will be deemed "available" despite failure to reach agreement on the terms of retransmission if the satellite carrier is not in compliance with Section 76.65.

The HD format requirement requires satellite carriage of a secondary HD stream of a local station's multicast signal if that stream is affiliated with the same network as an SV station retransmitted in HD to satellite subscribers in the local market.

- We modify the Commission's 2005 interpretation of the Section 340(b)(3) exception, which is unchanged by the STELA, and find that, in the context of the newly revised statute, this exception

permits a satellite carrier to offer an SV network station to a subscriber when there is no local affiliate of the same network present in the local market, even if the subscriber does not receive local-into-local service.

II. Background

4. In May 2010, Congress passed and the President signed the STELA, which amends the 1988 copyright laws¹⁹ and the Communications Act of 1934²⁰ to "modernize, improve and simplify the compulsory copyright licenses governing the retransmission of distant and local television signals by cable and satellite television operators."²¹ Congress intended for the STELA to increase competition between cable and satellite providers, increase service to satellite subscribers, and update the law to reflect the completion of the digital television (DTV) transition.²² Notably,

¹⁹ See 17 U.S.C. 119 and 122. 17 U.S.C. 119 contains the statutory copyright license for satellite carriage of "distant" network stations (limited to "unserved households") and 17 U.S.C. 122 contains the statutory copyright license for satellite carriage of "local" stations (generally defined as stations and subscribers in the same DMA but which now also includes SV stations, which are treated as "local" for copyright royalty purposes, even though such stations are not in the same DMA as the subscribers and are not entitled to mandatory carriage). The STELA also amended 17 U.S.C. 111, the statutory copyright license for cable carriage of broadcast stations.

²⁰ See 47 U.S.C. 325, 338, 339 and 340.

²¹ See House Judiciary Committee Report dated Oct. 28, 2009, accompanying House Bill, H.R. 3570, 111th Cong. (2009), H.R. Rep. No. 111-319, at 4 ("H.R. 3570 Report"). See also House Energy and Commerce Committee Report dated Dec. 12, 2009, accompanying House Bill, H.R. 2994, 111th Cong. (2009), H.R. Rep. No. 111-349, at 16 ("H.R. 2994 Report"); and Senate Judiciary Committee Report dated Nov. 10, 2009, accompanying Senate Bill, S. 1670, 111th Cong. (2009), H.R. Rep. No. 111-98, at 5 ("S. 1670 Report"). There was no final Report issued to accompany the final version of the STELA bill (S. 3333) as it was enacted. See Senate Bill, S. 3333, 111th Cong. (2010) (enacted). Therefore, for the relevant legislative history, we look to the Reports accompanying the various predecessor bills (e.g., H.R. 3570, H.R. 2994, and S. 1670). These Reports reflect Congressional intent with respect to the SV provisions, which were enacted as drafted in the House and Senate bills. (see STELA sec. 203, 103). Finally, also relevant are certain remarks made in floor statements in passing the bill (S. 3333). See "House of Representatives Proceedings and Debates of the 111st Congress, Second Session," 156 Cong. Rec. H3317, H3328-3330 (daily ed. May 12, 2010) (statements of Reps. Conyers and Smith) ("House Floor Debate") and "Senate Proceedings and Debates of the 111st Congress, Second Session," 156 Cong. Rec. S3435 (daily ed. May 7, 2010) (statement of Sen. Leahy) ("Senate Floor Debate"). We also find relevant certain remarks made in floor statements in passing the House Bill, H.R. 3570. See Chairmen Waxman's and Boucher's Floor Statements on the Satellite Home Viewer Reauthorization Act of 2009, 155 Cong. Rec. H13428, H13441-13442 (Dec. 2, 2009) ("H.R. 3570 Waxman and/or Boucher Floor Statement(s)").

²² See H.R. 3570 Report at 5 and H.R. 2994 Report at 16. As of the June 12, 2009 statutory DTV transition deadline, all full-power television

the STELA reauthorizes the statutory copyright license for satellite carriage of SV stations and moves that license from the distant signal statutory copyright license provisions to the local signal statutory copyright license provisions.²³

5. The STELA is the fourth in a series of statutes that address satellite carriage of television broadcast stations. In the 1988 Satellite Home Viewer Act ("1988 SHVA"). Congress established a statutory copyright license to enable satellite carriers to offer subscribers who could not receive the over-the-air signal of a broadcast station access to broadcast programming via satellite.²⁴ The 1988 SHVA was intended to protect the role of local broadcasters in providing over-the-air television by limiting satellite delivery of network broadcast programming to subscribers who were "unserved" by over-the-air signals. The 1988 SHVA also permitted satellite carriers to offer distant "superstations" to subscribers.²⁵

6. In the 1999 Satellite Home Viewer Improvement Act ("SHVIA"), Congress expanded satellite carriers' ability to retransmit local broadcast television signals directly to subscribers.²⁶ A key element of the SHVIA was the grant to satellite carriers of a statutory copyright license to retransmit local broadcast programming, or "local-into-local" service, to subscribers. A satellite carrier

stations stopped broadcasting in analog and are broadcasting only digital signals. 47 U.S.C. 309(j)(14)(A).

²³ STELA sec. 103 (moving the SV signal statutory copyright license from 17 U.S.C. 119(a)(3) to 17 U.S.C. 122 (a)(2)). In doing so, Congress now defines SV signals as another type of local signal, rather than as an exception to distant signals. The move also means that the SV signal license does not expire on December 31, 2014, when the distant signal license will expire. STELA sec. 107(a).

²⁴ The Satellite Home Viewer Act of 1988 (SHVA), Public Law 100-667, 102 Stat. 3935, Title II (1988) (codified at 17 U.S.C. 111, 119). The 1988 SHVA was enacted on November 16, 1988, as an amendment to the copyright laws. The 1988 SHVA gave satellite carriers a statutory copyright license to offer distant signals to "unserved" households. 17 U.S.C. 119(a).

²⁵ See *id.* 119(a)(1) (2009). The STELA sec. 102(g) replaces the term "superstation" with the term "non-network station." This change in wording has no substantive impact on our rules. A non-network station (previously superstation) is defined as a television station, other than a network station, licensed by the Commission that is retransmitted by a satellite carrier. As the term would suggest, non-network stations are still not considered "network stations" for copyright purposes. See *id.* 119(d)(9); see also *supra* notes 7 and 17.

²⁶ The Satellite Home Viewer Improvement Act of 1999 (SHVIA), Public Law 106-113, 113 Stat. 1501 (1999). The SHVIA was enacted on November 29, 1999, as Title I of the Intellectual Property and Communications Omnibus Reform Act of 1999 (IPACORA) (relating to copyright licensing and carriage of broadcast signals by satellite carriers). In the SHVIA, Congress amended both the copyright laws, 17 U.S.C. 119 and 122, and the Communications Act, 47 U.S.C. 325, 338 and 339.

¹⁸ 47 U.S.C. 340(b)(1) and (2).

provides "local-into-local" service when it retransmits a local television signal back into the local market of that television station for reception by subscribers.²⁷ Generally, a television station's "local market" is the DMA in which it is located.²⁸ Each satellite carrier providing local-into-local service pursuant to the statutory copyright license is generally obligated to carry any qualified local television station in the particular DMA that requests carriage and complies with Commission rules, unless the station's programming is duplicative of the programming of another station carried by the carrier in the DMA or the station does not provide a good quality signal to the carrier's local receive facility.²⁹ This is commonly referred to as the "carry one, carry all" requirement. The Commission implemented the SHVIA by adopting rules for satellite carriers with regard to carriage of broadcast signals, retransmission consent, and program exclusivity that generally paralleled the requirements for cable service.³⁰

7. In the 2004 Satellite Home Viewer Extension and Reauthorization Act (SHVERA), Congress established the framework for satellite carriage of "significantly viewed" stations.³¹

²⁷ 47 CFR 76.66(a)(6).

²⁸ See 17 U.S.C. 122(j)(2)(A); 47 U.S.C. 340(i)(1). DMAs, which describe each television market in terms of a unique geographic area, are established by Nielsen Media Research based on measured viewing patterns. See 17 U.S.C. 122(j)(2)(A) through (C).

²⁹ See 47 U.S.C. 338.

³⁰ See *SHVIA Signal Carriage Order*, 66 FR 7410, January 23, 2001; *OET SHVIA Report*, FCC 00-416 (rel. Nov. 29, 2000); *SHVIA Satellite Exclusivity Order*, 65 FR 68082, November 14, 2000; *SHVIA Retransmission Consent Enforcement Order*, 65 FR 10718, February 29, 2000; *SHVIA Good Faith Retransmission Consent Order*, 65 FR 15559, March 23, 2000.

³¹ The Satellite Home Viewer Extension and Reauthorization Act of 2004 (SHVERA), Public Law 108-447, 118 Stat 2809 (2004) (codified in scattered sections of 17 and 47 U.S.C.). The SHVERA was enacted on December 8, 2004 as title IX of the "Consolidated Appropriations Act, 2005." The SHVERA contained additional mandates requiring Commission action, but not relevant to this proceeding. See *SHVERA Reciprocal Bargaining Order*, 70 FR 40216, July 13, 2005 (imposing a reciprocal good faith retransmission consent bargaining obligation on multichannel video programming distributors); *SHVERA Section 210 Order*, 70 FR 51658, August 31, 2005 (requiring satellite carriers to carry local TV broadcast stations in Alaska and Hawaii); *SHVERA Procedural Rules Order*, 70 FR 21669, April 27, 2005 (adopting procedural rules concerning satellite carriers' notifications to TV broadcast stations and obligations to conduct signal testing); *Retransmission Consent and Exclusivity Rules: Report to Congress Pursuant to Section 208 of the Satellite Home Viewer Extension and Reauthorization Act of 2004*, dated Sept. 8, 2005, available at <http://www.fcc.gov/mb/policy/shvero.html> (Report analyzing comments received in MB Docket No. 05-28 and addressing impact of certain rules and statutory provisions on competition in the television marketplace).

Specifically, the SHVERA expanded the statutory copyright license to allow satellite carriers to retransmit an out-of-market network station as part of their local service to subscribers where the Commission determined that distant station to be "significantly viewed" (based on over-the-air viewing).³² In providing this authority to satellite carriers, Congress sought to create parity with cable operators, who had already had such authority to offer SV stations to subscribers for more than 38 years.³³ The Commission implemented the SHVERA's significantly viewed provisions by publishing a list of SV stations³⁴ and adopting rules in the satellite context for stations to attain eligibility for significantly viewed status and for subscribers to receive SV stations from satellite carriers.³⁵ The SHVERA mandated that the Commission apply the same station eligibility requirements (*i.e.*, rules and procedures for parties to show that a station qualifies for significantly viewed status) to satellite carriers that already applied to cable operators.³⁶ However, to prevent a satellite carrier from favoring SV stations over traditional local market stations, the SHVERA also imposed subscriber eligibility requirements that applied only to satellite carriers.³⁷

³² In the SHVERA, Congress again amended both the Communications Act, 47 U.S.C. 325, 338, 339 and 340, and the copyright laws, 17 U.S.C. 119 and 122. In creating a statutory copyright license for satellite carriers to offer significantly viewed stations to subscribers, Congress distinguished between out-of-market stations that had significant over-the-air viewership in another market (*i.e.*, significantly viewed stations) and truly "distant" stations.

³³ See *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17280-1, para. 2. In 1972, the Commission adopted the concept of "significantly viewed" stations for cable television to differentiate between out-of-market television stations "that have sufficient audience to be considered local and those that do not." 1972 *Cable R&O*, 36 FCC 2d at 174, para. 83. The Commission concluded at that time that it would not be reasonable if choices on cable were more limited than choices over-the-air, and gave cable carriage rights to stations in communities where they had significant over-the-air (non-cable) viewing. *Id.*

³⁴ See *supra* note 10 (for background on SV List).

³⁵ See 47 CFR 76.5(ee) (revised), 76.5(gg) (added), 76.54(a) through (c) (revised), 76.54(e) through (k) (added), 76.122(a) and (j) (revised), and 76.123(a) and (k) (revised).

³⁶ See 47 U.S.C. 340(a). As mandated by the SHVERA, the Commission required satellite carriers or broadcast stations seeking SV status for satellite carriage to follow the same petition process now in place for cable carriage. See 47 CFR 76.5, 76.7 and 76.54(a) through (d).

³⁷ 47 U.S.C. 340(b) (2004). The eligibility requirements also addressed the different carriage requirements that apply to cable (*i.e.*, "must carry" for all cable systems) as compared with satellite (*i.e.*, "carry one, carry all"). In the cable context, where mandatory carriage rules apply as opposed to satellite's carry one, carry all requirements, it was

8. The SHVERA limited subscribers' eligibility to receive SV digital television stations from satellite carriers in two key ways. First, the SHVERA allowed a satellite carrier to offer SV stations only to subscribers that received the carrier's "local-into-local" service (the "local service" requirement).³⁸ The Commission interpreted this local service requirement to further require that the subscriber receive the local station affiliated with a particular network (as part of the carrier's "local-into-local" service) in order for that subscriber to also receive an SV station affiliated with the same network (the "same network affiliate" requirement).³⁹ Second, the SHVERA allowed a satellite carrier to offer an SV digital station to a subscriber only if the carrier also provided to that subscriber the local station affiliated with the same network in a format that used either (1) an "equivalent" amount of bandwidth for the local and SV network station pair, or (2) the "entire" bandwidth of the local station (the "equivalent or entire bandwidth" requirement).⁴⁰ The Commission interpreted this provision to require an objective comparison of each station's use of its bandwidth in terms of

not necessary to include subscriber eligibility requirements, as it was presumed that all cable subscribers receive local broadcast stations as part of their cable package.

³⁸ The Commission found that "subscriber receipt of 'local-into-local' service [was] unambiguously required by the statute." *SHVERA Significantly Viewed Report and Order* at para. 68.

³⁹ *Id.* at para. 76 (discussing digital service limitations). The SHVERA's language differed with respect to the analog and digital service limitations. In 2004, television stations were transitioning from analog to digital service and most stations were broadcasting both analog and digital signals. Consequently, the SHVERA specified that certain provisions applied to analog signals and other, often different, provisions applied to digital signals. See 47 U.S.C. 340(b)(1) (analog service limitations) and 47 U.S.C. 340(b)(2)(A) (digital service limitations) (2004). The Commission noted that, "[u]nlike the ambiguity in its sister analog provision [of 47 U.S.C. 340(b)(1) (2004)], Section 340(b)(2)(A) of the Act, 47 U.S.C. 340(b)(2)(A) (2004), is clear in requiring a subscriber to receive "the digital signal of a network station in the subscriber's local market that is affiliated with the same television network." *Id.* See also *id.* at 17305, para. 70 (discussing analog service limitations).

⁴⁰ 47 U.S.C. 340(b)(2)(B) (2004) ("With respect to a signal that originates as a digital signal of a network station, this section shall apply only if— * * * (B) either—(i) the retransmission of the local network station occupies at least the equivalent bandwidth as the digital signal retransmitted pursuant to this section; or (ii) the retransmission of the local network station is comprised of the entire bandwidth of the digital signal broadcast by such local network station"). Congress sought to prevent satellite carriers from offering the local network station's digital signal "in a less robust format" than the significantly viewed affiliate station's digital signal. *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17314, para. 94.

megabits per second (mbps) or bit rate.⁴¹ The SHVERA provided for two exceptions to the local service limitations, contained in 47 U.S.C. 340(b)(3) and (b)(4). Section 340(b)(3) allows satellite carriage of an SV network station to a subscriber when there is no local station affiliated with the same television network as the SV station present in the local market. Section 340(b)(4) allows a satellite carrier to negotiate privately with the local network station to obtain a waiver of the subscriber eligibility restrictions in Sections 340(b)(1) and 340(b)(2).

III. Discussion

9. We adopt rules in this *R&O* to implement the STELA's amendments to Section 340(b) of the Communications Act. Our discussion below addresses the two substantive changes to Section 340(b)(1) and (b)(2), as well as how these amended provisions will work with the existing statutory exceptions in Section 340(b)(3) and (b)(4). We decline to address here the merits of Dish's petition for further rulemaking filed with its comments, as those issues are beyond the scope of this proceeding.⁴² Finally, we adopt some non-substantive, "housecleaning" rule changes.

10. The STELA amended Section 340(b) to read as follows:⁴³

(1) Service Limited to Subscribers Taking Local-Into-Local Service.—This section shall apply only to retransmissions to subscribers of a satellite carrier who receive retransmissions of a signal from that satellite carrier pursuant to section 338.

(2) Service Limitations.—A satellite carrier may retransmit to a subscriber in high definition format the signal of a station determined by the Commission to be significantly viewed under subsection (a) only if such carrier also retransmits in high definition format the signal of a station located in the local market of such subscriber and affiliated with the same network whenever such format is available from such station.

(3) The limitations in paragraphs (1) and (2) shall not prohibit a retransmission under this section to a subscriber located in a local market in which there are no network stations affiliated with the same television network as the station whose signal is

being retransmitted pursuant to this section.

(4) Paragraphs (1) and (2) shall not prohibit a retransmission of a network station to a subscriber if and to the extent that the network station in the local market in which the subscriber is located, and that is affiliated with the same television network, has privately negotiated and affirmatively granted a waiver from the requirements of paragraph (1) and (2) to such satellite carrier with respect to retransmission of the significantly viewed station to such subscriber.

11. These amendments simplify the significantly viewed provisions in Section 340(b) of the Communications Act to make it easier for satellite carriers to offer SV stations to subscribers.⁴⁴ Specifically, the STELA made two key changes to Section 340(b).⁴⁵ First, the STELA eliminated the language in Section 340(b)(2)(A) that had required that subscribers receive the same local network affiliate and, instead, retains only the language requiring that the subscriber receive local-into-local satellite service in order to be eligible to receive SV stations.⁴⁶ Second, the STELA replaces the "equivalent or entire bandwidth" requirement applicable to digital service, which was previously contained in Section 340(b)(2)(B), with an "HD format" requirement. The STELA did not amend the statutory exceptions in Sections 340(b)(3) and (b)(4) to the subscriber eligibility restrictions in Sections 340(b)(1) and (2).

⁴⁴ See *H.R. 3570 Report* at 4.

⁴⁵ STELA sec. 203(a) (amendments to be codified at 47 U.S.C. 340(b)(1) and (2)). We note that the subscriber eligibility limitations in 47 U.S.C. 340(b)(1) and (2), which are amended by the STELA sec. 203, do not apply to cable subscribers. We do not substantively amend our significantly viewed rules and procedures that satellite carriers share with cable operators. See 47 CFR 76.54(a) through (d). Furthermore, we note that the STELA sec. 203 does not amend the significantly viewed provisions in the Communications Act governing the eligibility of a television broadcast station to qualify for "significantly viewed" status. See 47 U.S.C. 340(a), (c) through (g). We do not make any substantive (non-"housecleaning") changes to our rules and procedures implementing the significantly viewed station eligibility requirements. See 47 CFR 76.54(a) through (f), (j) and (k). See *infra* Section III.F. (discussing housecleaning changes).

⁴⁶ Section 340(b)(1) as amended retains the reference to "a" signal carried pursuant to Section 338 and the explanatory heading referring to "subscribers taking local-into-local service." Congress removed from this section the phrase "that originates as an analog signal of a local network station" following the word "signal." See DIRECTV Reply at 5.

A. The STELA Directs the Commission To Create a Workable Framework That Will Enable Satellite Carriers To Offer Both the SV and Local Stations to Consumers

12. We find that, in the STELA, Congress intended that the Commission create a workable framework for the satellite carriage of SV stations.⁴⁷ Congress intended the 2004 SHVERA to promote parity with cable,⁴⁸ while protecting localism by preventing satellite carriers from favoring an SV network station over the local in-market station affiliated with the same TV network.⁴⁹ However, very few SV stations made their way into the living rooms of satellite TV consumers.⁵⁰ The Satellite Carriers attribute this to the Commission's "restrictive" interpretation of Section 340(b) in the 2005 *SHVERA Significantly Viewed Report and Order*,⁵¹ which they maintain made satellite carriage of SV

⁴⁷ See *STELA—Significantly Viewed NPRM*, *supra* note 3, at paras. 2, 11.

⁴⁸ See, e.g., 2004 House Commerce Committee Report dated July 22, 2004, accompanying House Bill, H.R. 4501, 108th Cong. (2004), H.R. Rep. No. 108-634, at 1 and 9 (2004) ("*2004 House Commerce Committee Report*") (noting purpose of the SHVERA included "increasing regulatory parity by extending to satellite carriers the same type of authority cable operators already have to carry 'significantly viewed' signals into a market"). See also, e.g., House of Representatives Floor Debate on the Satellite Home Viewer Extension and Reauthorization Act of 2004, House Bill H.R. 4518, 150 Cong. Rec. H8210, H8217-8219 (dated Oct. 6, 2004) ("*H.R. 4518 Floor Debate*"). In a statement in the floor debate, Rep. Joe Barton (Chairman, House Energy and Commerce Committee) stated: "The bill [H.R. 4518] would extend to satellite operators the authority to carry such significantly viewed signals on comparable terms as cable operators." *Id.* at H8219. See also The Honorable Joe Barton, Chairman, House Energy and Commerce Committee, "Floor Statement" on the Satellite Home Viewer Extension and Reauthorization Act of 2004, House Bill H.R. 4518, (dated Oct. 6, 2004) ("*Barton Floor Statement*") ("In implementing Section 340, the [Commission] should treat satellite operators in a comparable fashion to cable operators to the greatest extent possible with respect to carriage of significantly viewed stations, in terms of both current and future significantly viewed rulings.")

⁴⁹ See 2004 House Commerce Committee Report at 12 (noting that former "Section 340(b)(2)(B) prevents the satellite operator from retransmitting a local affiliate's digital signal in a less robust format than a significantly viewed digital signal of a distant affiliate of the same network, such as by down-converting the local affiliate's signal but not the distant affiliate's signal from high-definition digital format to analog or standard definition digital format").

⁵⁰ See DIRECTV Comments at 2 (noting that it has "offered only a handful" of SV stations since satellite carriage of such stations was authorized by SHVERA) and Dish Reply at 5 (noting that "when permitted to do so, Dish offered SV stations in certain counties of only seven DMAs").

⁵¹ DIRECTV Comments at 1-2 and Dish Reply at 5 (noting that "the SV program that Congress spearheaded has not succeeded").

⁴¹ See *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17315, para. 96.

⁴² Dish requested the Commission to undertake a rulemaking to revise the retransmission consent rules as they apply to carriage of SV stations. See Dish Comments (Petition) at 9.

⁴³ 47 U.S.C. 340(b) (2010), as amended by the STELA sec. 203(a). See also 17 U.S.C. 122(a)(2), as amended by STELA sec. 103(b).

stations impractical or technically infeasible.⁵²

13. Congress seemed to agree. As stated in one House Report:

The Commission's implementation of section 340, including its interpretation of the "equivalent bandwidth" requirement, has generally served to discourage satellite carriers from using section 340 to provide significantly viewed signals to qualified households.⁵³

To achieve more widespread carriage of SV stations, the STELA amends Sections 340(b). As discussed below, Congress eliminated both the former Section 340(b)(2)(A), which required that digital local service subscribers receive the same network affiliate, and the former Section 340(b)(2)(B), which contained the "equivalent or entire bandwidth" requirement.⁵⁴ Based on these changes to the statutory text, Congress intended more than merely to fix a technical implementation issue with the equivalent bandwidth requirement, as the Broadcaster Associations contend,⁵⁵ but rather sought to simplify the law and increase service to satellite subscribers by encouraging SV carriage.⁵⁶ In reauthorizing the SHVERA and mostly retaining its framework for the carriage of SV stations, the STELA also retains the key goals of its predecessor statute—to foster localism and promote parity between cable and satellite service.⁵⁷

14. The STELA's relocation of the statutory copyright license for SV stations into the "local" license provisions of the Copyright Act indicates that Congress considered the SV compulsory license to be more like the local license than like the distant

signal license, recognizing that the SV station is "local" to the community in which it is significantly viewed.⁵⁸ SV stations have SV status because they have been viewed over-the-air by a sufficient number of households in the community in the relevant market. The Senate Report notes that the SV provision "relates to the ability to receive locally-oriented programming."⁵⁹ Furthermore, satellite TV consumers deserve access to the same locally-oriented programming—including SV stations—as their cable-subscribing neighbors.⁶⁰ Moreover, providing satellite carriers parity with cable was a core goal of the SHVERA in 2004 and it remains one today in the STELA.⁶¹ Therefore, our

⁵² See S. 1670 Report at 5 (noting "The [STELA] moves locally-oriented provisions out of the distant signal license and places them into the permanent local license. These provisions include significantly viewed, special exception, and low-power stations. Shifting these provisions into the local license will ensure that the distant signal license is focused purely on providing truly distant signals to consumers unserved by their local broadcasters."). This makes sense given STELA's intent to create parity with cable, which characterizes SV signals as those with "sufficient audience to be considered local." See 1972 *Cable R&O*, 36 FCC 2d at 174, para. 83. But see H.R. 3570 Report at 10 (stating "Since significantly viewed signals are by definition a subset of distant signals, SHVERA included this provision in Section 119, the distant signal license. However, since significantly viewed signals do not incur royalties, the Committee believes it should be moved to Section 122, which governs all other royalty-free satellite transmissions under the compulsory license. The bill accordingly incorporates the significantly viewed provision, previously in Section 119(a)(3), into Section 122(a)."). The Broadcaster Associations argue that this statement means STELA considers SV signals to be distant by definition. See Broadcaster Associations Reply at 18. We disagree that these Congressional characterizations are necessarily at odds. The context of the H.R. 3570 Report referred to SHVERA's treatment of SV signals. In contrast, STELA intended to treat SV signals like "all other royalty-free satellite transmissions," i.e., like local signals. The change in license and treatment is also consistent with the statutory copyright license for cable retransmission of SV signals, which also treats them, for royalty purposes, as local signals. See 17 U.S.C. 111(a), (c), (d), and (f), as amended by STELA sec. 104.

⁵³ See S. 1670 Report at 4. See also DIRECTV Reply at 1, n.4; Dish Reply at 6.

⁵⁴ See, e.g., H.R. 4518 Floor Debate (on SHVERA bill), *supra* note 48, at H8223 (in which Rep. Conyers states that the SHVERA bill [H.R. 4518] "address[ed] the desires of consumers in that it permits the satellite companies to retransmit a significantly viewed local signal to a customer"); *Id.* at H8217 (in which Rep. Sensenbrenner states that the SHVERA bill, H.R. 4518, "changes both the copyright and communications acts to ensure, first, that consumers will have greater choice in programming; second, that satellite providers will have greater freedom to deliver the content consumers desire"); and *Id.* at H8219 (in which Rep. Barton states that "[b]y extending the expiring provisions, increasing parity, and promoting further competition, this legislation [H.R. 4518] will continue to enhance service to consumers.")

⁵⁵ See, e.g., H.R. 3570 Woxmon Floor Statement (on STELA bill), *supra* note 21, at H13441 (calling

implementation of the statutory changes to Section 340(b) focuses on enabling satellite TV consumers to receive both the local in-market and SV stations from their carriers, as is the plain intent of Section 340.⁶² To achieve this objective, our interpretation of the statute reflects the practical realities of satellite local carriage, in accordance with Congress's intent to remove barriers to SV carriage.⁶³

15. In the STELA, Congress directs us to implement Section 340 in a practical way that will better enable satellite carriers to offer SV stations to their subscribers. We find that carriage of both the SV and local in-market stations will best foster localism and promote parity with cable, and so, in implementing the law we must balance protection of local in-market stations against the cost of making SV carriage technically infeasible or impractical.

B. The STELA Eliminates the Requirement To Receive a Local Station Affiliated With the Same Network as the SV Station and Requires Instead That Subscribers Receive Local-Into-Local Service

16. We adopt our proposal to eliminate the requirement that a subscriber receive the local station affiliated with a specific network in order for that subscriber to also receive an SV station affiliated with the same network, and require instead that the subscriber receive local-into-local satellite service.⁶⁴ We clarify, however, that a satellite carrier must comply with Section 76.65 of our rules, which codifies the requirement for good faith in retransmission consent negotiations,

the bill [H.R. 3570] "an important step forward for consumers." Chairman Waxman notes, among other things, that the "bill makes changes to the existing rules on 'significantly viewed' signals in an effort to promote competition between satellite and cable companies"; and H.R. 4518 Floor Debate (on 2004 SHVERA bill), *supra* note 48, at H8223 (in which Rep. Dingell states that the bill [H.R. 4518] will not only "increase regulatory parity between cable and satellite providers" but that such "increased parity should help spur greater competition between cable and satellite providers and ultimately benefit consumers in the form of lower prices and better service"). Contrary to the Broadcaster Associations' argument, there is nothing in the record to suggest that cable carriage of SV stations has harmed localism over more than 30 years. See NAB *ex parte* (dated Oct. 7, 2010) Significantly Viewed Talking Points Appendix at 3 ("NAB Oct. 7 SV Talking Points") (claiming the Satellite Carriers ignore STELA's goal to protect localism).

⁶² As discussed above in *supra* para. 1, the purpose of Section 340 is to give satellite carriers the authority to offer SV stations as part of their local service to their subscribers.

⁶³ See DIRECTV and Dish *ex parte* (dated Sept. 20, 2010) Significantly Viewed Talking Points Appendix at 1 ("DIRECTV and Dish Sept. 20 SV Talking Points").

⁶⁴ STELA-Significantly Viewed NPRM, *supra* note 3, at para. 14.

⁵² DIRECTV and Dish *ex parte* (dated Sept. 22, 2010) Significantly Viewed Talking Points Appendix at 1 ("DIRECTV and Dish Sept. 22 SV Talking Points") (expressing concern that the Commission might adopt rules for SV carriage "that make it impractical to offer such stations").

⁵³ H.R. 2994 Report at 16. The use of the word "including" implies that Congress' dissatisfaction with the Commission's prior implementation of Section 340 was not limited to the "equivalent bandwidth" requirement.

⁵⁴ See 47 U.S.C. 340(b)(2)(A) and (B). See *infra* Sections III.B. and III.C.

⁵⁵ Broadcaster Associations Comments at 4 (arguing STELA's statutory changes only "address a technical implementation concern" with the "equivalent or entire bandwidth" requirement).

⁵⁶ See H.R. 3570 Report at 4 (noting STELA's general intent to "increase competition and service to satellite and cable consumers").

⁵⁷ See e.g., H.R. 2994 Report at 15 (noting that "the 'significantly viewed' provision was adopted in SHVERA to create parity with cable operators") and also H.R. 3570 Report at 10. See SHVERA Significantly Viewed Report and Order, 20 FCC Rcd at 17306-7, paras. 71-2 (noting statutory intent "to protect localism" by citing to the 2004 House Commerce Committee Report).

in order for it to carry an SV station. In the record, the Satellite Carriers support our proposal, while the Broadcaster Associations oppose it.⁶⁵

17. In the 2004 SHVERA, Congress authorized satellite carriers to offer SV stations to subscribers, but crafted Sections 340(b)(1) and 340(b)(2)(A) of the Act to protect localism by requiring that these subscribers also receive the local network affiliate (called the "local service" requirement).⁶⁶ These two provisions, however, contained different language. Whereas the analog local service requirement in Section 340(b)(1)⁶⁷ required only that the subscriber receive local service "pursuant to Section 338"—referring to the "carry one, carry all" carriage requirements that pertain to local stations,⁶⁸ the digital local service requirement in Section 340(b)(2)(A)⁶⁹ contained additional language that expressly required the subscriber to receive the local digital station that was "affiliated with the same television network" as the SV station (hereinafter referred to as the "same network affiliate" language). Thus, while each of these provisions explicitly required a subscriber to at least receive the satellite carrier's local-into-local service before that subscriber could receive an SV station, it was unclear (when considering the two provisions together) whether Section 340(b)(1) also required a subscriber to receive the specific local analog network station before that subscriber could receive the SV station affiliated with the same network.⁷⁰ For

⁶⁵ Broadcaster Associations Comments at 7 and Reply at 6; DIRECTV Comments at 3 and Reply at 3; Dish Comments at 4 and Reply at 7.

⁶⁶ 47 U.S.C. 340(b)(1) and (b)(2)(A) (2004). Congress intended for these provisions to protect localism "by helping ensure that the satellite operator cannot retransmit into a market a significantly viewed digital signal of a network broadcast station from a distant market without also retransmitting into the market a digital signal of any local affiliate from the same network." *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17306-7, paras. 71-2.

⁶⁷ 47 U.S.C. 340(b)(1) (2004), as enacted in 2004, stated: "With respect to a signal that originates as an analog signal of a network station, this section shall apply only to retransmissions to subscribers of a satellite carrier who receive retransmissions of a signal that originates as an analog signal of a local network station from that satellite carrier pursuant to section 338."

⁶⁸ 47 U.S.C. 338. See also *supra* para. 6 (discussing the "carry one, carry all" requirement).

⁶⁹ 47 U.S.C. 340(b)(2)(A) (2004), as enacted in 2004, stated: "With respect to a signal that originates as a digital signal of a network station, this section shall apply only if—(A) the subscriber receives from the satellite carrier pursuant to section 338 the retransmission of the digital signal of a network station in the subscriber's local market that is affiliated with the same television network."

⁷⁰ *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17304-8, paras. 68, 70-73.

example, it was unclear how the statute applied where there was a local network analog station, but such station failed to request local carriage, refused to grant retransmission consent, or was otherwise ineligible for local carriage.⁷¹

18. In the 2005 *SHVERA Significantly Viewed Report and Order*, the Commission interpreted former Sections 340(b)(1) and 340(b)(2)(A) to require that the subscriber receive the specific local station that is affiliated with the same network as the SV station, whether the station's signal was analog or digital.⁷² Although former Section 340(b)(1) lacked the express "same network affiliate" language as that contained in its digital counterpart, the Commission interpreted the two provisions together and read the "same network affiliate" requirement into former Section 340(b)(1), based largely on the concept that Congress intended the two provisions to achieve similar ends.⁷³ Accordingly, the Commission adopted Section 76.54(g) of the rules, based on the "same network affiliate" language in former Section 340(b)(2)(A).⁷⁴

19. As we tentatively concluded in the NPRM, new Section 340(b)(1) requires only that the subscriber receive local-into-local satellite service and no longer requires carriage of the local affiliate of the same network.⁷⁵ New Section 340(b)(1) applies "only to

⁷¹ See *id.* at 17304, para. 67.

⁷² *Id.* at 17305 and 17308, paras. 70 and 76. In the 2006 *DIRECTV-EchoStar Joint Petition*, the Satellite Carriers challenged the Commission's interpretation of the analog service limitation provision in 47 U.S.C. 340(b)(1). With the end of analog full-power broadcasting, this issue is now moot. See *infra* Section III.C. (discussing Order on Reconsideration).

⁷³ See *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17307, para. 72. We note that the Commission also stated that its interpretation of Section 340(b)(1) was necessary to give meaning to the statutory exceptions in Sections 340(b)(3) and (4); see *supra* para. 10 (for statutory text). As discussed, *infra*, in paras. 46-47 and note 167, we find the statutory exceptions remain meaningful to, and are consistent with, our interpretation of Section 340(b)(1) as amended by STELA.

⁷⁴ 47 CFR 76.54(g) states: "(g) Signals of analog or digital significantly viewed television broadcast stations may not be retransmitted by satellite carriers to subscribers who do not receive local-into-local service, including a station affiliated with the same network as the significantly viewed station, pursuant to § 76.66 of this chapter; except that a satellite carrier may retransmit a significantly viewed signal of a television broadcast station to a subscriber who receives local-into-local service but does not receive a local station affiliated with the same network as the significantly viewed station, if: (1) There is no station affiliated with the same television network as the station whose signal is significantly viewed; or (2) The station affiliated with the same television network as the station whose signal is significantly viewed has granted a waiver in accordance with 47 U.S.C. 340(b)(4)."

⁷⁵ *STELA-Significantly Viewed NPRM*, *supra* note 3, at para. 14.

retransmissions to subscribers of a satellite carrier who receive retransmissions of a signal from that satellite carrier pursuant to Section 338."⁷⁶ By providing simply that a subscriber must receive "a" signal from the satellite carrier pursuant to Section 338 before receiving a SV signal, the statute removes any precondition that a subscriber receive "the" local affiliate of the same network as the SV station. In drafting new Section 340(b)(1) for the STELA, Congress eliminated the "same network affiliate" language that appeared in the provision enacted as part of the SHVERA in 2004.⁷⁷ Our interpretation that the new Section 340(b)(1) requires only that the subscriber receive local-into-local service is also consistent with the provision's heading: "Service Limited To Subscribers Taking Local-Into-Local Service," as well as with the statutory copyright license for SV stations, which allows a satellite carrier to retransmit SV stations to subscribers that receive signals pursuant to the statutory copyright license for local signals but says nothing about the subscriber having to receive the signal of the local affiliate of the same network.⁷⁸

20. Based on the language of the amended text, Congress' purposes of facilitating SV carriage and achieving closer parity between cable and satellite providers, and the shift of the SV copyright license from the distant licensee to the local licensee,⁷⁹ we conclude that the best interpretation of new Section 340(b)(1) is that the subscriber need only receive a local station pursuant to Section 338 in order

⁷⁶ 47 U.S.C. 340(b)(1) (referring to retransmissions "pursuant to 47 U.S.C. 338"). Each satellite carrier providing a local station pursuant to the statutory copyright license is generally obligated to carry any qualified local television station in the same DMA that has requested carriage. 47 U.S.C. 338.

⁷⁷ In STELA, Congress eliminated most references distinguishing the treatment of "analog" versus "digital" signals or stations in light of the completion of the digital television transition for full power stations. In Section 340, Congress eliminated the text of the digital provision (former section 340(b)(2)(A), which had said: "With respect to a signal that originates as a digital signal of a network station, this section shall apply only if—(A) the subscriber receives from the satellite carrier pursuant to section 338 of this title the retransmission of the digital signal of a network station in the subscriber's local market that is affiliated with the same television network; and" (B) the retransmission complies with either the (i) equivalent or (ii) entire bandwidth requirement." (*Emphasis added.*)

⁷⁸ 17 U.S.C. 122(a)(2)(A) (providing a statutory copyright license to support satellite carriage of SV stations provided the subscriber is receiving stations pursuant to the statutory copyright license for local stations). See 17 U.S.C. 122(a)(1).

⁷⁹ We note that SV stations are treated as "local" for copyright purposes in 17 U.S.C. 111 (the cable copyright license). See *supra* note 58.

to be eligible to receive SV stations, and that it need not receive the network affiliate affiliated with the same network as the SV station.⁸⁰ The Broadcaster Associations disagree with the NPRM's interpretation of new Section 340(b)(1) and argue that the Commission should retain the interpretation it applied to the SHVERA, notwithstanding the change in the statutory language as enacted in the STELA.⁸¹ They note that, in implementing the SHVERA in 2005, the Commission interpreted the former analog local service provision in former Section 340(b)(1) and the former digital local service provision in former Section 340(b)(2)(A) to require that a satellite subscriber must receive the local affiliate of a specific network in order to be eligible to receive the SV station affiliated with the same network.⁸² The SHVERA, in contrast to the STELA, included language expressly requiring receipt of the "same network affiliate" in the provision applying to eligibility for a digital SV station.⁸³ The Commission, relying on the language in the former digital provision, applied the requirement to subscriber eligibility for both analog and digital SV stations.⁸⁴ The Broadcaster Associations contend that we should retain the former interpretation and apply it to the new STELA provision despite the removal of the old language.⁸⁵ They argue that nothing has materially changed with respect to the local service requirement, other than the completion of the DTV transition and, therefore, that the Commission's prior interpretation of Section 340(b)(1) should not change.⁸⁶ They argue that Congress "re-enacted" the Commission's 2005 interpretation of former Section 340(b)(1) because it did not substantively change that provision, thereby giving its "implicit approval" of that interpretation.⁸⁷ We reject these arguments as they ignore that the

⁸⁰ This conclusion affirms our tentative conclusion in the NPRM at paras. 14–17. See also DIRECTV Comments at 3–4 and Reply at 3–8; Dish Comments at 2 and Reply at 7.

⁸¹ Broadcaster Associations Comments at 8 (arguing that the "prior Section 340(b)(1) never contained the 'same network affiliate' requirement" and, therefore, "the same interpretation and the same result must apply here.").

⁸² See Broadcaster Associations Comments at 8. See also SHVERA Significantly Viewed Report and Order at paras. 71–3.

⁸³ See 47 U.S.C. 340(b)(2)(A).

⁸⁴ See SHVERA Significantly Viewed Report and Order, 20 FCC Rcd at 17306–7, paras. 71–2.

⁸⁵ See Broadcaster Associations Comments at 9.

⁸⁶ *Id.* at 8–11 (arguing "the only substantive change to the provision is the removal of references to 'analog signal'").

⁸⁷ *Id.* at 12 (arguing that "Congress's failure to expressly amend the statute to alter that interpretation * * * is tantamount to a legislative re-enactment of that interpretation.").

STELA does, in fact, materially change the SHVERA's local service requirements.⁸⁸

21. The Broadcaster Associations assert that we must presume that Congress was aware of the Commission's prior interpretation of the local service provision.⁸⁹ By the same reasoning, however, we must also presume that Congress was aware of the basis for that interpretation: Namely, the "same network affiliate" language in the former digital local service requirement in former Section 340(b)(2)(A). Congress intentionally removed that requirement when it chose to strike that language in favor of the former analog local service limitation language. As we said in the NPRM, Congress chose to discard the "same network affiliate" language in the former digital local service requirement in Section 340(b)(2)(A), which the Commission had relied upon for its more restrictive interpretation of the former analog local service requirement in Section 340(b)(1).⁹⁰ As Dish notes: "Congress' eraser is no less dispositive than its pen."⁹¹ Moreover, our interpretation is consistent with Congress' intent to facilitate carriage and availability of SV stations for more satellite subscribers, and, thereby, to achieve closer parity with cable carriage of SV stations.

22. The Broadcaster Associations also argue that because both the former and new Section 340(b)(2) contain the "same network affiliate" language, the need to reconcile these two provisions remains.⁹² Moreover, they argue that because three out of four of the Section 340(b) provisions contain the "same network affiliate" language, we should read that language into the one that does not: The new local service requirement.⁹³ We reject both claims. New Section 340(b)(2) is a different requirement from the other provisions of Section 340(b), and addresses only when a satellite carrier may provide the HD signal of an SV station.⁹⁴ Moreover, contrary to the Broadcaster

⁸⁸ See DIRECTV Reply at 5–6; Dish Reply at 7–8.

⁸⁹ Broadcaster Associations Comments at 12.

⁹⁰ See NPRM at para. 16. See NPRM at ¶ 16 (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983) ("[Where] Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.")).

⁹¹ Dish Reply at 10.

⁹² Broadcaster Associations Comments at 8 (claiming "[t]hat requirement appeared in prior Section 340(b)(2), and that very same requirement still appears in new Section 340(b)(2).").

⁹³ Broadcaster Associations Reply at 9–10 ("Congress maintained the 'same network affiliate' language in three of the four subparagraphs").

⁹⁴ Dish Reply at 9.

Associations' assertion, we find that Congress's inclusion of the "same network affiliate" language in three out of four of the Section 340(b) provisions and not in the amended digital local service provision indicates that such exclusion was intentional.⁹⁵

23. We recognize that there may be tension in some circumstances between the goals of protecting localism, on the one hand, and achieving closer parity between pay television providers and increasing SV carriage, on the other. Specifically, our interpretation below of the STELA's amendments to Sections 340(b)(1) and (b)(2) makes it possible for a satellite carrier to carry an SV network station, even in HD format, without also carrying the corresponding local in-market affiliate if that local station has not granted retransmission consent. The Broadcaster Associations argue that this undermines local service.⁹⁶ However, because SV status generally applies to only some areas in a DMA and not throughout an entire DMA, we find it unlikely that an SV station could permanently substitute for a local in-market station, even in the provision of network programming to the market.⁹⁷ Moreover, because most viewers want to watch their local stations, we do not think that carriage of only SV stations would satisfy most subscribers for an extended time. Furthermore, as the Broadcaster Associations have noted in a different proceeding, retransmission consent impasses resulting in loss of a local station are relatively rare⁹⁸ and, when they do occur, they are usually short-lived. Although the Broadcaster Associations do provide a few examples of markets where they have concerns that satellite carriers could rely on

⁹⁵ See, e.g., *Duncan v. Walker*, 533 U.S. 167, 173 (2001) (quoting *Bates v. U.S.*, 522 U.S. 23, 29–30 (1997)) ("where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion"). See also *supra* note 90.

⁹⁶ See Broadcaster Associations Reply at 14. The Commission recognized in the SHVERA Significantly Viewed Report and Order that "the legislative history repeatedly reflects Congressional concern that the amendments permitting carriage of out-of-market significantly viewed signals not detract from localism." See SHVERA Significantly Viewed Report and Order, 20 FCC Rcd at 17306–7, paras. 71–2 (noting statutory intent "to protect localism" by citing to the 2004 House Commerce Committee Report).

⁹⁷ See DIRECTV and Dish Sept. 20 SV Talking Points.

⁹⁸ See, e.g., Opposition of the Broadcaster Associations in MB Docket No. 10–71 (dated May 18, 2010) at vii and 43, n. 148 (citing Bernstein Research, Cable and Satellite: Asymmetrical "Retrans" Leverage Favors Cable over Satellite and Telcos (Mar. 21, 2006) (finding that "negotiating impasses that cause interruptions in access to broadcast signals are extremely rare").

carriage of an SV station to the exclusion of the local in-market station, the record does not reflect instances in which an SV station has supplanted an in-market station in the cable or satellite context.⁹⁹ Therefore, we will monitor how the rules adopted in this order are working to determine if there are abuses, unintended consequences, or misuse of the rules that might lead to violations of the good faith requirements associated with retransmission consent negotiations.¹⁰⁰ Now that we have established a practical framework for satellite carriage of SV stations, we expect Satellite Carriers to offer SV stations to consumers wherever possible. However, if our implementation of Section 340(b) results in satellite carriers using SV stations to supplant, rather than supplement, their carriage of local in-market stations, we will reexamine our rules and our statutory analysis here in light of Congress' goals. In light of our conclusion that the new language in the STELA no longer requires subscriber receipt of a specific local station, we revise Section 76.54(g).¹⁰¹ The amended rule requires that a subscriber receive the satellite carrier's local-into-local service as a precondition for the subscriber to receive SV stations.

C. The STELA Eliminates the "Equivalent or Entire Bandwidth" Requirement and Replaces it with an "HD Format" Requirement

24. We adopt our proposal to eliminate the "equivalent or entire bandwidth" requirement and to provide, in its place, that a satellite carrier may retransmit the HD signal of an SV station to a subscriber only if such carrier also retransmits the HD signal of the local station affiliated with the same network whenever that signal is available in HD format. Both the Broadcaster Associations and Satellite Carriers agree with this conclusion. The commenters disagree, however, how to interpret and implement the new "HD format" requirement.

25. In the 2004 SHVERA, Congress enacted the "equivalent or entire" bandwidth requirement to prevent a satellite carrier from using technological

means to discriminate against a local network station in favor of the SV network affiliate.¹⁰² The Commission codified these requirements in Section 76.54(h) of the rules, which tracks the language of SHVERA.¹⁰³ In implementing that provision, the Commission strictly interpreted the statutory requirement for "equivalent bandwidth." As a result, satellite carriers have been required to ensure equality between the satellite bandwidth allocated to carriage of the local station and the SV stations on virtually a minute-by-minute basis, making carriage of SV stations so burdensome that they are rarely carried.¹⁰⁴

26. The STELA eliminated the "equivalent or entire bandwidth" requirement from the statute,¹⁰⁵ and replaced it with "HD format."¹⁰⁶ In doing so, Congress intended to facilitate satellite carriage of SV stations, which Congress thought was thwarted by the Commission's implementation of the predecessor provision.¹⁰⁷ The legislative history also shows that Congress wanted to simplify the law and increase service

¹⁰² 47 U.S.C. 340(b)(2)(B) (2004). The law reflects Congress' intent to prevent a satellite carrier from offering the local digital station "in a less robust format" than the SV digital station). *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17314, para. 94.

¹⁰³ 47 CFR 76.54(h) states: "Signals of significantly viewed network stations that originate as digital signals may not be retransmitted to subscribers unless the satellite carrier retransmits the digital signal of the local network station, which is affiliated with the same television network as the network station whose signal is significantly viewed, in either (1) at least the equivalent bandwidth of the significantly viewed station or (2) the entire bandwidth of the digital signal broadcast by such local station."

¹⁰⁴ See *supra* para. 13 (quoting *H.R. 2994 Report* at 16). See also Testimony of Bob Gabrielli, Senior Vice President, Broadcasting Operations and Distribution, DIRECTV, Inc., before the U.S. House of Representatives Subcommittee on Communications, Technology and the Internet, Hearing on Reauthorization of the of the Satellite Home Viewer Extension and Reauthorization Act, at 9 (Feb. 24, 2009) ("*Gabrielli Testimony*") (asserting that it is "infeasible" for DIRECTV to "carry local stations in the same format as SV stations every moment of the day").

¹⁰⁵ In the 2006 *DIRECTV-EchoStar Joint Petition*, the Satellite Carriers challenged the Commission's interpretation of the "equivalent bandwidth" requirement. Because the STELA eliminates this requirement, this issue is now moot. See *infra* Section III.G. (discussing *Order on Reconsideration*).

¹⁰⁶ 47 U.S.C. 340(b)(2) (2010), as amended by the STELA sec. 203(a).

¹⁰⁷ *H.R. 2994 Report* at 16 (noting that the Commission's implementation of Section 340, including its interpretation of the "equivalent bandwidth" requirement, has generally served to discourage satellite carriers from using Section 340 to provide significantly viewed signals to qualified households). See also *Gabrielli Testimony* at 9 ("Fixing the 'Significantly Viewed Rules' will Rescue Congress's Good Idea from the FCC's Implementation Mistakes").

to satellite consumers.¹⁰⁸ Congress' principal concern was simply to clarify that a satellite carrier may provide an SV station in HD format as long as the carrier also carries the corresponding local network affiliate in HD format if it is available in HD format.¹⁰⁹

27. Accordingly, we revise Section 76.54(h) to eliminate the "equivalent or entire bandwidth" requirement and to provide that a satellite carrier may retransmit the HD signal of an SV station to a subscriber only if such carrier also retransmits the HD signal of the local station affiliated with the same network whenever that signal is available in HD format.¹¹⁰ This part of the rule tracks the amended statutory language.¹¹¹ In addition, as discussed below, we adopt additional rules to interpret and implement the new "HD format" requirement.

1. "HD Format" Requirement Applies Only Where a Satellite Carrier Retransmits the SV Station in HD Format

28. We adopt our tentative conclusion in the NPRM that the "HD format" requirement in Section 340(b)(2) applies only where a satellite carrier retransmits the SV station in HD format and does not restrict satellite carriage of the SV station in SD format.¹¹² The Satellite Carriers support this conclusion, while the Broadcaster Associations oppose it.¹¹³

29. The Broadcaster Associations object to the additional language in our proposed Section 76.54(g)(2) clarifying that the "HD format" requirement does not apply to satellite carriage of an SV station in SD format.¹¹⁴ They argue that the statute requires satellite carriage of a local station in SD format if the satellite carrier retransmits the SV station in SD format. We disagree. As discussed above, the amended local service requirement in Section 340(b)(1) now requires only that a satellite subscriber receive the satellite carrier's local-into-local service as a precondition for the subscriber to receive SV stations.¹¹⁵ Moreover, the express

¹⁰⁸ See *H.R. 3570 Report* at 4-5.

¹⁰⁹ *H.R. 2994 Report* at 16.

¹¹⁰ See Appendix B final rule 47 CFR 76.54(g)(2). We renumber former Section 76.54(h) as 76.54(g)(2).

¹¹¹ *Id.*

¹¹² *NPRM* at para. 12. We clarify that this requirement is separate from the local service requirement in Section 340(b)(1), which imposes restrictions on the satellite carriage of an SV station, regardless of format.

¹¹³ Broadcaster Associations Comments at 14; DIRECTV Comments at 4 and Reply at 8; Dish Comments at 2.

¹¹⁴ Broadcaster Associations Comments at 14-15.

¹¹⁵ See *supra* para. 16. See also *DIRECTV Reply* at 8.

⁹⁹ See NAB *ex parte* (dated Oct. 22, 2010) at 1, 3-6 ("*NAB Oct. 22 ex parte*") (suggesting local stations in four DMAs—Dayton, OH; Hartford-New Haven, CT; Lansing, MI; and Sherman, TX-Ada, OK—are at risk of being overshadowed by a SV station from an adjacent, larger market). In its *ex parte*, NAB provided staff with tables "reflecting the extent to which out-of-market duplicating network stations are 'significantly viewed' in several local markets." *Id.*

¹⁰⁰ See 47 CFR 76.65 (requiring broadcasters and MVPDs to negotiate in good faith).

¹⁰¹ See Appendix B final rule 47 CFR 76.54(g)(1).

language of the HD format requirement in Section 340(b)(2) applies only when a satellite carrier transmits an SV station in HD format. Therefore, in order for a satellite carrier to retransmit to a subscriber an SV station in SD format, the statute does not require satellite carriage of the local station affiliated with the same network in SD format.

30. Accordingly, we adopt our tentative conclusion that Section 340(b)(2) only limits satellite carriage of an SV station in HD format and does not apply if the satellite carrier only carries the SV station in SD format, and we adopt this requirement in new Section 76.54(g)(2).¹¹⁶ We also adopt our proposal that, for purposes of this provision, "HD format" refers to a picture quality resolution of 720p, 1080i, or higher.¹¹⁷ We received no opposition to this proposal.

2. "HD Format" Requirement Applies When a Local Station Makes Itself Technically and Legally "Available" to Satellite Carrier

31. We conclude that, for a local (in-market) station to be "available" for purposes of the "HD format" requirement in Section 340(b)(2), the local station must: (1) Timely request carriage (*i.e.*, elect mandatory carriage or grant retransmission consent); (2) provide a good quality HD signal to the satellite carrier's local receive facility (LRF) in accordance with Section 76.66(g) of the Commission's rules; and (3) otherwise comply with Sections 76.65 and 76.66.¹¹⁸ We believe that the statute's use of the term "available," instead of "broadcast" or "transmitted," signifies that Congress did not intend a narrow technical meaning and affords us discretion to create a workable framework for satellite carriage of SV stations. Our conclusion is supported by Dish and DIRECTV,¹¹⁹ while the Broadcaster Associations oppose it.¹²⁰

32. The STELA establishes the new "HD format" requirement in Section

340(b)(2) to permit a satellite carrier to retransmit an SV network station in HD "only if such carrier also retransmits in high definition format the signal of a station located in the local market of such subscriber and affiliated with the same network whenever such format is available from such station."¹²¹ In the NPRM, we sought comment on the significance of this language. We also sought comment on whether satellite carriers would face any technical problems in complying with our proposed rules.

33. The STELA does not define the term "available" for purposes of Section 340.¹²² The legislative history likewise does not explain the meaning of the term. The Satellite Carriers and Broadcaster Associations offer competing interpretations as to what "available" should mean in this context. Dish argues that we should interpret this language to mean that, "if the local station has not elected must carry and has not signed a retransmission consent agreement, or fails to provide a good quality signal in accordance with [Section] 76.66(g), then the signal should be deemed not available for purposes of the "HD format" requirement], and the satellite carrier should be able to supply the SV station in HD."¹²³ Dish argues that this interpretation is necessary to prevent a local station from depriving satellite subscribers of both the local and the SV station in the event of an impasse in retransmission negotiations, which they assert would be "a result directly at odds with Congress' express intent to make SV stations more available to satellite subscribers."¹²⁴ The Broadcaster Associations oppose Dish's proposal, asserting that the Satellite Carriers' interpretations of the new "HD format" requirement "are motivated by a desire to affect retransmission consent negotiations."¹²⁵

34. The Broadcaster Associations argue that the term "available" should

mean "whenever the television station is transmitting or broadcasting the relevant channel in HD format."¹²⁶ They argue that this interpretation is most consistent with other parts of the statute, such as Sections 339¹²⁷ and 342¹²⁸ of the Act.¹²⁹ We disagree. The Sections cited by the Broadcaster Associations pertain to a different use of the term "available" in different contexts and are expressly limited to those contexts. Moreover, even if we were to rely on the definition of "available" in Section 339 or the reference to "availability" in Section 342, the term "available" in the context of SV carriage would remain ambiguous. Section 339 relates to whether a satellite carrier's local-into-local package is "available" to a subscriber. If so, the subscriber is not eligible for distant signals (*i.e.*, "no distant, where local"). In the context of HD signal availability in Section 340, ascribing this meaning to the term "available" could support either the Satellite Carriers' interpretation that the HD signal is not available if the local station does not grant consent for retransmission or the Broadcaster Associations' interpretation that the HD signal is available if broadcast.¹³⁰ Similarly, Section 342 refers to the "availability level" of a satellite signal as a means of defining "good quality satellite signal" for purposes of a satellite carrier's eligibility for certification as a "qualified carrier."¹³¹ We do not see the relevance of satellite signal coverage in the context of Section 342 to the interpretation of Section 340. Moreover, here again, even by strained analogy, signal availability could mean the physical presence of the signal, as

¹²⁶ *Id.* at 15.

¹²⁷ Section 339(a)(2)(H) of the Act defines the term "available" in this limited context (*i.e.*, "no-distant where local"):

(H) Available defined. For purposes of this paragraph, a satellite carrier makes available a local signal to a subscriber or person if the satellite carrier offers that local signal to other subscribers who reside in the same zip code as that subscriber or person.

47 U.S.C. 339(a)(2)(H). See *also* Broadcaster Associations Reply at 14–15 (citing 47 U.S.C. 339(a)(2)(C)(i)).

¹²⁸ The Broadcaster Associations also argue that, in the qualified satellite carrier certification context in Section 342 of the Act, the "availability level of a satellite signal" "means that the satellite carrier is retransmitting the satellite signal in a manner to satisfy the 'good quality satellite signal' requirements." Broadcaster Associations Reply at 15 (citing 47 U.S.C. 342(e)(2)(A)(i)).

¹²⁹ *Id.* at 15.

¹³⁰ For example, the definition in Section 339 does not shed light on whether the term "available" takes into account practical considerations or whether it is sufficient for a signal simply to be theoretically available.

¹³¹ 47 U.S.C. 342 (describing the process and grounds for the Commission to issue a "qualified carrier" certification pursuant to 17 U.S.C. 119(g)).

¹¹⁶ See Appendix B final rule 47 CFR 76.54(g)(2)(i).

¹¹⁷ See Appendix B final rule 47 CFR 76.54(g)(2)(ii). NPRM at para. 12 (citing, *e.g.*, *Local Broadcast Signal Carriage First Report and Order*, 66 FR 16533, March 26, 2001 (discussing several formats that are considered "high definition"); *Local Broadcast Signal Carriage Second Report and Order*, 73 FR 24502, May 5, 2008. See also, *e.g.*, Newton's Telecom Dictionary definition of HDTV at 389 (20th ed. 2004) and the Commission's "DTV Shopping Guide" for consumers at <http://www.dtv.gov/shopgde.html>).

¹¹⁸ See 47 CFR 76.65 and 76.66. These rules govern, *inter alia*, requirements to negotiate in good faith, procedures for requesting carriage, carriage of stations that substantially duplicate, and other matters related to satellite carriage of local stations.

¹¹⁹ See Dish Comments at 7 and DIRECTV and Dish Sept. 22 SV Talking Points at 3.

¹²⁰ Broadcaster Associations Reply at 14–16.

¹²¹ See 47 U.S.C. 340(b)(2) (2010), as amended by the STELA sec. 203(a).

¹²² The STELA amendments to the Communications Act use the word "available" with respect to a signal in three different contexts: (1) In Section 340 with respect to an HD signal; (2) in Section 339 in reference to whether the satellite carrier is retransmitting the local station to a subscriber as part of the local-into-local service package, see 47 U.S.C. 339(a)(2)(A)(i)(I), (2)(B)(i)(I) and (II), (2)(C)(i) and (ii), (2)(D)(iii), (2)(E), and (2)(H); and (3) "availability" in Section 342 with respect to a satellite carrier's "good quality signal," see 47 U.S.C. 342(e)(2)(A)(i). As discussed, *infra*, only Section 339 offers a definition of "available" but expressly limits this definition: "for purposes of this paragraph," that is, to Section 339(a).

¹²³ Dish Comments at 7–8.

¹²⁴ *Id.* at 8.

¹²⁵ Broadcaster Associations Reply at 12.

the Broadcaster Associations argue, or the ability to receive and use the signal, as the satellite carriers contend.

35. In contrast to the Broadcaster Associations' attempt to import uses of the word from other contexts, the Satellite Carriers describe the circumstances in which the HD format requirement is intended to apply: When the satellite carrier receives a station's HD signal and the permission to retransmit it but chooses not to retransmit the HD version and instead converts the HD signal to a standard definition ("SD") signal.¹³² We believe that this interpretation is most consistent with common usage of the term "available." In contrast, we think it strains the common meaning of the term to consider "available" a signal that the satellite carrier is legally barred from carrying.

36. The Satellite Carriers also address the practical impact of defining the term "available" as suggested by the Broadcaster Associations. They explain that they offer local service in some markets only in HD.¹³³ Therefore, an SV station originating from such a market would have one HD feed covering both the station's local market and SV area and there would be no technical way for the satellite carrier to down-convert the HD feed signal to SD only in the SV area. Moreover, a satellite carrier would likely not have the capacity on its spot beam to add a duplicative, SD version of the station.¹³⁴ Therefore, if a local station withholds retransmission consent, the Satellite Carriers would have to either down-convert the SV station from HD to SD in its own local market or not carry it as an SV station, frustrating the intent of the statute.¹³⁵

37. The question then is whether an HD signal is "available" for purposes of the statute any time a broadcaster is transmitting an HD signal, or whether the term "available" takes into account

practical and legal considerations, such as whether the broadcaster is delivering a "good quality signal" to the satellite carrier¹³⁶ and the satellite carrier is legally permitted to carry it (*i.e.*, the broadcaster has elected mandatory carriage or granted retransmission consent).¹³⁷ We believe the term is ambiguous¹³⁸ and thus should be defined in a manner that best effectuates the text, history and purposes of the statute.¹³⁹ As discussed above, we believe the overriding goal of the legislative changes made in Section 340 is to facilitate satellite carriage of SV stations and remove the obstacles to carriage created by our interpretation of SHVERA.¹⁴⁰ With this goal in mind, we find that the term "available" within the context of Section 340(b)(2) is best interpreted by taking into account whether the satellite carrier has the legal authority to transmit the local broadcaster's signal and has been provided a "good quality" signal, and we believe that this interpretation is most consistent with common usage of the term.

38. We agree with the Broadcaster Associations that our rules must protect localism,¹⁴¹ but disagree that we must protect the in-market station at the cost of making satellite carriage of the SV

station impractical.¹⁴² The Broadcaster Associations' argument fails to take into account that the SV station is generally not significantly viewed throughout an entire market. Indeed, the Satellite Carriers contend that stations that are significantly viewed outside of their own markets are generally significantly viewed only in small portions of neighboring markets, making it unlikely that satellite carriers could use SV stations to replace local stations in other markets.¹⁴³ As noted above, we also find it unlikely that an SV station could permanently substitute for a local in-market station to the satisfaction of subscribers throughout the market.¹⁴⁴

39. We are persuaded that, if we were to adopt the Broadcaster Associations' interpretation that a station's HD signal is "available" even when it has not granted retransmission consent or is not providing a "good quality" signal, the satellite carrier in many cases will have to downconvert the SV station or not carry the SV station at all due to limited satellite capacity,¹⁴⁵ and Congressional intent will, again, be thwarted. If, on the other hand, we were to conclude that a station's HD signal is not "available" unless the carrier has the legal right to carry the station and a "good quality" signal is being provided, the satellite carrier will be able to carry an SV station and, in the overwhelming majority of cases, will continue to have the incentive to reach a retransmission consent agreement with the local station. Thus, this interpretation will likely result in carriage of both the SV and local stations. We acknowledge that this interpretation may affect retransmission consent negotiations in some situations by giving a satellite carrier the opportunity to provide network programming to some subscribers through the SV station. This interpretation may also affect the local

¹³⁶ See 47 U.S.C. 338(b).

¹³⁷ See 47 U.S.C. 325(b).

¹³⁸ See, e.g., *Notural Resources Defense Council v. EPA*, 571 F.3d 1245 (DC Cir. 2009) (term "reasonably available" is ambiguous where statute did not specify how to define the term, so agency is permitted to reasonably interpret statute); *State of Hawaii ex rel. Atty. Gen. v. FEMA*, 294 F.3d 1152, 1161–1162 (9th Cir. 2002) (observing that "[a]s the dictionary definitions of the word reveal, the term 'available' is ambiguous in the current context. * * * Under the first definition, 'available' takes into account practical considerations * * *; under the second definition, the term suggests instead a more abstract or theoretical concept without regard for cost, risk or uncertainty"). We note that the court finds ambiguous the definition from the dictionary on which the Broadcaster Associations rely on as being clear. Broadcaster Associations Reply at 15 (citing to American Heritage Dictionary of the English Language at 127 (3d ed. 1996) (defining available as "1. Present and ready for use; at hand; accessible * * * 2. Capable of being gotten; obtainable").

¹³⁹ See *Chevron U.S.A., Inc. v. Notural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (where statute's plain terms do not directly address precise question at issue and statute is ambiguous on the point, courts are required to defer to the implementing agency's reasonable construction); see also *Notional Cable and Telecommunications Ass'n v. Brond X Internet Services*, 545 U.S. 967, 980 (2005) (ambiguities in statutes within an agency's jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in a reasonable fashion); *Verizon Comm's Inc. v. FCC*, 535 U.S. 467, 539 (2002) (under *Chevron* doctrine, courts generally defer to agency's reasonable interpretation of an ambiguous provision in its enabling statute).

¹⁴⁰ See *supra* para. 15.

¹⁴¹ See, e.g., Broadcaster Associations Comments at iv.

¹⁴² See, e.g., NAB *ex parte* (dated Oct. 7, 2010) Significantly Viewed Talking Points Appendix at 3 ("NAB Oct. 7 SV Talking Points").

¹⁴³ DIRECTV and Dish *Sept. 22 SV Talking Points* at 1. *But see* NAB *Oct. 22 ex parte* at 1, 3–6 (the Broadcaster Associations disagree, and contend that there are some small markets in which there is substantial "overshadowing" by a SV station from an adjacent, larger market (e.g., Dayton, OH; Hartford-New Haven, CT; Lansing, MI; and Sherman, TX—Ada, OK DMAs)). Neither side quantifies the prevalence of (or potential for) overshadowing. We agree that overshadowing is a concern, but the potential for overshadowing already exists in the cable context, and there is no evidence that overshadowing is currently a problem in the cable context or would be more prevalent in the satellite context.

¹⁴⁴ See *supra* para. 23.

¹⁴⁵ DIRECTV and Dish *Sept. 20 SV Talking Points* at 2 ("explaining that under the Broadcaster Associations' interpretation, "in the event of a retrans dispute, the satellite carrier must downrez or black out the SV station").

¹³² DIRECTV and Dish *Sept. 22 SV Talking Points* at 1. "Every broadcast station that has an HD feed and is carried by a satellite carrier makes the HD feed 'available' to the satellite carrier—even if the satellite carrier does not retransmit the HD format of that station to its subscribers. This is because, as a technical matter, the satellite carrier offers [SD] service in such situations by taking the HD signal and downrezzing it to [SD]. Thus, the HD signal is 'available to the satellite carrier,' but the satellite carrier does not 'retransmit to a subscriber in [HD] format the signal of [such] station'—exactly the situation in which Congress meant to restrict the format of [SV] importation. So, if a satellite carrier offered an entire market in SD format only, it could not import a [SV] station in HD format because the HD format of the in-market station is 'available to it.'" Downrezzing refers to reducing the resolution from high definition to standard definition.

¹³³ See DIRECTV and Dish *Sept. 20 SV Talking Points*.

¹³⁴ See *id.* at 4.

¹³⁵ DIRECTV Comments 4–5; Reply at 12.

station's leverage in negotiations because in certain areas of the DMA it would no longer be the only source of programming from that network to some satellite subscribers. We conclude, however, that this is the best interpretation of the statutory language because it ensures that the overall intent of the statutory provisions to promote SV carriage is carried out.¹⁴⁶

40. Therefore, we find that Section 340(b)(2) is best interpreted to enable satellite TV consumers to receive both the SV and in-market stations as part of their carrier's local service package.¹⁴⁷ Accordingly, we amend Section 76.54(g)(2).¹⁴⁸ We note, however, that our interpretation here assumes that both parties are negotiating in good faith in compliance with our rules.¹⁴⁹ If the local station is willing to grant consent and make its HD signal available, but the satellite carrier is not negotiating for retransmission consent in good faith, as required by Section 76.65, then the local station's HD signal will be deemed available. The amended Section 76.54(g)(2) includes this condition.¹⁵⁰

3. "HD Format" Requirement Applies to a Local Station's HD Multicast Signal

41. We find that the "HD format" requirement is best interpreted to require carriage of any HD signal of a local station affiliated with the same network as the SV station, regardless of whether the local station broadcasts the HD signal as a primary or as a secondary multicast stream.¹⁵¹ The Broadcaster Associations and Dish debate whether the statute's use of the term "signal" includes a multicast stream, with the Broadcaster Associations arguing it does and Dish arguing it does not.

42. In the NPRM, we sought comment on how the "HD format" requirement in Section 340(b)(2) should apply in the event a satellite carrier wants to retransmit an SV network affiliate in HD and there is an in-market (local) station that is broadcasting multiple streams of programming ("multicasting") and more than one of the streams is in HD format

and affiliated with a network. We asked whether the satellite carrier is required to carry the secondary stream in HD in order to be permitted to retransmit an SV station affiliated with the same network in HD, notwithstanding that the in-market station's primary stream is affiliated with a different network. In other words, would a satellite carrier be required to carry more than one HD programming stream of an in-market station if the in-market station is multicasting HD streams that are affiliated with different networks in order for the satellite carrier to carry an SV station affiliated with each network in HD? We also considered whether we could address this situation on a case-by-case basis. In their comments, both the Broadcaster Associations and the Satellite Carriers seek a Commission decision on the multicast question.¹⁵²

43. We conclude that the statute's use of the term "signal" in this context does not differentiate between streams that are primary or secondary.¹⁵³ For purposes of carriage of SV signals in HD, the question is whether there is an in-market station affiliated with the same network as the SV station that makes its HD signal available to the satellite carrier. If so, the satellite carrier may not carry the SV station in HD format unless it carries the local station affiliated with the same network in HD format. Dish argues that Section 340(b)(2) does not expressly use the term "multicast stream," but, as noted by the Broadcaster Associations, this section also does not expressly use the term "primary stream."¹⁵⁴ Dish notes that, for purposes of the broadcast carriage requirements, a satellite carrier is generally only required to carry the stream that a station deems its "primary" stream if the station elects mandatory carriage.¹⁵⁵ That carriage requirement,

however, is not determinative of which signal a satellite carrier is required to carry in order to carry a particular SV station in HD format under Section 340(b)(2). As stated above, when an SV station is carried in HD, we interpret Section 340(b)(2) as requiring carriage of any available HD signal of a local station affiliated with the same network as the SV station. We amend Section 76.54(g)(2) accordingly.¹⁵⁶

44. Though appearing to acknowledge that the "HD format" requirement applies to multicast channels, DIRECTV expresses concern that applying the HD format requirement to multicast streams would make carriage of SV stations technically problematic because of what it calls the "mushroom" problem: that is, "if a new, [HD] network affiliate suddenly appeared on the multicast stream of an existing station, [DIRECTV] would have to drop or downrez the [SV] station until [DIRECTV] could negotiate carriage and make room for the 'new' local station."¹⁵⁷ We believe our definition of "available" in the HD format requirement may alleviate this "mushroom" problem in many cases because a new HD multicast stream would not be available to the satellite carrier until the station grants retransmission consent for that stream. Additionally, if the new HD multicast stream is a new station, our existing satellite carriage rules already recognize that satellite carriers may face technical issues associated with commencing carriage of new broadcast signals in a local market.¹⁵⁸ We recognize, however, that a satellite carrier may nonetheless face a "mushroom" problem where a new HD multicast stream is introduced by an existing station in the local market and such station has previously granted carriage consent. Furthermore, the satellite carrier may not be able to accommodate the new HD multicast stream in the market on its spot beam. Therefore, to minimize consumer disruption, we recognize that satellite carriers may need additional time to come into compliance with the HD format rule without having to drop an

¹⁴⁶ DIRECTV and Dish *Sept. 22 SV Talking Points* at 1 ("Treating satellite carriers like cable operators with respect to significantly viewed service would not give satellite carriers undue leverage in retransmission consent negotiations").

¹⁴⁷ DIRECTV Reply at 3, 11; DIRECTV Comments at 5. DIRECTV agreed with Dish's proposal in their joint *ex parte* presentations. See, e.g., DIRECTV and Dish *Sept. 20 SV Talking Points*. This interpretation of "available" applies only with respect to the SV provisions in STELA and not to other provisions in STELA, including Section 339 (47 U.S.C. 339).

¹⁴⁸ See Appendix B final rule 47 CFR 76.54(g)(2).

¹⁴⁹ See 47 CFR 76.65(a).

¹⁵⁰ See Appendix B final rule 47 CFR 76.54(g)(2)(iii).

¹⁵¹ A station may be affiliated with more than one network.

¹⁵² See Broadcaster Associations Comments at 16 and Dish Reply at 11. The Broadcaster Associations contend that case-by-case multicast determinations would be discriminatory and would violate the STELA. Broadcaster Associations Comments at 16.

¹⁵³ DIRECTV at 5; Broadcaster Associations Reply at 10. For example, a local station may be affiliated with two different networks and broadcast programming from both networks using its digital signal capacity to air two or more signal streams simultaneously. If the local station makes an HD signal affiliated with a network available to the satellite carrier, and that carrier wishes to carry the HD signal of an SV station affiliated with the same network, Section 340(b)(2) requires carriage of the local station's HD signal, as discussed, *infra*. We conclude that it is irrelevant whether the local affiliate's broadcast of the HD signal is aired on a primary or secondary multicast stream, as long as the HD signal is available to the satellite carrier.

¹⁵⁴ Dish Comments at 6; Broadcaster Associations Comments at 16.

¹⁵⁵ 47 CFR 76.66(b). Dish Reply at 12-13. Satellite carriers are required to carry multicast streams only in Alaska and Hawaii. See 47 CFR 76.66(b)(2).

¹⁵⁶ See Appendix B final rule 47 CFR 76.54(g)(2).

¹⁵⁷ DIRECTV Comments at 4-5. DIRECTV explains that, from its perspective, "a new multicast network affiliate can appear as quickly as a mushroom on the lawn after a rainy night." DIRECTV Reply at 12 (explaining "the moment a new multicast network affiliate appeared, DIRECTV would either have to carry it in HD or drop an SV station affiliated with the same network that it had been carrying").

¹⁵⁸ See 47 CFR 76.66(d)(3)(iii) (providing 90 days for the satellite carrier to commence carriage of a new station). See also 47 CFR 76.66(d)(2)(iv) (requiring satellite carriage within 90 days of receiving a mandatory carriage request in a new local-into-local market or upon commencing local-into-local service).

existing SV station while they make the technical adjustments necessary to carry a new HD format network stream.¹⁵⁹ We will consider special circumstances on a case-by-case basis, considering when the satellite carrier was informed of the introduction of a multicast stream containing HD signals in relation to the existing HD carriage of an SV station affiliated with the same network, as well as the carrier's compliance with its notice requirements with respect to carriage of SV signals.¹⁶⁰

D. Statutory Exceptions to the Subscriber Eligibility Limitations

45. While the STELA revises the subscriber eligibility limitations on receipt of SV service in Sections 340(b)(1) and 340(b)(2), it does not amend the statutory exceptions to those limitations in Sections 340(b)(3) and 340(b)(4).¹⁶¹ As noted above, the Section 340(b)(3) exception permits a satellite carrier to offer an SV network station to a subscriber when there is no local network affiliate present in the local market,¹⁶² and the Section 340(b)(4) exception permits a satellite carrier to privately negotiate with the local network station to obtain a waiver of the eligibility restrictions.¹⁶³ The Broadcaster Associations argue that if Section 340(b)(1) were construed simply to require receipt of some local-into-local service, rather than local-into-local carriage of the local affiliate of the same network as the SV station, that reading would render superfluous the exceptions to Section 340(b)(1) contained in Sections 340(b)(3) and (b)(4).¹⁶⁴ To support their argument, the Broadcaster Associations rely on the Commission's 2005 decision that the "best reading" of the SHVERA version of Section 340(b)(1) required receipt of the

local affiliate of the same network because, under any other reading, "there would be no need" for the Section 340(b)(3) or (b)(4) exceptions to Section 340(b)(1).¹⁶⁵ We reject the Broadcaster Associations' argument and find that our 2005 interpretation was not necessary to give effect to the Section 340(b)(3) and (b)(4) exceptions.¹⁶⁶ Giving effect to the most natural reading of Section 340(b)(1)—which lacks the "same network affiliate" language found elsewhere in Section 340 and simply requires receipt of some local-into-local service as a condition of retransmitting SV stations—does not render either Section 340(b)(3) or Section 340(b)(4) superfluous. For example, in a situation where a satellite carrier does not offer a local-into-local package and thus Section 340(b)(1) would otherwise prohibit retransmission of any SV network station, Section 340(b)(3) would allow retransmission of an SV station to subscribers where there is no local station affiliated with the same television network as the SV station in the market (e.g., an SV station that is an ABC affiliate could be retransmitted if there is no local ABC affiliate). Likewise, if a subscriber does not receive the local-into-local package, thereby failing to meet the requirements of Section 340(b)(1), retransmission of an SV station to that subscriber would nonetheless be permissible under Section (b)(4) if the local station affiliated with the same network as the SV station grants a waiver from the requirements of Section 340(b)(1) (e.g., the local ABC affiliate permits the satellite carrier to retransmit an SV station that is an ABC affiliate). These examples show that the exceptions of (b)(3) and (b)(4) have meaning even when we read (b)(1) simply to require receipt of some local-into-local service as a condition of retransmitting SV stations. Further, we reject the Broadcaster Associations' argument that because Congress did not amend Sections 340(b)(3) and (b)(4) when it adopted the STELA in 2010, the Commission may not depart from its 2005 interpretation of Section 340(b)(1).¹⁶⁷ This argument ignores that an agency is free within the limits of reasoned interpretation to change course so long as it adequately justifies the

change.¹⁶⁸ In 2005, the Commission construed what it found to be an ambiguous provision in Section 340(b)(1) by adopting a reading that the Commission believed would best harmonize Section 340(b)(1) with Sections 340(b)(2), (b)(3) and (b)(4).¹⁶⁹ Given the modifications to Sections 340(b)(1) and (b)(2) enacted in STELA and Congress's intent to ease carriage of SV stations, nothing in that legislation suggests that Congress intended to lock in the Commission's 2005 interpretation of Section 340(b)(1) or restrict the Commission's discretion to interpret the revised eligibility requirements. As explained above, we now conclude that our earlier reading was not in fact necessary to harmonize the various provisions of Section 340(b). Moreover, our reading of Section 340(b)(1) here better serves the STELA's goals of improving service options for satellite subscribers by allowing SV carriage in additional situations.

46. In the 2005 *SHVERA Significantly Viewed Report and Order*, the Commission interpreted the Section 340(b)(3) exception to allow a satellite carrier to retransmit an SV station to a subscriber when there is no local affiliate of the same network present in that market, provided that the subscriber subscribes to and receives the carrier's local-into-local service.¹⁷⁰ Under our new interpretation of the subscriber eligibility limitations in Section 340(b)(1) and (2), the Section 340(b)(3) exception permits a subscriber to receive an SV network affiliate, even if he or she does not subscribe to local-into-local service, if there is no affiliate of that network in his or her local market.¹⁷¹ In other words, Section 340(b)(3) operates as an exception to any limitations on subscriber eligibility to receive an SV station if there is no affiliate of the same network as the SV station in the local market. Because it gives effect to the language of Section

¹⁵⁹ We recognize that the HD format rule may require a satellite carrier to drop an existing SV station if it is not able to accommodate the new HD signal in the market on its spot beam. In such cases, the satellite carrier will be afforded a reasonable amount of time to inform its subscribers that it will be dropping the SV station.

¹⁶⁰ See 47 CFR 76.66(d)(3)(iii) and 47 CFR 76.54(e) (requiring satellite carriers that intend to carry SV stations to provide written 60 days notice to all TV stations assigned to the same local market).

¹⁶¹ 47 U.S.C. 340(b)(3) and (4). We note that the STELA § 103 does amend the waiver provision in the corresponding satellite statutory copyright license in 17 U.S.C. 122(a)(2) to eliminate the now out-dated "sunset" provision and replace the term "superstation" with "non-network station," consistent with other references in the statute (see *supra* note 25).

¹⁶² *Id.* at 340(b)(3). See *supra* para. 10 (for statutory text).

¹⁶³ *Id.* at 340(b)(4). See *supra* para. 10 (for statutory text).

¹⁶⁴ See NAB *ex parte* (dated Nov. 18, 2010) at 4-5 ("NAB Nov. 18 *ex parte*").

¹⁶⁵ Broadcaster Associations Comments at 10-11; NAB Nov. 18 *ex parte* at 4-5 (citing *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17305-17306, paras. 70-71).

¹⁶⁶ The Satellite Carriers support changing the interpretation to comport with the literal language of 47 U.S.C. 340(b)(1) and (b)(3). DIRECTV Comments at 4 and Reply at 8; Dish Comments at 2.

¹⁶⁷ NAB Nov. 18 *ex parte* at 6.

¹⁶⁸ See *National Cable and Telecommunications Association v. Brand X Internet Services*, 545 U.S. 967, 980-981 (2005).

¹⁶⁹ Compare *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17305, para. 70 ("Subscriber receipt of 'local-into-local' service is unambiguously required by the statute") with *id.* ("Subscriber receipt of a specific local network affiliate * * * ensp." is the best reading of 47 U.S.C. 340(b)(1) in the overall context of Section 340").

¹⁷⁰ *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17309, para. 80.

¹⁷¹ For example, the statutory exceptions in 47 U.S.C. 340(b)(3) and (4) would still apply where local-into-local service is not available to a subscriber for technical reasons (such as the spot beam does not cover the entire DMA or its reception is blocked for an individual subscriber by terrain or foliage) or if local-into-local service is not yet offered by the satellite carrier to a subscriber's market. See *STELA—Significantly Viewed NPRM*, *supra* note 3, at para. 18.

340(b)(3), as well as the amended language of the statute's subscriber eligibility limitations, and will serve the STELA's overarching goal of fostering SV carriage while protecting localism, we conclude that our new interpretation represents the best reading of Section 340(b)(3) in the context of the statute as a whole.

47. In this respect, we modify the Commission's 2005 interpretation of Section 340 and decline to adopt our tentative conclusion in the NPRM that the statutory exceptions should continue to apply as before. Section 340(b)(3) allows a satellite subscriber to receive an SV station notwithstanding the restrictions imposed by Sections 340(b)(1) and (b)(2) if there are no network stations affiliated with the same network as the SV station. Thus, even if the subscriber does not subscribe to local-into-local service, as would otherwise be required by Section 340(b)(1), the subscriber can receive an SV station if there is no local station affiliated with the same network as that SV station. We recognize that the compulsory copyright license, now in 17 U.S.C. 122(a)(2), limits SV service to markets in which local-into-local service is offered. However, we disagree that this requires us to read a requirement into the Communications Act that is not there. The compulsory copyright license in 17 U.S.C. 122(a)(2) permits waivers and automatically grants them if the in-market station affiliated with the same network as the out-of-market SV station does not respond to the satellite carrier's waiver request.¹⁷² As a practical matter, if there is no affiliate in the market, then there is no affiliate who can respond to a waiver request or grant a waiver under Section 122(a)(2). Thus, the satellite carrier could ultimately offer the SV station because the waiver request would, inevitably, go unanswered.¹⁷³ Accordingly, we interpret the Section 340(b)(3) in accordance with its express language. We find it unnecessary to change the text of the rule that corresponds to the Section 340(b)(3) exception because the rule uses the

¹⁷² See 17 U.S.C. 122(a)(2)(B).

¹⁷³ As a practical matter, we also agree with the Satellite Carriers that there would be no aggrieved party by this interpretation. DIRECTV Reply at 9 (noting that "if the same-network broadcaster grants a waiver, it has determined that it would benefit from the delivery of the neighboring station" * * *. If there is no such broadcaster, there is nobody to be harmed even in theory."). Our interpretation, however, is limited to the provisions of the Communications Act. We do not intend to render any opinion with respect to a party's rights under the Copyright Act. See 17 U.S.C. 122(a)(2)(B).

statutory language and is consistent with the interpretation adopted here.¹⁷⁴

E. Dish Petition for Further Rulemaking

48. We decline to consider here Dish's petition for further rulemaking (filed with its comments in this docket) as it is not within the scope of this proceeding.¹⁷⁵ The Dish petition seeks two changes to the Commission's rules.¹⁷⁶ First, Dish asks the Commission to adopt a rule "that tying retransmission consent to restrictions on SV station carriage" violates the requirement that parties negotiate retransmission consent in good faith.¹⁷⁷ Dish's first proposal to change the retransmission consent rules could have been filed in our open proceeding on retransmission consent issues in MB Docket No. 10-71.¹⁷⁸ Second, Dish seeks to amend the Commission's rules for determining when a station qualifies for "significantly viewed" status in order to address the "orphan county" problem, which refers to the situation in which a county in one State is assigned to a neighboring State's DMA and there are few, if any, stations assigned to that DMA which are licensed to communities located in the State in which the county is located.¹⁷⁹ This proposal is better addressed in our proceeding to implement Section 304 of the STELA.¹⁸⁰ We also note, as the Broadcaster Associations point out,¹⁸¹

¹⁷⁴ See Appendix B final rule 47 CFR 76.54(g)(3) and (g)(4). We renumber Sections 76.54(g)(1) and (g)(2) as Sections 76.54(g)(3) and (g)(4), as well as make some other non-substantive changes to these rules.

¹⁷⁵ See Broadcaster Associations Reply at 17 and 23.

¹⁷⁶ See Dish Comments (Petition) at 9.

¹⁷⁷ *Id.* at 9. Section 76.65 of our rules requires TV stations and satellite carriers "to negotiate in good faith the terms and conditions of retransmission consent." 47 CFR 76.65(a). For example, Dish argues that it is not good faith if a local station conditions the grant of its retransmission consent in its local market on a concession from the satellite carrier that it will not carry an SV station affiliated with the same network in the local market. *Id.*

¹⁷⁸ See Broadcaster Associations Reply at 17.

¹⁷⁹ *Id.* at 11. Dish seeks changes to Sections 76.5(i) (definition of "significantly viewed") and 76.54 (rules for demonstrating a station qualifies for "significantly viewed" status). 47 CFR 76.5(i) and 76.54. Several government representatives and citizens from southwest Colorado filed comments in support of Dish's proposals and any other ways for viewers in the counties of La Plata and Montezuma, CO, to receive in-state programming (such as from the Denver, CO DMA). See Appendix. The counties of La Plata and Montezuma, CO are assigned to the Albuquerque-Santa Fe, NM DMA.

¹⁸⁰ Section 304 of the STELA requires the Commission to produce a "Report on In-State Broadcast Programming," due to Congress in August 2011, to address the concerns, such as those voiced by the southwest Colorado group, that in some DMAs, some subscribers are not able to receive stations licensed to communities in their state via satellite. STELA sec. 304.

¹⁸¹ See Broadcaster Associations Reply at 24.

that any changes to the Commission's existing rules for determining significantly viewed status would be inconsistent with the statute's requirement that we use the same rules for making significantly viewed determinations that were in effect for cable operators as of April 15, 1976.¹⁸²

F. Housecleaning Rule Changes

49. In this section, we make non-substantive changes to update our significantly viewed rules. In the NPRM, we sought comment on these rule changes. The Broadcaster Associations and Satellite Carriers support these changes. Accordingly, we adopt the NPRM's proposed housecleaning rule changes.

50. *Section 76.5(i)*. We amend Section 76.5(i) of the rules to replace its references to the term "non-cable" with the term "over-the-air."¹⁸³ In the 2005 *SHVERA Significantly Viewed Report and Order*, the Commission made this change to Section 76.54 to reflect the rule's true meaning, that being to indicate over-the-air viewing.¹⁸⁴ The Commission explained that, in the 1972 *Order*, the concept of significant viewing was adopted to apply to over-the-air households, which at the time essentially meant households without cable (*i.e.*, non-cable households).¹⁸⁵ Thus, amending Section 76.5(i) to change "non-cable" to "over-the-air" reflects the true intent of the rule as it was in 1976, and is more consistent with the STELA's intent to establish parity between cable and satellite.

51. *Section 76.54(c)*. We amend Section 76.54(c) of the rules to strike the outdated reference to the analog Grade B contour.¹⁸⁶ In the 2004 *SHVERA Significantly Viewed Report and Order*, the Commission revised this rule to add the appropriate service contour relevant for a station's digital signal—that being the noise limited service contour ("NLSC").¹⁸⁷ With the completion of the transition, we now can eliminate the reference to the Grade B contour.

¹⁸² 17 U.S.C. 122(a)(2), as amended by STELA (which retained the SHVERA's requirement in the statutory copyright license for SV stations (previously 17 U.S.C. 119(a)(3)) that the Commission use the same rules established for cable operators that were in effect as of April 15, 1976.

¹⁸³ See Appendix B final rule change to 47 CFR 76.5(i).

¹⁸⁴ *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17292-3, para. 32.

¹⁸⁵ *Id.* (citing to 1972 *Cable R&O*, 36 FCC 2d at 175-6, paras. 83-6).

¹⁸⁶ See Appendix B final rule change to 47 CFR 76.54(c).

¹⁸⁷ *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17292, para. 31. (The digital NLSC is defined in 47 CFR 73.622(e).)

G. Order on Reconsideration Dismisses Pending Petition as Moot

52. In this *Order on Reconsideration*, we dismiss as moot the petition for reconsideration filed jointly by DIRECTV and Dish of the Commission's *SHVERA Significantly Viewed Report and Order*.¹⁸⁸ The petition seeks reconsideration of two decisions in the *SHVERA Significantly Viewed Report and Order*.

53. First, the petition challenges the Commission's interpretation that the analog "local service" requirement in former Section 340(b)(1) also contains the "same network affiliate" requirement.¹⁸⁹ The STELA eliminates former Sections 340(b)(1) and (b)(2)(A).¹⁹⁰ The *R&O* accompanying this *Order on Reconsideration* revises the satellite television significantly viewed rules to eliminate the analog local service requirement, as well as the digital "same network affiliate" requirement.¹⁹¹ Accordingly, this issue is moot.

54. Second, the petition challenges the Commission's interpretation of the digital service "equivalent bandwidth" requirement in former Section 340(b)(2)(B).¹⁹² The STELA eliminates the "equivalent bandwidth" requirement in former Section 340(b)(2)(B)¹⁹³ and, in the *R&O* accompanying this *Order*, we revise the satellite television significantly viewed rules to eliminate this requirement.¹⁹⁴ Accordingly, this issue is also moot and we dismiss the petition.

IV. Conclusion

55. In this *R&O*, we implement the STELA amendments to the SV provisions that apply to satellite carriers. We have been mindful that Congress amended the SV provisions to create a more workable framework to facilitate satellite carriage of SV stations and thereby provide satellite subscribers with greater choice of programming and to improve parity and competition between satellite and cable carriage of

broadcast stations. We have also considered the importance of localism and balanced access to SV stations with the benefits of continued carriage of local stations. The rules adopted by this *Order* will advance these goals for the benefit of consumers and the competitive market for video distribution.

V. Procedural Matters

A. Final Regulatory Flexibility Act Analysis

56. As required by the Regulatory Flexibility Act of 1980, as amended ("RFA")¹⁹⁵ the Commission has prepared this present Final Regulatory Flexibility Analysis ("FRFA") relating to this *Report and Order*. As required by the RFA, an Initial Regulatory Flexibility Analysis ("IRFA") was incorporated in the *Notice of Proposed Rulemaking ("NPRM")* to this proceeding.¹⁹⁶ The Commission sought written public comment on the proposals in the *NPRM*, including comment on the IRFA.¹⁹⁷ The Commission received no comments on the IRFA. This present FRFA conforms to the RFA.¹⁹⁸

1. Need for, and Objectives of, the Final Rule Changes

57. This document adopts changes to the Commission's satellite television "significantly viewed" rules to implement Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA).¹⁹⁹ We initiated this proceeding on July 23, 2010 by issuing a Notice of Proposed Rulemaking (NPRM). With this *R&O*, we satisfy the STELA's mandate that the Commission adopt final rules in this proceeding on or before November 24, 2010.

58. Section 203 of the STELA amends Section 340 of the Communications Act, which gives satellite carriers the authority to offer out-of-market but "significantly viewed" broadcast television stations as part of their local service to subscribers.²⁰⁰ The designation of "significantly viewed"

status allows a station assigned to one DMA to be treated as a "local" station with respect to a particular cable or satellite community in another DMA, and, thus, enables cable or satellite carriage into said community in that other DMA. Whereas cable operators have had carriage rights for "significantly viewed" ("SV") stations since 1972, satellite carriers have had such authority only since the 2004 Satellite Home Viewer Extension and Reauthorization Act of 2004 (SHVERA) and may only retransmit SV network stations to "eligible" satellite subscribers. The satellite subscriber eligibility rules impose conditions on when satellite carriers may retransmit SV stations to subscribers. These conditions are intended to prevent satellite carriers from favoring an SV network station over the in-market (local) station affiliated with the same network. We note that the nature of SV carriage under Section 340 is permissive (and not mandatory), meaning the statute applies when a satellite carrier chooses to carry an SV station and has obtained retransmission consent from such SV station.²⁰¹

59. Section 203 of the STELA changes the restrictions on subscriber eligibility to receive SV network stations from satellite carriers. To implement the STELA, we revise our satellite subscriber eligibility rules as follows:

- We find that the local service requirement in amended Section 340(b)(1) requires only that a satellite subscriber receive local-into-local satellite service as a precondition for that subscriber to receive SV stations. We find that the statute no longer requires a satellite subscriber to receive the specific local network station as a precondition for that subscriber to receive an SV station affiliated with the same network.

- We find that amended Section 340(b)(2) no longer requires that a satellite carrier offer "equivalent bandwidth" to the local and SV network station pair and instead imposes an "HD format" requirement. We find that the HD format requirement in amended Section 340(b)(2) requires that, in order to carry an SV station in high definition (HD) format, a satellite carrier must carry the local station affiliated with the same network in HD whenever such format is available from the local station.

- The HD format requirement applies only where a satellite carrier retransmits to a subscriber the SV station in HD format. This requirement does not restrict a satellite carrier from

¹⁸⁸ 2006 *DIRECTV-EchoStar Joint Petition*, at *supra* note 6.

¹⁸⁹ 2006 *DIRECTV-EchoStar Joint Petition* at 9. The petition does not challenge the Commission's interpretation that the digital requirement in former Section 340(b)(2)(A) contains the "same network affiliate" requirement, essentially conceding the plain meaning of that provision.

¹⁹⁰ See *supra* notes 66 and 68 (for former statutory text).

¹⁹¹ See *supra* Section III.B. (for discussion of new Section 340(b)(1)).

¹⁹² 2006 *DIRECTV-EchoStar Joint Petition* at 2.

¹⁹³ See *supra* notes 66 and 68 (for former statutory text).

¹⁹⁴ See *supra* Section III.C. (for discussion of new Section 340(b)(2)). See also *supra* note 40 (for former statutory text).

¹⁹⁵ See 5 U.S.C. 603. The RFA, see 5 U.S.C. 601 *et. seq.*, has been amended by the Contract With America Advancement Act of 1996, Public Law 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

¹⁹⁶ STELA—*Significantly Viewed NPRM*, *supra* note 3, at app. B.

¹⁹⁷ *Id.*

¹⁹⁸ See 5 U.S.C. 604.

¹⁹⁹ The Satellite Television Extension and Localism Act of 2010 (STELA) sec. 203, Public Law 111-175, 124 Stat. 1218, 1245 (2010) (sec. 203 codified as amended at 47 U.S.C. 340, other STELA amendments codified in scattered sections of 17 and 47 U.S.C.).

²⁰⁰ 47 U.S.C. 340.

²⁰¹ *Id.* at 340(d).

retransmitting to a subscriber the SV station in standard definition (SD) format.

For purposes of the HD format requirement, the corresponding local (in-market) station will be considered "available" to the satellite carrier when the station: (1) Elects mandatory carriage or grants retransmission consent; (2) provides a good quality signal to the satellite carrier as required by Section 76.66(g) of the rules; and (3) is otherwise in compliance with the "good faith negotiation" and carriage provisions set forth in Sections 76.65 and 76.66 of the rules. However, the HD signal of the corresponding local station will be deemed "available" despite failure to reach agreement on the terms of retransmission if the satellite carrier is not in compliance with Section 76.65.

The HD format requirement requires satellite carriage of a secondary HD stream of a local station's multicast signal if that stream is affiliated with the same network as an SV station retransmitted in HD to satellite subscribers in the local market.

We modify the Commission's 2005 interpretation of the Section 340(b)(3) exception, which is unchanged by the STELA, and find that, in the context of the newly revised statute, this exception permits a satellite carrier to offer an SV network station to a subscriber when there is no local affiliate of the same network present in the local market, even if the subscriber does not receive local-into-local service.

2. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

60. There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

3. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

61. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.²⁰² The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."²⁰³ In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.²⁰⁴ A

small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration ("SBA").²⁰⁵ Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

62. *Satellite Carriers.* The term "satellite carrier" means an entity that uses the facilities of a satellite or satellite service licensed under Part 25 of the Commission's rules to operate in the Direct Broadcast Satellite (DBS) service or Fixed-Satellite Service (FSS) frequencies.²⁰⁶ As a general practice (not mandated by any regulation), DBS licensees usually own and operate their own satellite facilities as well as package the programming they offer to their subscribers. In contrast, satellite carriers using FSS facilities often lease capacity from another entity that is licensed to operate the satellite used to provide service to subscribers. These entities package their own programming and may or may not be Commission licensees themselves. In addition, a third situation may include an entity using a non-U.S. licensed satellite to provide programming to subscribers in the United States pursuant to a blanket earth station license.²⁰⁷ In the *SHVERA Significantly Viewed Report and Order*, the Commission concluded that the definition of "satellite carrier" includes all three of these types of entities.²⁰⁸

63. *Direct Broadcast Satellite ("DBS") Service.* DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic "dish" antenna at the subscriber's location. DBS, by exception, is now included in

agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the *Federal Register*." 5 U.S.C. 601(3).

²⁰⁵ 15 U.S.C. 632. Application of the statutory criteria of dominance in its field of operation and independence are sometimes difficult to apply in the context of broadcast television. Accordingly, the Commission's statistical account of television stations may be over-inclusive.

²⁰⁶ The Communications Act defines the term "satellite carrier" by reference to the definition in the copyright laws in title 17. See 47 U.S.C. 340(i)(1) and 338(k)(3); 17 U.S.C. 119(d)(6). Part 100 of the Commission's rules was eliminated in 2002 and now both FSS and DBS satellite facilities are licensed under Part 25 of the rules. *Policies and Rules for the Direct Broadcast Satellite Service*, 67 FR 51110, August 7, 2002; 47 CFR 25.148.

²⁰⁷ See, e.g., *DIRECTV 5 Blanket Earth Station License*, DA 04-2526, August 12, 2004.

²⁰⁸ *SHVERA Significantly Viewed Report and Order*, 20 FCC Rcd at 17302-3, paras. 59-60.

the SBA's broad economic census category, "Wired Telecommunications Carriers,"²⁰⁹ which was developed for small wireline firms. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees.²¹⁰ However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled "Cable and Other Program Distribution." The definition of Cable and Other Program Distribution provided that a small entity was one with \$12.5 million or less in annual receipts.²¹¹ Currently, only two entities provide DBS service, which requires a great investment of capital for operation: DIRECTV and EchoStar Communications Corporation ("EchoStar") (marketed as the DISH Network).²¹² Each currently offer subscription services. DIRECTV²¹³ and EchoStar²¹⁴ each report annual revenues that are in excess of the threshold for a small business. Because DBS service requires significant capital, we believe it is unlikely that a small

²⁰⁹ See 13 CFR 121.201, NAICS code 517110 (2007). The 2007 North American Industry Classification System ("NAICS") defines the category of "Wired Telecommunications Carriers" as follows: "This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services; wired (cable) audio and video programming distribution; and wired broadband Internet services. *By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.*" (Emphasis added to text relevant to satellite services.) U.S. Census Bureau, 2007 NAICS Definitions, "517110 Wired Telecommunications Carriers"; <http://www.census.gov/naics/2007/def/ND517110.HTM>.

²¹⁰ 13 CFR 121.201, NAICS code 517110 (2007).

²¹¹ 13 CFR 121.201, NAICS code 517510 (2002).

²¹² See *Thirteenth Annual Cable/MVPD Competition Report*, 74 FR 11102, March 16, 2009. We note that, in 2007, EchoStar purchased the licenses of Dominion Video Satellite, Inc. ("Dominion") (marketed as Sky Angel). See Public Notice, "Policy Branch Information; Actions Taken," Report No. SAT-00474, 22 FCC Rcd 17776 (IB 2007).

²¹³ As of June 2006, DIRECTV is the largest DBS operator and the second largest MVPD, serving an estimated 16.20% of MVPD subscribers nationwide. See *id.* at 687, Table B-3.

²¹⁴ As of June 2006, DISH Network is the second largest DBS operator and the third largest MVPD, serving an estimated 13.01% of MVPD subscribers nationwide. *Id.* As of June 2006, Dominion served fewer than 500,000 subscribers, which may now be receiving "Sky Angel" service from DISH Network. See *id.* at 581, para. 76.

²⁰² 5 U.S.C. 603(b)(3).

²⁰³ 5 U.S.C. 601(6).

²⁰⁴ 5 U.S.C. 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an

entity as defined by the SBA would have the financial wherewithal to become a DBS service provider. We seek comments that have data on the annual revenues and number of employees of DBS service providers.

64. *Fixed-Satellite Service ("FSS")*. The FSS is a radiocommunication service between earth stations at a specified fixed point or between any fixed point within specified areas and one or more satellites.²¹⁵ The FSS, which utilizes many earth stations that communicate with one or more space stations, may be used to provide subscription video service. FSS, by exception, is now included in the SBA's broad economic census category, "Wired Telecommunications Carriers,"²¹⁶ which was developed for small wireline firms. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees.²¹⁷ However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled "Cable and Other Program Distribution." The definition of Cable and Other Program Distribution provided that a small entity was one with \$12.5 million or less in annual receipts.²¹⁸ Although a number of entities are licensed in the FSS, not all such licensees use FSS frequencies to provide subscription services. The two DBS licensees (EchoStar and DIRECTV) have indicated interest in using FSS frequencies to broadcast signals to subscribers. It is possible that other entities could similarly use FSS frequencies, although we are not aware of any entities that might do so.

65. *Television Broadcasting*. The SBA defines a television broadcasting station as a small business if such station has no more than \$14.0 million in annual receipts.²¹⁹ Business concerns included in this industry are those "primarily engaged in broadcasting images together with sound."²²⁰ The Commission has

estimated the number of licensed commercial television stations to be 1,392.²²¹ According to Commission staff review of the BIA/Kelsey, MAPRO Television Database ("BIA") as of April 7, 2010, about 1,015 of an estimated 1,380 commercial television stations²²² (or about 74 percent) have revenues of \$14 million or less and, thus, qualify as small entities under the SBA definition. The Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 390.²²³ We note, however, that, in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations²²⁴ must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. The Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

66. In addition, an element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply do not exclude any television station from the definition of a small business on this basis and are therefore over-inclusive to that extent. Also, as noted, an additional element of the definition of "small business" is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities and our estimates of small businesses to which they apply may be over-inclusive to this extent.

Production, NAICS code 512110; Motion Picture and Video Distribution, NAICS Code 512120; Teleproduction and Other Post-Production Services, NAICS Code 512191; and Other Motion Picture and Video Industries, NAICS Code 512199.

²²¹ See News Release, "Broadcast Station Totals as of December 31, 2009," 2010 WL 676084 (F.C.C.) (dated Feb. 26, 2010) ("Broadcast Station Totals"); also available at http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-296538A1.pdf.

²²² We recognize that this total differs slightly from that contained in *Broadcast Station Totals*, *supra*, note 33; however, we are using BIA's estimate for purposes of this revenue comparison.

²²³ See *Broadcast Station Totals*, *supra*, note 33.

²²⁴ "Business concerns" are affiliates of each other when one concern controls or has the power to control the other or a third party or parties controls or has to power to control both." 13 CFR 121.103(a)(1).

67. *Satellite Master Antenna Television (SMATV) Systems*, also known as *Private Cable Operators (PCOs)*. SMATV systems or PCOs are video distribution facilities that use closed transmission paths without using any public right-of-way. They acquire video programming and distribute it via terrestrial wiring in urban and suburban multiple dwelling units such as apartments and condominiums, and commercial multiple tenant units such as hotels and office buildings. SMATV systems or PCOs are now included in the SBA's broad economic census category, "Wired Telecommunications Carriers,"²²⁵ which was developed for small wireline firms.²²⁶ Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees.²²⁷ However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled "Cable and Other Program Distribution." The definition of Cable and Other Program Distribution provided that a small entity was one with \$12.5 million or less in annual receipts.²²⁸ As of June 2004, there were approximately 135 members in the Independent Multi-Family Communications Council (IMCC), the trade association that represents PCOs.²²⁹ The IMCC indicates that, as of June 2006, PCOs serve about 1 to 2 percent of the multichannel video programming distributors (MVPD) marketplace.²³⁰ Individual PCOs often serve approximately 3,000–4,000 subscribers, but the larger operations serve as many as 15,000–55,000 subscribers. In total, as of June 2006, PCOs serve approximately 900,000 subscribers.²³¹ Because these operators are not rate regulated, they are not required to file financial data with the Commission. Furthermore, we are not aware of any privately published financial information regarding these operators. Based on the estimated number of operators and the estimated number of units served by the largest 10 PCOs, we believe that a substantial number of PCOs may have been

²²⁵ See 13 CFR 121.201, NAICS code 517110 (2007).

²²⁶ Although SMATV systems often use DBS video programming as part of their service package to subscribers, they are not included in Section 340's definition of "satellite carrier." See 47 U.S.C. 340(j)(1) and 338(k)(3); 17 U.S.C. 119(d)(6).

²²⁷ 13 CFR 121.201, NAICS code 517110 (2007).

²²⁸ 13 CFR 121.201, NAICS code 517510 (2002).

²²⁹ See *Eleventh Annual Cable/MVPD Competition Report*, FCC 05–13 (rel. Feb. 4, 2005).

²³⁰ See *Thirteenth Annual Cable/MVPD Competition Report*.

²³¹ *Id.*

²¹⁵ See 47 CFR 2.1(c).

²¹⁶ See 13 CFR 121.201, NAICS code 517110 (2007).

²¹⁷ 13 CFR 121.201, NAICS code 517110 (2007).

²¹⁸ 13 CFR 121.201, NAICS code 517510 (2002).

²¹⁹ See 13 CFR 121.201, NAICS Code 515120 (2007).

²²⁰ *Id.* This category description continues, "These establishments operate television broadcasting studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studios, from an affiliated network, or from external sources." Separate census categories pertain to businesses primarily engaged in producing programming. See Motion Picture and Video

categorized as small entities under the now superseded SBA small business size standard for Cable and Other Program Distribution.²³²

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

68. The final rules do not impose any new reporting, recordkeeping or other compliance requirements.

5. Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

69. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.²³³

70. In the NPRM, we invited comment on whether there were any alternatives we should consider to our proposed implementation of the statutory amendments to Section 340(b) that would minimize any adverse impact on small businesses, but which are consistent with the statute and its goals and also maintain the benefits of our proposals. We explained that STELA's amendments to Section 340(b) intend to facilitate satellite carriage of SV stations, with the expectation that this will increase satellite TV service to consumers and promote regulatory parity between cable and satellite service.²³⁴ We tentatively concluded that our proposed rule changes implement the statute in the way that is most consistent with the plain language of the statute.²³⁵ We also noted that the plain language of the statute did not appear to give us discretion to treat small entities differently from larger ones, but sought comment on this question. We received no comments to the IRFA in the NPRM. We, therefore, affirm our conclusions in the NPRM's IRFA.

71. We find in the *R&O* that Congress amended the SV provisions to create a

more workable framework to facilitate satellite carriage of SV stations and, thus, improve parity and competition between satellite and cable. Satellite carriers, and the SV stations which they would carry,²³⁶ will certainly benefit from the opportunity for increased TV service afforded by the STELA's changes to the SV program. Furthermore, consumers of satellite TV service will benefit from greater choice of programming. We find that any adverse impact to these entities is unlikely because SV carriage under Section 340 is permissive (and not mandatory); that is, the satellite carrier chooses to carry an SV station and the SV station must grant its consent to be carried.²³⁷

72. While we have included this complete FRFA, we note that we could have certified that this rulemaking will not have a "significant economic impact on a substantial number of small entities."²³⁸ The rules impose compliance requirements only on the two DBS service providers, neither of which qualify as a small entity.²³⁹

6. Report to Congress

73. The Commission will send a copy of this *R&O*, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act.²⁴⁰ In addition, the Commission will send a copy of the *R&O*, including the FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the *R&O* and FRFA (or summaries thereof) will also be published in the *Federal Register*.²⁴¹

B. Final Paperwork Reduction Act of 1995 Analysis

74. This Report and Order has been analyzed with respect to the Paperwork Reduction Act of 1995 ("PRA"),²⁴² and does not contain any new or modified information collection requirements.²⁴³ In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small

²³⁶ For example, small broadcast stations will benefit from the opportunity to be delivered as an SV station to more viewers.

²³⁷ See 47 U.S.C. 340(d).

²³⁸ See 5 U.S.C. 605(b).

²³⁹ See *supra* section VIII.A.3.

²⁴⁰ See 5 U.S.C. 801(a)(1)(A).

²⁴¹ See *id.* 604(b).

²⁴² The Paperwork Reduction Act of 1995 ("PRA"), Public Law 104-13, 109 Stat 163 (1995) (codified in Chapter 35 of title 44 U.S.C.).

²⁴³ The Commission does not modify the existing information collections that relate to the Commission's significantly viewed rules and procedures. See OMB Control Nos. 3060-0311 (47 CFR 76.54), 3060-0960 (47 CFR 76.122, 76.123, 76.124, 76.127), and 3060-0888 (47 CFR 76.7).^{*} The Commission will maintain these collections.

Business Paperwork Relief Act of 2002.²⁴⁴

C. Congressional Review Act

75. The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office, pursuant to the Congressional Review Act.²⁴⁵

D. Additional Information

76. For more information on this Report and Order, please contact Evan Baranoff, *Evan.Baranoff@fcc.gov*, of the Media Bureau, Policy Division, (202) 418-2120.

VI. Ordering Clauses

77. Accordingly, *it is ordered* that pursuant to Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA), and Sections 1, 4(i) and (j), and 340 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), and 340, this Report and Order *IS adopted*, and the Commission's rules *are hereby amended* as set forth in the final rule changes appendix (Appendix B) attached to this Report and Order.

78. *It is also ordered* that, pursuant to the authority contained in Sections 203(b) and 307 of the STELA, STELA secs. 203(b) and 307, the rules adopted in this Report and Order *are adopted* and *will be effective* 30 days after date of publication in the *Federal Register*.

79. *It is also ordered* that, pursuant to Sections 1, 4(i) and (j), and 340 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), and 340; and Section 1.429 of our rules, 47 CFR 1.429, the petition for reconsideration in MB Docket No. 05-49 which was filed jointly by DIRECTV and Dish (formerly Echostar) *is dismissed as moot*.

80. *It is further ordered* that, pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), the Commission *will send* a copy of this Report and Order in a report to Congress and the General Accounting Office.

81. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *will send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

²⁴⁴ The Small Business Paperwork Relief Act of 2002 ("SBPRA"), Public Law 107-198, 116 Stat 729 (2002) (codified in Chapter 35 of title 44 U.S.C.); see 44 U.S.C. 3506(c)(4).

²⁴⁵ See 5 U.S.C. 801(a)(1)(A).

²³² 13 CFR 121.201, NAICS code 517510 (2002).

²³³ 5 U.S.C. 603(c)(1) through (c)(4).

²³⁴ See *H.R. 3570 Report* at 4-5; *H.R. 2994 Report* at 16.

²³⁵ Our proposed rules are based on, and largely track, the amended language of the statute.

List of Subjects in 47 CFR Part 76

Satellite television.

Marlene H. Dortch,
Secretary, Federal Communications
Commission.

Final Rules

■ For the reasons discussed in the preamble, the FCC amends 47 CFR part 76 as follows:

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

■ 1. The authority citation for part 76 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

■ 2. Amend § 76.5(i) by removing the words “other than cable television” and adding in their place the words “over-the-air” and in the Note following paragraph (i) remove the word “noncable” each place it appears and add in its place the words “over-the-air”.

■ 3. Amend § 76.54 by revising the first sentence in paragraph (c), revising paragraph (g), removing and reserving paragraph (h), and revising paragraph (i), to read as follows:

§ 76.54 Significantly viewed signals; method to be followed for special showings.

* * * * *

(c) Notice of a survey to be made pursuant to paragraph (b) of this section shall be served on all licensees or permittees of television broadcast stations within whose predicted noise limited service contour, as defined in § 73.622(e) of this chapter, the cable or satellite community or communities are located, in whole or in part, and on all other system community units, franchisees, and franchise applicants in the cable community or communities at least (30) days prior to the initial survey period. * * *

* * * * *

(g) *Limitations on satellite subscriber eligibility.* A satellite carrier may retransmit a significantly viewed network station to a subscriber, provided the conditions in paragraphs (g)(1) and (g)(2) of this section are satisfied or one of the two exceptions to these conditions provided in paragraphs (g)(3) and (g)(4) of this section apply.

(1) *Local service requirement.* A satellite carrier may retransmit to a subscriber the signal of a significantly viewed station if:

(i) Such subscriber receives local-into-local service pursuant to § 76.66; and
(ii) Such satellite carrier is in compliance with § 76.65 with respect to the stations located in the local market into which the significantly viewed station will be retransmitted.

(2) *HD format requirement.* Subject to the conditions in paragraphs (g)(2)(i) through (iv) of this section, a satellite carrier may retransmit to a subscriber in high definition (HD) format the signal of a significantly viewed station only if such carrier also retransmits in HD format the signal of a station located in the local market of such subscriber and affiliated with the same network whenever such format is available from such station, including when the HD signal is broadcast on a multicast stream.

(i) The requirement in paragraph (g)(2) of this section applies only where a satellite carrier retransmits to a subscriber the significantly viewed station in HD format, and does not restrict a satellite carrier from retransmitting to a subscriber a significantly viewed station in standard definition (SD) format.

(ii) For purposes of paragraph (g)(2) of this section, the term “HD format” refers to a picture quality resolution of 720p, 1080i, or higher.

(iii) For purposes of paragraph (g)(2) of this section, the local station’s HD signal will be considered “available” to the satellite carrier when the station:

- (A) Elects mandatory carriage or grants retransmission consent;
- (B) Provides a good quality HD signal to the satellite carrier’s local receive facility (LRF); and
- (C) Complies with the requirements of §§ 76.65 and 76.66.

(iv) Notwithstanding the provisions of paragraph (g)(2)(iii) of this section, if the local station is willing to grant retransmission consent and make its HD signal available to the satellite carrier, but the satellite carrier does not negotiate with the local station in good faith, as required by § 76.65, then the local station’s HD signal will be deemed “available” for purposes of paragraph (g)(2) of this section.

(3) *Exception if no network affiliate in local market.* The limitations in paragraphs (g)(1) and (g)(2) of this section will not prohibit a satellite carrier from retransmitting a significantly viewed network station to a subscriber located in a local market in which there are no network stations affiliated with the same television network as the significantly viewed station.

(4) *Exception if waiver granted by local station.* The limitations in

paragraphs (g)(1) and (g)(2) of this section will not apply if, and to the extent that, the local network station affiliated with the same television network as the significantly viewed station has granted a waiver in accordance with 47 U.S.C. 340(b)(4).

* * * * *

(i) For purposes of paragraph (g) of this section, television network and network station are as defined in 47 U.S.C. 339(d).

* * * * *

Note: The following Appendix will not be included in the Code of Federal Regulations.

Appendix: List of Commenters

Comments:

1. Atkinson, Ronald; resident of Durango, Colorado
2. Brown, Marilyn T.; League of Women Voters of La Plata County
3. Bruen, Elizabeth; resident of Durango, Colorado
4. Calahan, Michael; Citizens For Colorado TV Access
5. City of Durango; City Manager
6. DIRECTV, Inc. (“DIRECTV”)
7. DISH Network L.L.C. (“Dish”)
8. Dulson, Laurie; resident of southwest Colorado
9. Flatten, Ann; resident of La Plata County, Colorado
10. La Plata County, Colorado; Board of County Commissioners
11. National Association of Broadcasters (“NAB”) and the ABC, CBS, FBC (Fox), and NBC Television Affiliates Associations (joint comments) (jointly, the “Broadcaster Associations”)
12. Necchik, Elayne and John; residents of Durango, Colorado
13. Roberts, Ellen; Colorado State Representative, House District 59
14. Salazar, John T.; U.S. House Representative, 3rd District of Colorado
15. Schafer, Marie L.; resident of southwest Colorado
16. Staby, Paul and Carolyn; residents of Durango, Colorado
17. Whitehead, Bruce T.; Colorado State Senator, Senate District 6

Reply Comments:

1. Broadcaster Associations
2. DIRECTV
3. Dish

[FR Doc. 2010–29968 Filed 11–23–10; 4:15 pm]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 371, 375, 386, and 387

[Docket No. FMCSA-2004-17008]

RIN 2126-AA84

Brokers of Household Goods Transportation by Motor Vehicle

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Final rule.

SUMMARY: FMCSA amends its regulations to require brokers that arrange the transportation of household goods in interstate or foreign commerce for consumers to comply with certain consumer protection requirements. Brokers must provide: their U.S. DOT number on their advertisements and Internet Web sites; estimates of expected moving charges and brokerage fees; FMCSA pamphlets containing tips for successful moves and the consumer's rights and responsibilities; and the broker's policies concerning deposits, cancellations, and refunds. This rulemaking is in response to the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) and a petition for rulemaking from the American Moving and Storage Association. This rulemaking is intended to ensure that individual shippers who arrange for transportation of household goods through brokers receive necessary information regarding their rights and responsibilities in connection with interstate household goods moves.

DATES: *Effective date:* The effective date of this final rule is January 28, 2011. *Compliance date for 49 CFR*

387.307(a)(2): Brokers that arrange the transportation of household goods in interstate or foreign commerce must increase their surety bonds or trust funds to the new minimum amount of \$25,000 and have surety companies or trust fund managers file appropriate Forms BMC-84 or BMC-85 with FMCSA no later than January 1, 2012.

ADDRESSES: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> at any time or to U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Brodie Mack, FMCSA Household Goods

Enforcement and Compliance Team Leader, (202) 385-2400.

SUPPLEMENTARY INFORMATION:**Legal Basis for the Rulemaking**

The Secretary of Transportation's (Secretary) general jurisdiction to establish regulations concerning the procurement by property brokers of for-hire transportation in interstate or foreign commerce is found at 49 U.S.C. 13501. Brokers of household goods are a subset of all property brokers and specifically register with FMCSA as household goods brokers as required by 49 U.S.C. 13901 and 13904. This rulemaking applies only to household goods brokers that procure for-hire transportation in interstate or foreign commerce.

The Secretary is authorized to collect from household goods brokers "information the Secretary decides is necessary" to ensure a transportation system that meets the needs of the United States (49 U.S.C. 13101 and 13301). The Secretary also has authority to adopt regulations applicable to registered household goods brokers which "shall provide for the protection of shippers by motor vehicle" (49 U.S.C. 13904(c)). The Secretary's authority to inspect and copy household goods broker records is found at 49 U.S.C. 14122. The Secretary has delegated these various authorities to the FMCSA Administrator (49 CFR 1.73(a)).

This rulemaking is based on the statutory provisions cited above and on the Household Goods Mover Oversight Enforcement and Reform Act of 2005, Title IV, Subtitle B of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) (Pub. L. 109-59). This rulemaking focuses on the business practices of household goods brokers engaged in interstate or foreign commerce. Household goods brokers arrange, but do not perform, the transportation of household goods shipments.

Section 4212 of SAFETEA-LU directs the Secretary to require a household goods broker to provide shippers with the following information whenever the broker has contact with a shipper or a potential shipper:

1. The broker's U.S. DOT number.
2. The FMCSA pamphlet titled, "Your Rights and Responsibilities When You Move."
3. A list of all motor carriers providing transportation of household goods used by the broker and a statement that the broker is not a motor carrier providing transportation of household goods.

Section 4209 of SAFETEA-LU adds new civil penalties for unlawful broker estimating practices and increases existing civil penalties for providing household goods motor carrier or broker services subject to FMCSA jurisdiction without being registered with FMCSA.

The Secretary's general jurisdiction at 49 U.S.C. 13501 authorizes FMCSA to establish shipment estimating and other requirements not specifically mandated by SAFETEA-LU in this final rule.

Background*Existing FMCSA Regulations Applicable to Household Goods Brokers*

Household goods brokers have been regulated by FMCSA and its predecessor agencies for many years and a number of regulations apply to them, including registration requirements (49 CFR part 365), process agent requirements (49 CFR part 366), and financial responsibility¹ requirements (49 CFR part 387). Section 387.307 requires property brokers, including household goods brokers, to maintain a surety bond or trust fund agreement in the amount of at least \$10,000 to provide for payments to motor carriers or shippers, if the broker fails to carry out its agreement to supply transportation by authorized motor carriers.

Part 371 of FMCSA's regulations specifies general property broker transaction record requirements, prohibits misrepresentation of the broker's name or non-carrier status, and prohibits certain rebating and compensation practices. Part 379 specifies general recordkeeping retention periods.

FMCSA may also issue orders to compel compliance, impose civil monetary penalties, revoke the broker's license, or seek Federal court orders to stop statutory and/or regulatory violations. Because household goods brokers do not provide the actual transportation, they are not subject to FMCSA's safety jurisdiction.

Petition for Rulemaking

On March 6, 2003, the American Moving and Storage Association (AMSA) petitioned FMCSA to initiate a rulemaking to amend 49 CFR part 371, "Brokers of Property," to impose specific

¹ The term "financial responsibility," is not specifically defined in subpart C of 49 CFR part 387 (property brokers) and takes the general, commonly understood meaning of responsibility to compensate a party for losses, whether those losses are caused by physical damage, breach of contract, or other type of injury. The use of the term "financial responsibility" in Subpart C does not incorporate the definitions of that term found at 49 CFR 387.5 and 387.29, which apply to Subparts A (motor carriers of property) and B (motor carriers of passengers), respectively, of 49 CFR part 387.

additional requirements on household goods brokers. A copy of AMSA's petition is in docket FMCSA-2004-17008. AMSA's main argument for additional rulemaking was its assertion that there were an increasing number of moving-related Web sites hosted by household goods brokers engaging in unfair business practices.

FMCSA granted AMSA's petition and issued an Advance Notice of Proposed Rulemaking (ANPRM) in 2004 (69 FR 76664, December 22, 2004). In the ANPRM, FMCSA sought answers to 36 questions related to household goods broker issues. By posing these questions, the Agency sought to determine the extent to which the public believes a problem exists with household goods brokers and, if so, whether regulatory or non-regulatory solutions would better solve the problem.

Also in the ANPRM, FMCSA discussed how it became responsible for household goods broker regulatory oversight through the Interstate Commerce Commission Termination Act of 1995 (ICCTA) (Pub. L. 104-88, December 29, 1995, 109 Stat. 803) and the Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Pub. L. 106-159, December 9, 1999, 113 Stat. 1748). The ICCTA gave the Secretary of Transportation jurisdiction over the procurement of interstate motor carrier transportation (49 U.S.C. 13501). The MCSIA, in establishing FMCSA, granted to the Agency regulatory oversight of the property broker regulations. The former Interstate Commerce Commission (ICC) decided on May 16, 1949 (Ex Parte MC-39 "Practices of Property Brokers," 49 M.C.C. 277, at 286) (14 FR 2833, May 28, 1949) that it was necessary to regulate all property brokers, including household goods brokers, in interstate or foreign commerce. In that proceeding, the ICC decided it was unnecessary to regulate household goods brokers separately from general freight brokers.

Generally, the commenters to the ANPRM did not express support for rulemaking action or address many of the specific questions raised in the ANPRM. For example, none of the commenters submitted specific information related to the questions about the estimated number of household goods brokers, or questions about details of the household goods broker business. Commenters did, however, offer useful information and suggestions in other areas to assist FMCSA in developing a rulemaking proposal.

The Proposed Rule

The Notice of Proposed Rulemaking (NPRM) (72 FR 5947, February 8, 2007), addressed the problems and recommendations identified by AMSA in its petition, incorporated requirements mandated by SAFETEA-LU, and adopted some of the recommendations made by commenters to the ANPRM. FMCSA proposed to amend the current broker regulations in part 371 by adding a new subpart B specifically for household goods brokers; amend appendix B of part 386 to incorporate the civil penalties applicable to household goods brokers added by SAFETEA-LU; and amend part 387 to increase the amount of the surety bond or trust fund currently required for household goods brokers.

The proposed rule consisted of five basic elements that are being made final in this rule:

- It would require household goods brokers to disclose to individual shippers critical information designed to educate the shipper and facilitate a satisfactory moving experience.
- It would require household goods motor carriers that are properly licensed and insured.
- It would impose requirements governing estimates, consistent with those statutorily imposed on household goods motor carriers.
- It would incorporate new statutory penalties for providing estimates without an agreement with a household goods motor carrier and for operating without being registered with FMCSA.
- It would adjust for inflation the current minimum level of financial responsibility required of household goods brokers.

Discussion of Comments on the Proposed Rule

FMCSA received 11 comments on the notice of proposed rulemaking (NPRM) (72 FR 5947, February 8, 2007). Several commenters expressed general support for the requirements imposed on household goods brokers. The following sections discuss comments on specific issues and FMCSA's responses to those comments.

Scope of Part 371, Subpart B

Proposed § 371.101 would require household goods brokers that operate in interstate or foreign commerce to comply with all of the provisions of subpart B. AMSA recommends adding a phrase to state that the rule applies to a broker offering services "to individual shippers."

FMCSA response. FMCSA agrees with AMSA. The subpart's scope should be

limited to only household goods brokers offering services to individual shippers. It should not include commercial and government shippers that are generally more knowledgeable of brokerage transactions. FMCSA will change the rule to the following. "Yes, you must comply with all regulations in this subpart when you operate as a household goods broker offering services to individual shippers in interstate or foreign commerce. The regulations in this subpart do not apply to a household goods broker when providing services to commercial or government shippers in interstate or foreign commerce."

Definitions of Terms

Proposed § 371.103 would define terms used in subpart B. FMCSA proposed definitions for the terms "household goods," "household goods broker," and "individual shipper." The acronym "FMCSA" was used numerous times in the proposed rule, but the Agency does not show a definition of the term in part 371. The Agency will add the acronym "FMCSA" in the final rule and define it to mean "Federal Motor Carrier Safety Administration."

Qualifications of Motor Carriers Used by the Broker

Proposed § 371.105 would make it clear that a household goods broker may only act as a household goods broker for a household goods motor carrier that has a valid, active U.S. DOT number and valid, active operating authority issued by FMCSA. This requirement was requested by AMSA in its Petition for Rulemaking and was suggested by some of the commenters to the ANPRM. The use of FMCSA-registered household goods motor carriers to provide the transportation will provide a greater level of assurance that the household goods motor carrier will comply with applicable FMCSA regulations. The Public Utilities Commission of Ohio (PUCO) believes it would be useful to keep a database of consumer complaints against each carrier so that potential shippers could identify potentially troublesome movers.

FMCSA response. FMCSA maintains a consumer complaint database and allows public access to consumer complaint information regarding household goods carriers and brokers. This database can be accessed on the Internet by going to <http://www.protectyourmove.gov> and selecting the hyperlink "Search for Moving Companies and View Complaint History" which will lead to <http://ai.volpe.dot.gov/hhg/search.asp>. In a separate rulemaking (73 FR 9266,

February 20, 2008). FMCSA proposed that each household goods carrier must submit a statutorily-mandated quarterly report about consumer complaints it receives, which should assist individual shippers in evaluating their transportation options.

Information in Advertisements and Internet Web Sites

FMCSA proposed (§ 371.107) implementing section 4212 of SAFETEA-LU by requiring that household goods brokers disclose to potential shippers their Department of Transportation registration number and that they are not motor carriers providing transportation of household goods. FMCSA also proposed that household goods brokers disclose certain information not required by SAFETEA-LU, but which FMCSA believes is necessary to assist individual shippers. The Agency proposed that household goods brokers prominently display in their advertisements and on their Web sites the following:

1. The physical location of the business.
2. Its "MC" operating authority number and U.S. DOT registration number.²
3. Its status as a household goods broker that does not transport household goods but that arranges for such transportation.

AMSA urges FMCSA to monitor brokers' Web sites to ensure that unscrupulous brokers are not providing misleading information. The commenter also recommends an additional subparagraph in the rule to prohibit the broker from including the names or logos of motor carriers unless they are FMCSA-authorized household goods motor carriers with which the broker has a written agreement, as specified in § 371.115.

FMCSA response. As a part of its enforcement program, FMCSA already monitors the Web sites of household goods brokers and carriers to determine

²Brokers currently receive "MC" numbers, not U.S. DOT registration numbers. FMCSA proposed eliminating the "MC" operating authority number in its May 19, 2005 NPRM regarding the Unified Registration System (URS) mandated by 49 U.S.C. 13908 (70 FR 28990). FMCSA intends to issue and notify each household goods broker of the U.S. DOT number FMCSA will assign to that active household goods broker before the URS final rule is published. The URS final rule will remove the requirements for household goods brokers to display their "MC" numbers in their advertisements, Web sites, and agreements with household goods motor carriers. Household goods brokers will only be required to display their assigned U.S. DOT number after the URS final rule becomes effective. Until FMCSA publishes a final rule in that proceeding, household goods brokers must display their "MC" numbers in their advertisements.

if they are providing misleading information on the Internet. We conduct compliance reviews and initiate enforcement action when appropriate.

We add a subparagraph in the final rule to provide more information to individual shippers receiving estimates prepared by brokers pursuant to § 371.113(b). A household goods broker that provides an estimate on behalf of a motor carrier must state on the broker's Web site that any estimate must be based on the carrier's tariff and that the carrier is required to make the tariff available for public inspection upon a reasonable request. We add this requirement to better ensure that individual shippers understand their rights with respect to broker-prepared estimates.

We have adopted AMSA's suggestion to add a subparagraph in the final rule to prohibit household goods brokers from including the names or logos of motor carriers unless they are FMCSA-authorized household goods motor carriers with which the broker has a written agreement, as required by § 371.115. We agree that brokers should not misrepresent to shippers that their shipments will be moved by specific moving companies, when the broker does not have agreements with those companies. The provision is intended to further full and honest disclosure to the shipper.

List of Motor Carriers

FMCSA proposed (§ 371.109) that a household goods broker must provide to each potential individual shipper who has contact with the household goods broker a list of all household goods motor carriers used by the broker, to implement sec. 4212(3) of SAFETEA-LU. National Relocation Services and Pro Movers Network believe that the requirement is burdensome on the broker and does not serve a consumer protection purpose for the shipper.

FMCSA response. Notwithstanding the commenters' concerns about burden, the carrier list requirement is mandated by SAFETEA-LU. To address concerns regarding potential burdens on household goods brokers, FMCSA revises its proposal to allow household goods brokers to provide the information required by § 371.109 electronically either through a Web site or by electronic messaging (e-mail), as an alternative to a paper-based communication.

Consumer Protection Information

FMCSA proposed (§ 371.111) requiring that each household goods broker provide potential shippers with one copy of each of the two FMCSA

consumer pamphlets: "Your Rights and Responsibilities When You Move," and "Ready to Move?—Tips for a Successful Interstate Move." Section 4205 of SAFETEA-LU requires household goods motor carriers to distribute both pamphlets and the proposal would impose the same requirement on household goods brokers. Proposed paragraph (a) permitted the household goods broker to make the information available through its Web site or by distribution of paper copies to each potential shipper. PUCO supports the proposed requirement. AMSA suggests FMCSA's requirements for household goods motor carriers in part 375 should allow use of a hyperlink on the carrier's Web site to provide the required consumer protection information.

FMCSA response. To better verify that shippers have been fully informed of their opportunity to access the consumer protection information via the broker's Web site, FMCSA has added a new paragraph (b) to § 371.111 to provide that the broker must state on any written estimate provided pursuant to § 371.113 that the individual shipper has expressly agreed to accept access to the information via the Web site in lieu of paper copies. FMCSA has also revised § 371.111 paragraph (c) to require written or electronic verification of the shipper's agreement to access the Federal consumer protection information via the Internet, instead of receiving the booklet copies in paper form.

AMSA's suggested revision of part 375 has merit and FMCSA will make the change it requested. This change will allow household goods motor carriers also to use a hyperlink on the carrier's Web site to provide the required consumer protection information. FMCSA believes it is in the best interests of shippers, brokers, and carriers for the consumer protection information to be distributed electronically if consumers choose to receive the information in that format. A shipper's ability to receive consumer protection information in his/her preferred medium should not depend on whether he/she arranges for transportation through a broker or directly with a motor carrier.

Written Estimate Based on a Physical Survey

Proposed § 371.113(a) would require that, if the household goods broker provides an estimate, it must be in writing and must be based on a physical survey of the shipper's household goods, if the household goods are located within a 50 air-mile radius of the broker or its estimating agent. The

Owner Operator Independent Drivers Association (OOIDA) believes the household goods broker should be required to conduct a physical survey regardless of the distance from the broker's place of business, unless the shipper can provide the broker a weight by which to determine an estimate of charges.

AMSA argues that proposed § 371.113(a) does not adequately address the inaccurate, "lowball" broker estimating problems experienced by consumers who receive estimates over the telephone or Internet without a physical survey because, in most cases, brokers are not located anywhere near shipping sites. Accordingly, AMSA recommends that the Agency revise its proposal by requiring that estimates be based on a physical survey conducted by the authorized motor carrier on whose behalf the estimate is provided, if the goods are located within a 50-mile radius of the motor carrier or its agent. AMSA also proposes that 49 CFR 375.409(a) be revised to require that all estimates provided by the broker be based on physical surveys conducted by the motor carrier transporting the shipment.

Pro Movers Network opposes the requirement for an in-home survey, because the provision is especially burdensome for consumers who are shipping a very small amount of goods. Pro Movers Network believes that if the list of goods provided by the shipper is complete, an accurate non-binding estimate based on weight does not require an in-home estimate. Also, Pro Movers Network commented that requiring in-home surveys limits a consumer's choices and the ability to receive a moving estimate remotely via the Internet.

FMCSA response. In the NPRM, FMCSA expressly invited comment on the impact to shippers, brokers, and motor carriers of applying or removing the 50-mile requirement for household goods broker estimates based on physical surveys, and invited comments on alternatives to this requirement. The Agency agrees with AMSA that because household goods brokers are rarely located within 50 miles of the shippers to whom they provide estimates, it is likely that the 50-mile radius exception, if implemented as proposed, would become the standard practice. As a result, FMCSA revised § 371.113(a) to require brokers to conduct or arrange for someone to conduct physical surveys of goods that are located within 50 miles of either the broker or the carrier on whose behalf the broker submits an estimate. As we stated in the NPRM, FMCSA recognizes that SAFETEA-LU

did not prescribe estimating requirements for household goods brokers as it did for household goods motor carriers. Nevertheless, 49 U.S.C. 13904(c) grants FMCSA the authority to promulgate this requirement. The Agency believes that an individual shipper's protection against unreliable estimates should not depend upon whether the shipper uses a broker or carrier to provide the estimate. We believe AMSA's suggested revision to proposed § 371.113(a) accomplishes the goal more effectively than FMCSA's original proposal and we adopt that revision in the final rule, with a minor modification as described below.

We decline to adopt AMSA's proposed revision to 49 CFR 375.409(a) requiring that all estimates be based on physical surveys conducted by motor carriers because it would essentially prevent household goods brokers from making estimates under any circumstances. Such a prohibition is inconsistent with section 4209 of SAFETEA-LU, which prohibits household good brokers from making estimates before entering into an agreement with a carrier to provide the transportation. Section 4209, therefore, implicitly recognizes that brokers are permitted to make estimates after entering into agreements with carriers, and not simply to provide shippers with estimates prepared by motor carriers or their agents. However, we have revised § 375.409(a) to make it consistent with revised § 371.113(a).

We also decline to adopt OOIDA's suggestion to require household goods brokers to perform a physical survey regardless of the distance from the broker's place of business. We do not require household goods motor carriers or their agents to perform a physical survey regardless of the distance from the motor carrier's or agent's place of business. We do not believe it would be appropriate to place this burden on brokers when we do not place it on motor carriers.

FMCSA does not agree with the suggestion of Pro Movers Network that the requirement for a physical survey should be eliminated because it limits a consumer's choice to receive a remote estimate. Section 371.113(c) expressly permits the individual shipper to waive the physical survey requirement.

Explanation of Waiving the Physical Survey

PUCO states that estimates are most frequently a disputed issue and it is important that the broker be required to provide estimates in writing based on a survey of the property to be shipped. It believes the option of waiving the

physical survey should be explained and should be printed in a required font size in a required location on a standard document to ensure that the shippers are fully informed.

FMCSA response. We agree with PUCO that waiving the physical survey requirement, where it would otherwise apply, should be explained, printed on a standard document and printed with a minimum font size and font typeface. We have adopted PUCO's suggestion for the final rule. FMCSA will adopt in today's final rule the minimum font size and font typeface following the General Services Administration (GSA) guidelines in the "Standard and Optional Forms Procedural Handbook." The GSA handbook requires the font typeface Universe and minimum font size of 7 points for all standard Federal forms and documents.

Estimates Based on Published Tariffs

FMCSA proposed (§ 371.113(b)) requiring household goods brokers to base their estimates upon the published tariffs (as defined in § 375.103) of the authorized household goods motor carriers they use. Nationwide Relocation Services believes the rule should require any motor carrier accepting jobs from a broker to adopt the broker's tariff as its own for all jobs secured from the broker. AMSA suggests that the rule should require the broker's fee or service charge to be separately stated in the estimate and not included in the motor carrier's estimate of transportation charges.

FMCSA response. Household goods motor carriers are required to maintain tariffs under 49 U.S.C. 13702 and must charge individual shippers in accordance with those tariffs. Implementing regulations of the Surface Transportation Board (STB) governing household goods carrier tariffs, at 49 CFR 1310.3(a), require such tariffs to provide "the specific applicable rates, charges and service terms; and must be arranged in a way that allows for the determination of the exact rate, charges and service terms applicable to any given shipment." Section 1310.3(b) permits use of multiple tariffs to determine applicable rates and charges, provided "the tariff containing the rates must make specific reference to all other tariffs required to determine applicable rates, charges and service terms. The carrier(s) party to the rate(s) must participate in all of the tariffs so linked * * *". A "carrier party to the rate" means more than one carrier can use the same rates. A broker's rate schedule is not a tariff subject to 49 U.S.C. 13702 and the STB regulations. There is no regulatory requirement that brokers adhere to such rate schedules, as there

is for household goods motor carriers to adhere to the terms of their tariffs. FMCSA believes Nationwide Relocation Services' suggestion would be inconsistent with 49 CFR 1310.3 and therefore, FMCSA will not adopt it.

At this time, the Agency does not adopt AMSA's suggestion that the broker's fee or service charge be separately stated in the estimate. The Agency does not have sufficient information about how different brokers charge their fees and what affect this change would have.

Agreements With Motor Carriers

Proposed § 371.115(a) would require household goods brokers to maintain written agreements with authorized household goods motor carriers before providing estimates and lists the items that must be included in these agreements. Nationwide Relocation Services suggests all agreements should be submitted and filed with FMCSA. Paragraph (a)(6) would require the signatures on the agreement to be notarized. Pro Movers Network believes the requirement for a notarized agreement is unrealistic and would almost certainly be impossible to execute successfully. Because household goods carriers typically have working agreements with between 5 and 15 brokers, the commenter asserts, the notary requirement would have to be repeated many times for each carrier. The commenter believes the rule would ultimately be too stressful to the broker-carrier business relationships and transactions. The commenter argues that the potential of lost opportunity costs caused by strained business relationships between household goods brokers and carriers is a distinct possibility and FMCSA's cost and risk assessments did not take these lost opportunity costs into account.

We also proposed changing § 375.409 to state that the written agreement between the household goods broker and the household goods motor carrier must contain all of the items required in proposed § 371.115. AMSA recommends adding a sentence stating that the estimate is based on a physical survey of the goods conducted by the motor carrier.

FMCSA response. We believe the filing requirement suggested by Nationwide Relocation Services would create an unnecessary burden for FMCSA, carriers, and brokers that would have little usefulness in protecting individual shippers. Based on comments received, we agree that the notarization requirement will be unduly burdensome and is unnecessary. We

have removed the requirement that the agreements be notarized.

We have also revised § 375.409 to reflect the changes to § 371.113(a) discussed above (requiring a physical survey if the carrier on whose behalf the broker makes an estimate is within 50 miles of the household goods). However, as discussed earlier in this preamble, we are not adopting AMSA's suggested change to require that all estimates be based on physical surveys of the property conducted by household goods motor carriers, because it would prohibit anyone other than the authorized motor carrier from performing the estimate. As such, it would be inconsistent with SAFETEA-LU and would limit the flexibility FMCSA intends to afford household goods brokers and carriers to provide services to their individual shippers. Motor carriers can certainly provide additional restrictions in their agreements with household goods brokers beyond FMCSA's minimum requirements.

Verifying the Motor Carrier's Authority

As proposed, § 371.119 would have required that each household goods broker "inspect, verify, and document" the validity of the U.S. DOT registration and MC operating authority for each household goods motor carrier with which it arranges transportation each month. The household goods broker would comply with this requirement by using FMCSA's Web site (<http://www.protectyourmove.gov>) to check whether the motor carrier has active for-hire authority to transport household goods and evidence of the necessary financial responsibility on file with FMCSA. Nationwide Relocation Services suggests that monitoring the authority and licensing status of motor carriers is a role best suited for FMCSA, and a private broker should not be required to undertake the regulatory duty of FMCSA in policing the authority status of motor carriers. Pro Movers Network believes FMCSA should devise an e-mail notification system to register a broker's carriers and automatically e-mail the broker when one of its carrier's authorities is suspended or revoked. Manual checks by the broker of its entire network of carriers would be time- and resource-intensive, the commenter asserts, and a once per month check by the broker is not a fool-proof method of verification. The commenter believes the broker should only have to confirm whether the carrier is in "Active" or "NonActive" status in FMCSA's Safety and Fitness Electronic Records (SAFER) database. The commenter also states that it is not the

broker's obligation and responsibility to report carrier non-compliance to FMCSA.

FMCSA response. In response to comments and after further consideration, FMCSA has decided to eliminate proposed § 371.119 from the final rule. The intent of proposed § 371.119 was to provide additional protection to shippers by requiring brokers to verify the validity of carriers' registration and operating authority on a monthly basis. However, proposed § 371.105 independently prohibits anyone from acting as a household goods broker for household goods motor carriers that do not have valid U.S. DOT numbers and valid operating authority from FMCSA. Regardless of whether a broker complies with the monthly verification and recordkeeping requirements, it would nonetheless be bound by § 371.105 and subject to penalties for arranging moves with unregistered or unauthorized carriers. Considering this redundancy, it is unclear what additional protections § 371.119 would provide to shippers. Because brokers would be required to comply with § 371.105 under threat of penalty with or without § 371.119, the Agency does not believe that eliminating § 371.119 would diminish brokers' incentives to avoid doing business with unregistered or unauthorized carriers. Thus, the Agency believes that eliminating § 371.119 would leave shippers with the same level of protection against unregistered or unauthorized carriers, while reducing the administrative burden on brokers. Furthermore, striking this provision would eliminate any confusion over whether compliance with § 371.119 excuses or provides mitigating circumstances for failure to comply with § 371.105. FMCSA is concerned that proposed § 371.119, as written, could be interpreted as a safe haven for brokers who comply with the verification and recordkeeping requirements, but nonetheless arrange a move with an unregistered or unauthorized carrier. FMCSA never intended for proposed § 371.119 to be interpreted this way. As a result, FMCSA leaves it to the household goods brokers to determine the most effective and efficient manner in which to ensure compliance with § 371.105.

Broker Surety Bond or Trust Fund

FMCSA proposed to add specific language to § 387.307(a) to require household goods brokers to have a surety bond or trust fund in effect for \$25,000, based on adjustments for inflation. The former ICC increased the financial responsibility requirement for

brokers in 1979 from \$5,000 to \$10,000.³ See 44 FR 70167, December 6, 1979. The NPRM proposed adjusting the \$10,000 minimum figure for inflation as measured by the Consumer Price Index, which resulted in purchasing power of \$24,490.29 in 2006. Because a final rule based on the NPRM would not be in effect until after the 2007's NPRM, FMCSA found it reasonable to round the minimum requirement up to \$25,000. The requirement was raised to \$10,000 to ensure shippers or motor carriers would be paid if the broker failed to carry out its contracts, agreements, or arrangements for the supplying of transportation by authorized motor carriers. Sandra Irwin supports raising the amount of the surety bond or trust fund, and AMSA, PUCO, and OOIDA believe an increase to \$25,000 is inadequate. According to OOIDA, surety companies have reported an aggregate amount of outstanding claims against broker bonds of between \$300,000 and \$500,000 in response to OOIDA's efforts to submit claims by its members against broker bonds. Nationwide Relocation Services believes the amount of the surety bond or trust fund should be \$50,000, and David Marsh suggests \$100,000. Sandra Irwin, David Marsh, and the Transportation Intermediaries Association suggest the increase in the surety bond or trust fund should apply to all property brokers, not just household goods brokers.

On the other hand, Pro Movers Network points out that household goods brokers may incur a high cost of doing business, such as increased costs of advertising, and increasing the surety bond or trust fund requirement to \$25,000 represents an unnecessary financial burden.

FMCSA response. Commenters that favored increasing the amount of the surety bond or trust fund did not provide adequate justification for an increase above \$25,000, especially in light of the number of small business household goods brokers and the potential impact of significantly increasing the amount of financial responsibility beyond a level adjusted for inflation. Inasmuch as OOIDA did not provide specific information regarding the number and amount of outstanding claims per broker, its argument that an aggregate amount of \$300,000 to \$500,000 in outstanding claims warrants an increase in the amount of the bond to that level is not justifiable.

³The ICC established the broker surety bond amount at \$5,000 in 1936, 1 FR 1156, August 20, 1936.

The surety bond and trust fund provisions apply only to household goods transportation. FMCSA may consider applying the increased surety bond and trust fund provisions to general freight brokers in the future. Finally, FMCSA acknowledges Pro Movers Network's comment about high costs of doing business, however, it did not provide sufficiently specific information to justify changing FMCSA's proposal to something other than an adjustment for inflation.

Implementation of the Household Goods Broker Surety Bond or Trust Fund Amount

FMCSA did not propose how the Agency would implement the additional \$15,000 increase in the amount of the surety bond or trust fund agreement. FMCSA believes it is necessary to provide household goods brokers a sufficient amount of time to acquire the additional \$15,000 for surety bonds and trust funds. The Agency will set one year from the date of the final rule as the date when all brokers of household goods must have filed new BMC-84s or BMC-85s, as appropriate, to prove they have the minimum \$25,000 in effect. This should give sufficient time to household goods brokers, especially small entities, to find sureties willing to write \$25,000 surety bonds to replace their \$10,000 bonds. Likewise, for those household goods brokers using trust fund agreements, this should give sufficient time for these entities to raise the additional \$15,000 of capital to place in escrow with their trust fund managers.

The Final Rule

FMCSA adopts the proposed rule as final with minor changes in response to the comments. First, as discussed in the section on the "Scope of part 371, subpart B," at the suggestion of AMSA, we are limiting the scope of part 371, subpart B to only household goods brokers offering services to individual shippers. We have made the appropriate changes to § 371.101 to limit the scope to individual shippers. Second, as discussed in the section of the "Definitions," the Agency is adding the acronym "FMCSA" and the definition that it means the Federal Motor Carrier Safety Administration, an agency within the U.S. Department of Transportation. Third, as discussed in the section on "information in advertisements and Internet Web homepages," we are adding § 371.107(d) to require household goods brokers who provide estimates on behalf of household goods motor carriers, to state prominently on their Web site(s) that the estimates must

be based on the carrier's tariff and that the carrier is required to make the tariff available for public inspection upon a reasonable request. Fourth, also as discussed in the section on "information in advertisements and Internet Web homepages," at the suggestion of AMSA, we are adding § 371.107(e) to prohibit the broker from including the names or logos of motor carriers unless they are FMCSA-authorized household goods motor carriers with which the broker has a written agreement as specified in § 371.115. Fourth, as discussed in the section "list of motor carriers," FMCSA will allow household goods brokers to provide the information required by § 371.109 electronically as an alternative to a paper-based communication.

Fifth, as discussed in the section "consumer protection information," FMCSA is adding § 371.111(b) to require that, if a shipper elects to access the statutorily-mandated consumer information via the household goods broker's Web site, then the broker must state on the written estimate described in § 371.113 that the individual shipper expressly agreed to access the consumer protection information via the Internet in lieu of a paper copy.

Sixth, as discussed further in the section "consumer protection information," FMCSA has also revised § 371.111 paragraph (c) to require written or electronic verification of the shipper's agreement to access the Federal consumer protection information on the Internet, instead of receiving the booklet copies in paper form.

Seventh, as discussed in the section "Written estimate based on a physical survey," we are adopting one of AMSA's two suggestions to require in § 371.113(a) that a physical survey of the household goods must be conducted by the authorized motor carrier on whose behalf the estimate is provided, if the shipment is located within a 50-mile radius of the carrier's "household goods agent preparing the estimate," unless the physical survey requirement is waived by the shipper.

Eighth, for § 371.113(c)(2), as discussed in the section on "Explanation of waiving the physical survey," we are adopting PUCO's suggestion that the final rule require brokers to explain the physical survey and waiver requirement to individual shippers, print the waiver agreement on the written estimate, and print the agreement with a minimum font size and font typeface. Ninth, as discussed in the section "verifying the motor carrier's authority," FMCSA is eliminating proposed § 371.119 from the final rule. Tenth, as discussed in the sections on "Written estimate based on

a physical survey” and “Estimates provided by household goods brokers,” we have revised the household goods motor carrier requirements applicable to household goods broker estimates in § 375.409(a) to make them consistent with our revised written estimate revisions in § 371.113(a). Finally, we are adding a 1-year compliance date in § 387.307(a)(2) for household goods brokers to obtain the additional \$15,000 of financial responsibility over the current \$10,000 requirement, and to file with FMCSA the required proof (Forms BMC-84 or BMC-85, as appropriate) of the total \$25,000 minimum financial responsibility required by the 1-year compliance date.

Regulatory Analyses

Executive Order 12866 (Regulatory Planning and Review); DOT Regulatory Policies and Procedures

FMCSA has determined that this action is a not a significant regulatory action within the meaning of Executive Order 12866 and the U.S. Department of Transportation regulatory policies and procedures (44 FR 11034, February 26, 1979). The Agency received only 11 comments and the costs are minimal.

The total cost of the final rule is approximately \$5.543 million in the first year with annual, recurring costs of \$1.776 million thereafter. As such, the costs of this final rule do not exceed the \$100 million annual threshold as defined in Executive Order 12866. The ten-year costs and benefits of the final rule are shown in Table 1:

TABLE 1—SUMMARY OF TEN-YEAR COSTS AND BENEFITS FOR FINAL RULE
[In millions]

7% Discount Rate	Option 3
Costs	\$17.11
Benefits	46.97
Net Benefits	32.25
3% Discount Rate	Option 3
Costs	16.58
Benefits	54.91
Net Benefits	38.33

FMCSA’s full Final Regulatory Evaluation is in the docket for this rule. It explains in detail how we estimated cost impacts for the final rule.

This rule establishes additional consumer protection regulations specifically for household goods brokers to supplement the regulations at 49 CFR part 375, which apply to motor carriers transporting household goods by commercial motor vehicle in interstate and foreign commerce.

FMCSA estimates these regulatory changes will produce three primary cost impacts on household goods brokers: (1) Costs of training certain employees on the proper application of the regulatory changes; (2) costs to revise broker marketing materials, forms, and orders for service, including technical writing, Web site editing, and printing costs associated with incorporating mandated consumer information; and (3) additional information collection burdens associated with the new regulations, including traveling to and performing on-site physical surveys for written estimates; making written agreements with household goods motor carriers, stating on the written estimate that the individual shipper expressly agreed to access the consumer protection information on the Internet; obtaining written or electronic verification of the shipper’s agreement to access the Federal consumer protection information on the Internet; explaining the physical survey and waiver requirement to individual shippers; printing the waiver agreement on the written estimate; printing the agreement with a minimum font size and font typeface; and, finally, requiring household goods brokers to have their sureties or trust fund managers file proof of their \$25,000 minimum financial responsibility on the Forms BMC-84 or BMC-85, as appropriate.

Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), requires Federal agencies, as a part of each rulemaking, to consider regulatory alternatives that minimize the impact on small entities while achieving the objectives of the rulemaking. The Agency’s Initial Regulatory Flexibility Analysis is available in docket FMCSA–2004–17008 at item 0018. FMCSA received no specific comments about its Initial Regulatory Flexibility Analysis. The Agency’s Final Regulatory Flexibility Analysis (FRFA) for this final rule is discussed below.

(1) A description of the reasons why action by the agency is being considered.

The American Moving and Storage Association (AMSA) petitioned the DOT for a rulemaking in March 2003 that would amend the property broker regulations in part 371 to require brokers that arrange for household goods transportation by motor carrier (household goods brokers) to provide

consumer information that only household-goods motor-carriers must now provide, as well as establish additional consumer protection requirements. Many of AMSA’s concerns were addressed in the Safe Accountable, Flexible, Efficient Transportation Equity Act: A Legacy For Users (SAFETEA–LU), Public Law 109–59, which was enacted into law on August 10, 2005. Specifically, section 4212 of SAFETEA–LU directs FMCSA to issue regulations requiring household goods brokers to provide this information to consumers.

(2) Objectives of, and legal basis for, the final rule.

This rulemaking is mandated by section 4212 of SAFETEA–LU. FMCSA’s general authority to enact consumer protection regulations governing broker operations is contained in 49 U.S.C. 13904(c). The objective of this rule is to ensure that individual shippers of household goods that arrange for transportation through household goods brokers (rather than directly through motor carriers) receive necessary information regarding the parties with which they are dealing and their rights and responsibilities in connection with interstate household goods moves. It also is intended to ensure that household goods brokers deal only with properly registered and insured motor carriers and that estimates provided by household goods brokers be provided under specific circumstances designed to protect the shipper against abuse. Finally, it increases the level of financial responsibility required to ensure that household goods brokers perform their transportation contracts.

(3) Significant issues raised by small entities’ comments.

A summary of the significant issues raised by the public in response to the NPRM and the assessment of each significant issue are discussed earlier in this final rule under the heading “Discussion of Comments on the Proposed Rule.”

FMCSA is adopting the proposed rule as final with the minor changes discussed above under the heading The Final Rule, based mainly on comments to the NPRM. FMCSA believes most household goods brokers that commented to the NPRM would meet the definition of a small business entity.

(4) Description and estimate of the number of small entities to which the final rule will apply.

There are currently 615 active, registered household goods brokers and another 394 registered household goods

brokers that are inactive.⁴ We do not know the number of unregistered household goods brokers, but we suspect that there are many. For the purposes of our analysis, we assume the number is 75—which would put the percentage of unregistered brokers at just over ten percent (75 is 10.87% of (615 + 75)). The figure is based on conversations with industry experts and information from broker Web sites. We use 690, then, as the estimate of total active brokers—registered and (now) unregistered. Almost all are small entities according to the definition in Small Business Administration (SBA) regulations (13 CFR part 121) which defines a “small entity” in the North American Industrial Classification System (NAICS) Code 488510 “Freight Transportation Arrangement” industry by average annual receipts, which are currently set at \$7 million per firm. The motor carriers with whom household goods brokers deal may also be indirectly affected.

(5) *Description of the projected reporting, record-keeping and other compliance requirements for small entities.*

The final rule requires additional record-keeping on the part of household goods brokers to demonstrate compliance. The cost to the household goods broker industry of this additional record-keeping (\$5,543 million in the first year and \$1,776 million annually to inform, display, and disclose information to shippers and maintain the files for three years) is reflected in our cost estimates. Additionally, the aggregate cost to the household goods broker industry of raising the financial responsibility requirement to \$25,000 from \$10,000 (approximately \$50,000 annually) is also reflected in our cost estimates. The total cost has a present value of approximately \$17.11 million over ten years when discounted at 7 percent, and does not require any special skills that would be available to large entities any more than to small entities.

(6) *Duplication with other Federal rules.*

FMCSA is unaware of any other Federal rules which will duplicate, overlap, or conflict with this proposed rule except for the household goods carriers rule published on July 12, 2005.⁵ Because these rules apply only to household goods motor carriers, it was necessary to establish separate rules applicable to household goods brokers,

even though they contain certain similarities. For example, SAFETEA-LU requires every shipper to receive the pamphlet “Your Rights and Responsibilities When You Move.” Household goods carriers are already required to make this pamphlet available to every shipper. This rule requires household goods brokers to make the same pamphlet available to shippers. There is no practical way around the duplication because some shippers do not use a household goods broker and those who do often do not have any direct contact with a household goods carrier early enough in the process to make effective use of the information contained in the pamphlet.

(7) *Description of any significant alternatives to the final rule.*

FMCSA believes that there are no significant alternatives to the final rule which would accomplish the stated objectives of the Household Goods Mover Oversight Enforcement and Reform Act of 2005, otherwise known as Title IV, Subtitle B of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) (Pub. L. 109-59) and which would minimize any significant economic impact of the final rule on small entities.

The Agency did consider ways in which it could assist small household goods broker entities to mitigate the impact of increasing the trust fund resources to the new minimum requirement of \$25,000. The Agency decided it could extend the compliance date regarding the financial responsibility requirement so that brokers will have a full year after publication of the final rule to come into compliance with the \$25,000 requirement, increasing trust funds from the minimum of \$10,000 to the final rule’s minimum requirement of \$25,000.

Therefore, FMCSA is mitigating the impact of obtaining the additional \$15,000 of financial responsibility over the current \$10,000 requirement by adding a 1-year compliance date in § 387.307(a)(2). Thus, all household goods brokers will have one year from the date of publication of this final rule to obtain the additional \$15,000 of financial responsibility over the current \$10,000 requirement, and to have their sureties and trust fund managers file with FMCSA the required proof (Forms BMC-84 or BMC-85, as appropriate) of the total \$25,000 minimum financial responsibility required by the compliance date for § 387.307(a)(2).

As we stated above, almost all of the 690 household goods brokers subject to this final rule meet the definition of a small business entity under the RFA.

We have estimated this final rule will cause the average household goods broker to incur an estimated, additional \$8,030 in the first year of implementation and annual recurring costs of about \$2,575. The Administrator of the FMCSA believes this final rule will have a significant economic impact on a substantial number of small entities (SEISONOSE).

Unfunded Mandates Reform Act

This rule does not impose a Federal mandate resulting in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$140.3 million or more in any one year (2 U.S.C. 1531 *et seq.*). The present value of the final rule is about \$17.11 million.

National Environmental Policy Act

The Agency analyzed this rule for the purpose of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and determined under our environmental procedures Order 5610.1 published March 1, 2004 (69 FR 9680), that this action is categorically excluded under Appendix 2, paragraphs 6.d, 6.m, and 6.q of the Order from further environmental documentation. These categorical exclusions relate to rulemaking actions affecting household goods brokers. In addition, the Agency believes that the action includes no extraordinary circumstances that would have any effect on the quality of the environment. Thus, the action does not require an environmental assessment or an environmental impact statement.

We have also analyzed this rule under the Clean Air Act, as amended (CAA) section 176(c), (42 U.S.C. 7401 *et seq.*) and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA’s general conformity requirement since it involves rulemaking and policy development and issuance. See 40 CFR 93.153(c)(2). It will not result in any emissions increase nor will it have any potential to result in emissions that are above the general conformity rule’s *de minimis* emission threshold levels. Moreover, it is reasonably foreseeable that the rule will not increase total CMV mileage, or change the routing of CMVs, how CMVs operate, or the CMV fleet-mix of motor carriers. This action merely establishes regulations applicable to the business practices of household goods brokers, which do not operate CMVs. FMCSA received no comments to its NEPA and Clean Air Act analyses.

⁴ A broker generally becomes inactive after registering with FMCSA when its surety bond or trust fund is cancelled.

⁵ 70 FR 39949 (Jul. 12, 2005).

Privacy Impact Assessment

FMCSA conducted a privacy impact assessment of this rule as required by section 522(a)(5) of the FY 2005 Omnibus Appropriations Act, Public Law 108-447, 118 Stat. 3268 (Dec. 8, 2004) [set out as a note to 5 U.S.C. 552a]. The assessment considers any impacts of the rule on the privacy of information in an identifiable form and related matters. FMCSA has determined this rule imposes no privacy impacts.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), a Federal agency must obtain approval from the Office of Management and Budget (OMB) for each collection of information it conducts, sponsors, or requires through regulations. FMCSA seeks approval of the information collection requirements in a new information collection to be entitled "Practices of Household Goods Brokers."

The collected information encompasses that which is generated, maintained, retained, disclosed, and provided to, or for, the agency under 49 CFR part 371. It will assist shippers in their commercial dealings with interstate household goods brokers. The collection of information will be used by prospective shippers to make informed decisions about contracts and

services to be ordered, executed, and settled within the interstate household goods motor carrier industry. Some of these information collection items were required by regulations issued by the former ICC; however, that agency was not required to comply with the PRA. When these items transferred from the ICC to the Federal Highway Administration, and ultimately to FMCSA, no OMB control number was assigned to cover this information collection transfer. It was therefore necessary to calculate the old information collection burden hours for these items approved under the ICC rules and to add the new burden that will be generated by this final rule.

Assumptions used for calculation of the information collection burden include the following: (1) There are currently approximately 690 active household goods brokers; (2) on average, each household goods broker will enter into written agreements to estimate shipment costs with about 31 motor carriers, (3) household goods brokers will eventually sever some of these written agreements and make agreements with new household goods motor carriers. We assume that an average agreement lasts for about six years, meaning that brokers will enter into about five new agreements each year, and (4) FMCSA estimates household goods brokers handle about

100,000 moves each year. The first two items result in 24,390 respondents subject to the information collection (690 x 31 = 24,390). The third item results in an additional 3,450 respondents subject to the information collection (690 x 5 = 3,450). Together with the fourth item, a total of about 127,900 respondents (24,390 + 3,450 + 100,000) would be subject to the information collection.

The PRA regulations at 5 CFR 1320.3(b)(2) allow FMCSA to calculate no burden when the agency demonstrates to OMB that the activity needed to comply with the specific regulation is usual and customary. FMCSA sought comment in the NPRM on whether setting up the first accounting system for a new business is a usual and customary business practice. FMCSA received no comments from the public about this accounting system issue. Thus, FMCSA concludes the public believes it is a usual and customary practice when starting a new business.

Table 2 summarizes the information collection burden hours by the actions being taken in the final rule. See attachment S of the supporting statement for the Paperwork Reduction Act Submission in docket FMCSA-2004-17008 for the detailed FMCSA analysis.

TABLE 2—ANNUAL BURDEN HOURS ACROSS THE 127,900 RESPONDENTS

Section	Description	Calculation	Total hours
371.3	Transaction records	60hr x 690	41,400
371.13	Second accounting system	8hr x 125	1,000
371.107	Web site/Ad Modification	20hr x 690	13,800
371.109	Create A List of Carriers	10hr x 690	6,900
371.111(a)	Pamphlet Provision (One-Time)	0.5hr x 690	345
371.111(c)	Confirming Required Information	0.5hr/month x 12 x 690	4,140
371.113	Explanation of Waiver-Agreement	(1/12)hr x 20,000	1,667
371.115	Negotiation of Agreements (One-Time)	4hr x 31 agreements x 690	85,560
	Additional Agreements Through Turnover	4 hrs x 5 agreements x 690	13,800
371.117	Disclosure and Records	10hr x 690	6,900
371.119	Removed Verification Requirement	Removed	0
	Total First Year Hours		175,512
	Total Recurring Annual Hours		89,607

We have rounded the estimates and have asked OMB for approval for first-year burden-hours of 175,500, and subsequent-year burden-hours of 89,600. We particularly request your comments on whether the collection of information is necessary for FMCSA to meet the goal of 49 CFR part 371 to protect consumers and household goods motor carriers, including: (1) Whether the information is useful to this goal; (2) the accuracy of the estimate of the burden of the information collection; (3)

ways to enhance the quality, utility and clarity of the information collected; and (4) 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.

You must submit comments on the information collection burden addressed by this final rule to the Office of Management and Budget (OMB). The deadline for such submissions is December 29, 2010. Interested persons

are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via electronic mail to oir_submission@omb.eop.gov, or faxed to (202) 395-6974, or mailed to the Office of Information and Regulatory

Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503.

Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, entitled "Civil Justice Reform," to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 12630 (Taking of Private Property)

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, entitled "Governmental Actions and Interference with Constitutionally Protected Property Rights."

Executive Order 13132 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132. The FMCSA has determined that this rulemaking would not have a substantial direct effect on States, nor would it limit the policy-making discretion of the States.

Executive Order 13211 (Energy Effects)

FMCSA has analyzed this action under Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use." The Agency has determined that it is not a "significant energy action" under that order because it does not appear to be economically significant (i.e., imposing a cost of more than \$100 million in a single year) based upon analyses performed at this stage of the rulemaking process, and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

List of Subjects

49 CFR Part 371

Brokers, Motor carriers, Reporting and recordkeeping requirements.

49 CFR Part 375

Advertising, Arbitration, Consumer protection, Freight, Highways and roads, Insurance, Motor carriers, Moving

of household goods, Reporting and recordkeeping requirements.

49 CFR Part 386

Administrative practice and procedure, Brokers, Freight forwarders, Hazardous materials transportation, Highway safety, Motor carriers, Motor vehicle safety, Penalties.

49 CFR Part 387

Buses, Freight, Freight forwarders, Hazardous materials transportation, Highway safety, Insurance, Intergovernmental relations, Motor carriers, Motor vehicle safety, Moving of household goods, Penalties, Reporting and recordkeeping requirements, Surety bonds.

■ For the reasons discussed above, FMCSA is amending title 49, Code of Federal Regulations, chapter III, subchapter B, as set forth below:

PART 371—BROKERS OF PROPERTY

■ 1. Revise the authority citation for part 371 to read as follows:

Authority: 49 U.S.C. 13301, 13501, and 14122; subtitle B, title IV of Pub. L. 109–59; and 49 CFR 1.73.

Subpart A—General Requirements

■ 2. Add a heading for subpart A to read as set forth above, and designate §§ 371.1 through 371.13 under subpart A.

■ 3. Add a new subpart B to read as follows:

Subpart B—Special Rules for Household Goods Brokers

Sec.

371.101 If I operate as a household goods broker in interstate or foreign commerce, must I comply with subpart B of this part?

371.103 What are the definitions of terms used in this subpart?

371.105 Must I use a motor carrier that has a valid U.S. DOT number and valid operating authority issued by FMCSA to transport household goods in interstate or foreign commerce?

371.107 What information must I display in my advertisements and Internet Web homepage?

371.109 Must I inform individual shippers which motor carriers I use?

371.111 Must I provide individual shippers with Federal consumer protection information?

371.113 May I provide individual shippers with a written estimate?

371.115 Must I maintain agreements with motor carriers before providing written estimates on behalf of these carriers?

371.117 Must I provide individual shippers with my policies concerning cancellation, deposits, and refunds?

371.121 What penalties may FMCSA impose for violations of this part?

Subpart B—Special Rules for Household Goods Brokers

§ 371.101 If I operate as a household goods broker in interstate or foreign commerce, must I comply with subpart B of this part?

Yes, you must comply with all regulations in this subpart when you operate as a household goods broker offering services to individual shippers in interstate or foreign commerce. The regulations in this subpart do not apply to a household goods broker when providing services to commercial or government shippers in interstate or foreign commerce.

§ 371.103 What are the definitions of terms used in this subpart?

FMCSA means the Federal Motor Carrier Safety Administration within the U.S. Department of Transportation.

Household goods has the same meaning as the term is defined in § 375.103 of this subchapter.

Household goods broker means a person, other than a motor carrier or an employee or bona fide agent of a motor carrier, that as a principal or agent sells, offers for sale, negotiates for, or holds itself out by solicitation, advertisement, or otherwise as selling, providing, or arranging for, transportation of household goods by motor carrier for compensation.

Individual shipper has the same meaning as the term is defined in § 375.103 of this subchapter.

§ 371.105 Must I use a motor carrier that has a valid U.S. DOT number and valid operating authority issued by FMCSA to transport household goods in interstate or foreign commerce?

You may only act as a household goods broker for a motor carrier that has a valid, active U.S. DOT number and valid operating authority issued by FMCSA to transport household goods in interstate or foreign commerce.

§ 371.107 What information must I display in my advertisements and Internet Web homepage?

(a) You must prominently display in your advertisements and Internet Web homepage(s) the physical location(s) (street or highway address, city, and State) where you conduct business.

(b) You must prominently display your U.S. DOT registration number(s) and MC license number issued by the FMCSA in your advertisements and Internet Web homepage(s).

(c) You must prominently display in your advertisements and Internet Web site(s) your status as a household goods broker and the statement that you will not transport an individual shipper's

household goods, but that you will arrange for the transportation of the household goods by an FMCSA-authorized household goods motor carrier, whose charges will be determined by its published tariff.

(d) If you provide estimates on any carrier's behalf pursuant to § 371.113(b), you must prominently display on your Internet Web site(s) that the estimate must be based on the carrier's tariff and that the carrier is required to make its tariff available for public inspection upon a reasonable request.

(e) You may only include in your advertisements or Internet Web site(s) the names or logos of FMCSA-authorized household goods motor carriers with whom you have a written agreement as specified in § 371.115 of this part.

§ 371.109 Must I inform individual shippers which motor carriers I use?

(a) You must provide to each potential individual shipper who contacts you a list of all authorized household goods motor carriers you use, including their U.S. DOT registration number(s) and MC license numbers. You may provide the list electronically or on paper.

(b) You must provide to each potential individual shipper who contacts you a statement indicating that you are not a motor carrier authorized by the Federal Government to transport the individual shipper's household goods, and you are only arranging for an authorized household goods motor carrier to perform the transportation services and, if applicable, additional services. You may provide the statement electronically or on paper.

§ 371.111 Must I provide individual shippers with Federal consumer protection information?

(a) You must provide potential individual shippers with Federal consumer protection information by one of the following three methods:

(1) Provide a hyperlink on your Internet Web site to the FMCSA Web site containing the information in FMCSA's publications "Ready to Move?—Tips for a Successful Interstate Move" and "Your Rights and Responsibilities When You Move."

(2) Distribute to each shipper and potential shipper at the time you provide an estimate, copies of FMCSA's publications "Ready to Move?—Tips for a Successful Interstate Move" and "Your Rights and Responsibilities When You Move."

(3) Distribute to each shipper and potential shipper at the time you provide an estimate, copies of "Ready to Move?—Tips for a Successful Interstate

Move" and "Your Rights and Responsibilities When You Move" as modified and produced by the authorized, lawful motor carrier to which you intend to provide the shipment under your written agreement required by § 371.115.

(b) If an individual shipper elects to waive physical receipt of the Federal consumer protection information by one of the methods described in paragraphs (a)(2) and (a)(3) of this section, and elects to access the same information via the hyperlink on the Internet as provided in paragraph (a)(1) of this section, you must include a clear and concise statement on the written estimate described in § 371.113 that the individual shipper expressly agreed to access the Federal consumer protection information on the Internet.

(c) You must obtain a signed, dated, electronic or paper receipt showing the individual shipper has received both booklets that include, if applicable, verification of the shipper's agreement to access the Federal consumer protection information on the Internet.

(d) You must maintain the signed receipt required by paragraph (c) of this section for three years from the date the individual shipper signs the receipt.

§ 371.113 May I provide individual shippers with a written estimate?

(a) You may provide each individual shipper with an estimate of transportation and accessorial charges. If you provide an estimate, it must be in writing and must be based on a physical survey of the household goods conducted by the authorized motor carrier on whose behalf the estimate is provided if the goods are located within a 50-mile radius of the motor carrier's or its agent's location, whichever is closer. The estimate must be prepared in accordance with a signed, written agreement, as specified in § 371.115 of this subpart.

(b) You must base your estimate upon the published tariffs of the authorized motor carrier who will transport the shipper's household goods.

(c)(1) A shipper may elect to waive the physical survey required in paragraph (a) of this section by written agreement signed by the shipper before the shipment is loaded.

(2) The household goods broker must explain the physical survey waiver agreement to the individual shipper in plain English. The physical survey waiver agreement must be printed on the written estimate and must be printed at no less than 7-point font size and with the font typeface Unifont.

(3) A copy of the waiver agreement must be retained as an addendum to the

bill of lading and is subject to the same record inspection and preservation requirements as are applicable to bills of lading.

(d) You must keep the records required by this section for three years following the date you provide the written estimate for an individual shipper who accepts the estimate and has you procure the transportation.

§ 371.115 Must I maintain agreements with motor carriers before providing written estimates on behalf of these carriers?

(a) In order to provide estimates of charges for the transportation of household goods, you must do so in accordance with the written agreement required by § 375.409 of this subchapter. Your written agreement with the motor carrier(s) must include the following items:

(1) Your broker name as shown on your FMCSA registration, your physical address, and your U.S. DOT registration number and MC license number;

(2) The authorized motor carrier's name as shown on its FMCSA registration, its physical address, and its U.S. DOT registration number and MC license number;

(3) A concise, easy to understand statement that your written estimate to the individual shipper:

(i) Will be exclusively on behalf of the authorized household goods motor carrier;

(ii) Will be based on the authorized household goods motor carrier's published tariff; and

(iii) Will serve as the authorized household goods motor carrier's estimate for purposes of complying with the requirements of part 375 of this chapter, including the requirement that the authorized household goods motor carrier relinquishes possession of the shipment upon payment of no more than 110 percent of a non-binding estimate at the time of delivery;

(4) Your owner's, corporate officer's, or corporate director's signature lawfully representing your household goods broker operation and the date;

(5) The signature of the authorized household goods motor carrier's owner, corporate officer, or corporate director lawfully representing the household goods motor carrier's operation and the date; and

(b) The signed written agreement required by this section is public information and you must produce it for review upon reasonable request by a member of the public.

(c) You must keep copies of the agreements required by this section for as long as you provide estimates on behalf of the authorized household

goods motor carrier and for three years thereafter.

§ 371.117 Must I provide individual shippers with my policies concerning cancellation, deposits, and refunds?

(a) You must disclose prominently on your Internet Web site and in your agreements with prospective shippers your cancellation policy, deposit policy, and policy for refunding deposited funds in the event the shipper cancels an order for service before the date an authorized household goods motor carrier has been scheduled to pick up the shipper's property.

(b) You must maintain records showing each individual shipper's request to cancel a shipment and the disposition of each request for a period of three years after the date of a shipper's cancellation request. If you refunded a deposit, your records must include:

- (1) Proof that the individual shipper cashed or deposited the check or money order, if the financial institution provides documentary evidence; or
- (2) Proof that you delivered the refund check or money order to the individual shipper.

§ 371.121 What penalties may FMCSA impose for violations of this part?

The penalty provisions of 49 U.S.C. chapter 149, *Civil and Criminal Penalties* apply to this subpart. These penalties do not overlap. Notwithstanding these civil penalties, nothing in this section deprives an individual shipper of any remedy or right of action under existing law.

PART 375—TRANSPORTATION OF HOUSEHOLD GOODS IN INTERSTATE COMMERCE; CONSUMER PROTECTION REGULATIONS

- 4. Revise the authority citation for part 375 to read as follows:

Authority: 5 U.S.C. 553; 49 U.S.C. 13102, 13301, 13704, 13707, 14104, 14706, 14708; subtitle B, title IV of Pub. L. 109-59; and 49 CFR 1.73.

- 5. Amend § 375.213 by revising paragraphs (a), (b)(1), and (d), and adding paragraph (e) to read as follows:

§ 375.213 What information must I provide to a prospective individual shipper?

(a) When you provide the written estimate to a prospective individual shipper, you must also provide the individual shipper with a copy of Department of Transportation publication FMCSA-ESA-03-005 (or its successor publication) entitled "Ready to Move?—Tips for a Successful Interstate Move." You may provide the

individual shipper with a paper copy or you may provide a hyperlink on your Internet Web site to the FMCSA Web site containing the information in FMCSA's publication "Ready to Move?—Tips for a Successful Interstate Move."

(b) * * *

(1) The contents of appendix A of this part, entitled "Your Rights and Responsibilities When You Move" (Department of Transportation publication FMCSA-ESA-03-006, or its successor publication). You may provide the individual shipper with a paper copy or you may provide a hyperlink on your Internet Web site to the FMCSA Web site containing the information in FMCSA's publication "Your Rights and Responsibilities When You Move."

* * * * *

(d) Paragraphs (c)(2) and (c)(3) of this section do not apply to exact copies of appendix A published in the **Federal Register**, the Code of Federal Regulations, or on FMCSA's Web site.

(e) If an individual shipper elects to waive physical receipt of the Federal consumer protection information by one of the methods described in paragraphs (a) and (b)(1) of this section, and elects to access the same information via the hyperlink on the Internet as provided in paragraphs (a) and (b)(1) of this section:

(1) You must include a clear and concise statement on the written estimate described in § 375.401 that the individual shipper expressly agreed to access the Federal consumer protection information on the Internet.

(2) You must obtain a signed, dated, electronic or paper receipt showing the individual shipper has received both booklets that includes, if applicable, verification of the shipper's agreement to access the Federal consumer protection information on the Internet.

(3) You must maintain the signed receipt required by paragraph (e)(2) of this section for three years from the date the individual shipper signs the receipt.

- 5. Revise § 375.409 to read as follows:

§ 375.409 May household goods brokers provide estimates?

(a) Subject to the limitations in § 371.113(a) of this subchapter, household goods brokers may provide estimates to individual shippers provided there is a written agreement between the broker and you, the motor carrier, adopting the broker's estimate as your own estimate. If you, the motor carrier, make such an agreement with a household goods broker, you must ensure compliance with all requirements of this part pertaining to estimates, including the requirement

that you must relinquish possession of the shipment if the shipper pays you no more than 110 percent of a non-binding estimate at the time of delivery.

(b) Your written agreement with the household goods broker(s) must include the items required in § 371.115(a) of this subchapter.

PART 386—RULES OF PRACTICE FOR MOTOR CARRIER, BROKER, FREIGHT FORWARDER, AND HAZARDOUS MATERIALS PROCEEDINGS

- 6. Revise the authority citation for part 386 to read as follows:

Authority: 49 U.S.C. 113, chapters 5, 51, 59, 131-141, 145-149, 311, 313, and 315; Sec. 204, Pub. L. 104-88, 109 Stat. 803, 941 (49 U.S.C. 701 note); Sec. 217, Pub. L. 105-159, 113 Stat. 1748, 1767; Sec. 206, Pub. L. 106-159, 113 Stat. 1763; subtitle B, title IV of Pub. L. 109-59; and 49 CFR 1.45 and 1.73.

- 7. Amend appendix B to part 386 by revising the heading and by adding paragraphs (g)(22) and (23) to read as follows:

Appendix B to Part 386—Penalty Schedule; Violations and Monetary Penalties

* * * * *

(g) * * *

(22) A broker for transportation of household goods who makes an estimate of the cost of transporting any such goods before entering into an agreement with a motor carrier to provide transportation of household goods subject to FMCSA jurisdiction is liable to the United States for a civil penalty of not less than \$10,000 for each violation.

(23) A person who provides transportation of household goods subject to jurisdiction under 49 U.S.C. chapter 135, subchapter I, or provides broker services for such transportation, without being registered under 49 U.S.C. chapter 139 to provide such transportation or services as a motor carrier or broker, as the case may be, is liable to the United States for a civil penalty of not less than \$25,000 for each violation.

* * * * *

PART 387—MINIMUM LEVELS OF FINANCIAL RESPONSIBILITY FOR MOTOR CARRIERS

- 8. The authority citation for part 387 continues to read as follows:

Authority: 49 U.S.C. 13101, 13301, 13906, 14701, 31138, 31139, and 31144; and 49 CFR 1.73.

- 9. Amend § 387.307 by redesignating paragraph (a) as paragraph (a)(1) and adding new paragraph (a)(2) to read as follows:

§ 387.307 Property broker surety bond or trust fund.

(a) *Security.* (1) * * *

(2) A household goods broker must have a surety bond or trust fund in effect for \$25,000 on and after January 1, 2012. The FMCSA will not issue a household goods broker license until a surety bond or trust fund for the full limits of liability prescribed herein is in effect. The household goods broker

license remains valid or effective only as long as a surety bond or trust fund remains in effect and ensures the financial responsibility of the household goods broker. The compliance date for paragraph (a)(2) is January 1, 2012.

* * * * *

Issued on: November 19, 2010.

Anne S. Ferro,
Administrator.

[FR Doc. 2010-29813 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-EX-P

Proposed Rules

Federal Register

Vol. 75, No. 228

Monday, November 29, 2010

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.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 701, 704, and 741

RIN 3133-AD74

Corporate Credit Unions

AGENCY: National Credit Union Administration.

ACTION: Proposed rule.

SUMMARY: NCUA is issuing proposed amendments to its rule governing corporate credit unions (corporates). The amendments include internal control and reporting requirements for corporates similar to those required for banks under the Federal Deposit Insurance Act and the Sarbanes-Oxley Act. The amendments require each corporate to establish an enterprise-wide risk management committee staffed with at least one risk management expert. The amendments provide for the equitable sharing of Temporary Corporate Credit Union Stabilization Fund (TCCUSF) expenses among all members of corporates, including both credit union and noncredit union members. The amendments increase the transparency of decision-making by requiring that corporates conduct all board of director votes as recorded votes and include the votes of individual directors in the meeting minutes. The amendments permit corporates to charge their members reasonable one-time or periodic membership fees as necessary to facilitate retained earnings growth. For senior corporate executives who are dual employees of corporate credit union service organizations (CUSOs), the amendments require disclosure of certain compensation received from the corporate CUSO. In addition, this proposal would amend our regulations to limit natural person credit unions (NPCUs) to membership in one corporate credit union at any particular time and provide that a natural person credit union may not make any investment in a corporate credit union

of which the natural person credit union is not also a member. These proposed amendments will further strengthen individual corporates and the corporate system as a whole.

DATES: Comments must be received on or before December 29, 2010.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

NCUA Web site: <http://www.ncua.gov/Resources/RegulationsOpinionsLaws/ProposedRegulations.aspx>. Follow the instructions for submitting comments.

E-mail: Address to regcomments@ncua.gov. Include "[Your name] Comments on 'Notice of Proposed Rulemaking for Part 704—Corporate Credit Unions'" in the e-mail subject line.

Fax: (703) 518-6319. Use the subject line described above for e-mail.

Mail: Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428.

Hand Delivery/Courier: Same as mail address.

Public Inspection: All public comments are available on the agency's Web site at <http://www.ncua.gov/Resources/RegulationsOpinionsLaws/ProposedRegulations.aspx> as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518-6546 or send an e-mail to OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Jacqueline Lussier, Staff Attorney, Office of General Counsel; Elizabeth Wirick, Staff Attorney, Office of General Counsel; and Lisa Henderson, Staff Attorney, Office of General Counsel, at the address above or telephone (703) 518-6540; or David Shetler, Deputy Director, Office of Corporate Credit Unions, at the address above or telephone (703) 518-6640.

SUPPLEMENTARY INFORMATION: The NCUA performs its mission of ensuring

the safety and soundness of Federally-insured credit unions by examining all Federal credit unions, participating in the examination and supervision of Federally-insured, State-chartered credit unions in coordination with State regulators, and insuring Federally-insured credit union members' accounts. In its statutory role as the administrator of the National Credit Union Share Insurance Fund (NCUSIF), NCUA insures and supervises approximately 7,500 Federally-insured credit unions (FICUs), representing 98 percent of all credit unions and serving approximately 90 million members.

Corporate Credit Union System

A corporate credit union is an organization, chartered under the Federal Credit Union Act (the Act) or under applicable State law as a credit union that receives share deposits from and provides loan and other services primarily to other credit unions. 12 CFR 704.2. There are 26 *retail* corporates that provide services directly to NPCUs, and there is one *wholesale* corporate, U.S. Central Bridge Federal Credit Union (U.S. Central Bridge), that provides services to many of the 26 retail corporates. Fourteen retail corporates and U.S. Central Bridge are Federally-chartered and 12 retail corporates are State-chartered.

Like NPCUs, corporates are member-owned cooperatives. However, at corporates the member-owners are primarily NPCUs. Over 95 percent of NPCUs belong to corporate credit unions. In addition, other entities that are not Federally-insured credit unions (i.e., "non FICUs") also may become members of corporates. These nonfederally-insured members consist of nonfederally-insured credit unions¹ and non credit union entities. Non credit union entities include credit union leagues and trade associations, CUSOs, certain banks, and other types of organizations. These other organizations include, for example, credit union political action committees, credit union charitable and educational foundations, and law firms, insurance agencies, and mortgage

¹ Within the 50 states, approximately 152 state-chartered credit unions have private, primary share insurance and are not subject to NCUA regulation or oversight.

companies that are connected to the credit union industry.

The corporate system offers a broad range of support to its members. The products and services provided by U.S. Central Bridge to retail corporates, and by retail corporates to their members, include, among other things: investment and deposit services, wire transfers, share draft processing and imaging, automated clearinghouse (ACH) transactions processing, automated teller machine (ATM) processing, bill payment services, and security safekeeping. The volume of payment systems-related transactions throughout the system annually runs into the millions and the dollar amounts associated with those transactions are in the billions each month. Corporates also serve as liquidity providers for their members. An NPCU invests excess liquidity in a corporate when the NPCU has lower loan demand and draws down the invested liquidity when loan demand increases.

Some NPCUs depend heavily on corporates; for example, 75 percent of NPCUs rely on a corporate as their primary settlement agent. Corporates provide NPCUs with convenient and quality services and expertise, all at a fair price. For many NPCUs, this is a combination that makes the corporate system a valuable resource and, for some smaller NPCUs, an essential resource.

Federally-chartered corporates are governed by Federal law and State-chartered corporate credit unions by State law. In addition, all corporates that are Federally insured, or that accept share deposits from NPCU members that are Federally insured, must comply with NCUA's part 704 corporate rule. 12 CFR 704.1, 12 U.S.C. 1766(a).

NCUA recently made substantial revisions to part 704 (with conforming amendments to parts 702, 703, 709, and 747). Final Rule, 75 FR 64786 (October 20, 2010) (September Rulemaking). The most significant amendments establish a new capital scheme, including risk-based capital requirements; impose new prompt corrective action requirements; place various new limits on corporate investments; impose new asset-liability management controls; amend some corporate governance provisions; and limit a corporate CUSO to categories of services preapproved by NCUA. The preamble to the September Rulemaking also stated that shortly after its promulgation the Board intended to issue another proposal that would further amend Part 704 and related provisions. *Id.* at 64824. This current proposal is the referenced follow-on rulemaking.

These proposed amendments would:

(1) Increase the transparency of corporate credit union decision-making by requiring corporates conduct all board of director votes as recorded votes and include the votes of individual directors in the meeting minutes;

(2) Incorporate certain sound audit, reporting, and audit committee practices from the Federal Deposit Insurance Act (FDI Act), Part 363 of the Federal Deposit Insurance Corporation (FDIC) Regulations, and the Sarbanes-Oxley Act of 2002 (SOX);

(3) Provide for the equitable sharing of TCCUSF expenses among all members of corporate credit unions, including both credit union and noncredit union members, by establishing procedures for requesting members not insured by the NCUSIF to make voluntary premium payments to the TCCUSF;

(4) Protect against unnecessary competition between corporates by limiting NPCUs to membership in one corporate of the NPCU's choice at any one time and prohibiting an NPCU from making any investment in a corporate where the NPCU is not also a member;

(5) Improve risk management at corporates by requiring corporates to establish enterprise-wide risk management committees staffed with at least one independent risk management expert;

(6) Provide corporates with more options to grow retained earnings by allowing corporates to charge their members reasonable one-time or periodic membership fees; and

(7) Require the disclosure of compensation received from a corporate CUSO by certain highly compensated corporate credit union executives.

These proposals are discussed in more detail below in the section-by-section analysis.

Section-by-Section Analysis of Proposed Amendments

Section 701.5 Membership Limited to One Corporate Credit Union

In the recent past, some NPCUs "rate shopped" among corporates for the highest deposit rates and lowest service costs. This rate shopping resulted in increased competition and, in some cases, led to unsafe investment activities as corporates sought higher investment yields to subsidize share dividends and service costs.

Proposed § 701.5 seeks to prevent unhealthy competition among corporates by requiring Federal credit unions to make a decision to commit to membership in one corporate at a time. The proposal provides that a Federal credit union may belong to two

corporates for a short period of time, but only when transitioning between those corporates. In addition, the proposal prohibits a Federal credit union from making any investment, including a share or deposit account, a loan, or a capital investment, in a corporate of which the Federal credit union is not a member.² This will avoid unhealthy competition among corporates driven by rate shopping among nonmembers.

Proposed § 701.5 has prospective impact only. That is, credit unions that are currently members of two or more corporates do not have to relinquish memberships in any of those corporates. The Board believes that the members of a credit union are owners of that credit union, including the members of a corporate, and that "once a member, always a member."

The Board also notes that § 704.8(k) applies a 15 percent investment limit to investments in a corporate made by a "member or nonmember credit union." This section does not authorize investments by nonmembers, and, if the Board adopts § 701.5(c) as proposed, it is unlikely that a nonmember credit union would be able to make any investments in a corporate where it is not already a member.

These same restrictions, through language added in new § 741.226 of part 741, would apply to State-chartered Federally-insured NPCUs as well as FCUs.

This proposal also contains the following changes to part 704.

Section 704.2 Definitions

The NCUA Board is proposing to add a number of new definitions to § 704.2 to assist in complying with the proposed revisions to § 704.15 discussed below. The defined terms include: *Critical accounting policies*, *Enterprise risk management*, *Examination of internal control*, *Family*, *Financial statements*, *Financial statement audit*, *Generally accepted auditing standards*, *Independent public accountant*, *Internal control*, *Internal control framework*, *Internal control over financial reporting*, and *Supervisory committee*.

The associated definitions come from a variety of sources, including other sections of the NCUA Rules and Regulations, auditing and accounting industry standards, and Securities and Exchange Commission (SEC) rules. The Board requests comment on the appropriateness of these definitions.

² The FCU Act provisions generally authorizing such nonmember transactions, such as 12 U.S.C. 1757(6) and 1757(7)(C), are specifically subject to the regulation of the Board. 12 U.S.C. 1757 and 1782.

Section 704.11 Corporate Credit Union Service Organizations; § 704.19 Disclosure of Executive and Director Compensation

The recently adopted revisions in the September Rulemaking require that each corporate annually prepare, and provide to its members, a document that discloses the compensation of certain employees. 12 CFR 704.19(a). An employee of a corporate may also, however, be an employee of a corporate CUSO and receive additional compensation from the CUSO. The dual employee's compensation disclosure under § 704.19(a) would be incomplete without a disclosure of both sources of compensation, particularly where the employee's corporate has made a loan to, or other investment in, that corporate CUSO and so has some control over the CUSO.

The proposal amends § 704.19 to clarify that for CUSOs in which a corporate has invested, the corporate must include compensation received from the CUSO in disclosures of compensation paid to the corporate's most highly compensated employees. To facilitate this disclosure, the proposal also amends § 704.11(g), which lists certain items with which a CUSO must agree in writing before a corporate credit union may make a loan to or invest in the CUSO. The amendment to § 704.11(g) requires a corporate CUSO disclose compensation paid to any employees that are also employees of a corporate credit union lending to, or investing in, the CUSO. This ensures that CUSOs will provide corporate credit unions the information necessary for the corporate to make the full disclosure required by § 704.19.

The proposal applies only to corporate employees. It does not amend or otherwise modify § 704.11(f), which prohibits officials of corporate credit unions which have invested in or loaned to a corporate CUSO from receiving any compensation or other payments from the corporate CUSO.

Section 704.13 Board Responsibilities

The proposal adds a new subparagraph (c)(8) to § 704.13, *Board responsibilities*, to require that all board of directors votes be conducted by recorded votes.³

The minutes reporting the vote must identify the board members, by name, who voted for or against the proposal, as well as, if applicable, the board members who were absent or otherwise failed to vote, and any board members

who abstained from voting. The Board believes this provision is necessary so as to increase the transparency of corporate board actions.

The corporate credit union system has confronted profound challenges during the economic crisis of the past several years. Some corporate credit unions made poor investment decisions, and these decisions caused billions of dollars of losses. Unfortunately, the role of individual directors in these decisions was not always clear because the board secretary did not always record the votes of individual directors in the minutes of the board meeting.

Corporate boards are likely to continue to face crucial decisions. For example, the ongoing effects of the financial crisis may force some corporates to confront critical restructuring questions in which the interests of NPCUs utilizing different services of the corporate may diverge. In these situations, members may need to know how each director voted in addition to knowing the outcome of the vote.

Also, requiring recorded votes will help to ensure that corporate directors comply with their obligation to recuse themselves from deliberating and voting on items which may involve a conflict of interest. Article XI, § 2 of the Standard Corporate Federal Credit Union Bylaws prohibits corporate insiders, including directors, from participating "in any manner, directly, or indirectly in the deliberation upon or the determination of any question affecting his/her pecuniary interest or the pecuniary interest of any corporation, partnership, or association (other than the corporate credit union) in which he/she is directly or indirectly interested." If a director is disqualified because of a conflict, the director must withdraw from deliberation and determination of the issue. *Id.* Under the bylaw, the director has the obligation to identify issues that may pose a conflict of interest and withdraw from deliberation and determination of these issues. If, however, a director fails to self-identify or report a potential conflict, it would be difficult to determine whether or how the director voted on an issue without disclosure of votes on a director-by-director basis. The accountability and transparency that results from recording vote tallies by name will provide an important backstop to the self-policing aspect of the corporate bylaw conflict-of-interest provision.

NCUA's existing regulations provide some transparency to members, but may not be sufficient absent a specific requirement to record votes by name.

For example, NCUA's regulations provide a process by which members of credit unions, including members of corporate credit unions, may inspect the credit union's books and records as well as minutes of member, board, and committee meetings. 12 CFR 701.3(a). Members seeking access to records must submit a petition signed by one percent of the credit union's members; the petition must identify particular records and state a purpose related to the protection of the members' financial interest in the credit union. 12 CFR 701.3(b). Like the current proposal, the rule providing for member access to records increases the transparency of actions and decisions of the credit union's leadership. If, however, the corporate credit union's records lack recorded votes showing how each director voted on a particular issue, members would not be able to get the director-by-director tally even after submitting a petition.

There are multiple sources of authority for NCUA's proposed amendment to paragraph 704.13(c). The Act grants NCUA broad authority to require FICUs, including corporate credit unions, to submit financial data and other information as required by the NCUA Board. 12 U.S.C. 1761, 1766, 1781, and 1789. Further, the Act authorizes the NCUA Board to request additional information as it may require. 12 U.S.C. 1782(a)(2). NCUA's recommended standard procedures for corporate credit union examinations include a review of minutes of the board of directors' meetings or actions. NCUA Corporate Examination Procedures § 301P-004 (2003). Like the review of board minutes, the proposal falls under NCUA's general powers to require both Federal credit unions and Federally-insured State-chartered credit unions to prepare and submit information in connection with insurance examinations.

Section 704.15 Audit and Reporting Requirements

Both NCUA and natural person credit unions rely upon financial information to evaluate the condition of insured corporate credit unions and to determine the adequacy of regulatory capital. Accurate and reliable measurement of a corporate credit union's assets and earnings has a direct bearing on the determination of regulatory capital. Interested parties can place greater reliance on recognition, measurement, and disclosures contained in financial statements that have been subject to an independent audit. Independent audits help to identify weaknesses in internal control

³ The September Rulemaking redesignated the *Board Responsibilities* section from § 704.4 to § 704.13.

over financial reporting and risk management at corporate credit unions and reinforce corrective measures, thus complementing supervisory efforts in contributing to the safety and soundness of corporate credit unions.

NCUA currently requires that a corporate credit union's board of directors ensure the preparation of timely and accurate balance sheets, income statements, and internal risk assessments and that systems are audited periodically in accordance with industry standards. 12 CFR 704.4(c). In addition, a corporate credit union's supervisory committee must ensure that: (1) An external audit is performed annually in accordance with generally accepted auditing standards; and (2) the audit report is submitted to the board of directors, to NCUA, and in a summary version, to the members. 12 CFR 704.15(a).

To facilitate early identification of problems in financial management at corporate credit unions, the NCUA Board is proposing to amend § 704.15 to add certain additional auditing, reporting, and supervisory committee requirements. The most significant proposed revisions would require a corporate credit union to:

Ensure that its financial reports reflect all material correcting adjustments necessary to conform with generally accepted accounting principles (GAAP) that were identified by the corporate credit union's independent public accountant (IPA).

Prepare an annual management report, signed by the chief executive officer and the chief accounting officer or chief financial officer, that contains: (1) A statement of management's responsibility for preparing financial statements, responsibility for establishing and maintaining an adequate internal control structure, responsibility for procedures for financial reporting, and responsibility for complying with laws and regulations relating to safety and soundness designated by NCUA; (2) an assessment of the corporate credit union's compliance with such laws and regulations; and (3) for a corporate with assets of at least \$1 billion, an assessment of the effectiveness of the internal control structure and procedures over financial reporting, including identifying the internal control framework used to evaluate such internal control.

Ensure that its IPA: (1) Reports on a timely basis to the supervisory committee all critical accounting policies, alternative accounting practices discussed with management, and written communications provided

to management; (2) retains the working papers related to an audit and, if applicable, the evaluation of the corporate credit union's internal control over financial reporting, for seven years from the report release date; (3) complies with the independence standards and interpretations of the American Institute of Certified Public Accountants (AICPA); (4) has, prior to beginning any services for a corporate, a peer review that meets acceptable audit industry guidelines; (5) notifies NCUA if the IPA ceases being a corporate credit union's independent accountant; and (6) for a corporate with assets of at least \$1 billion, reports separately to the supervisory committee on management's assertions concerning the effectiveness of the corporate credit union's internal control structure and procedures for financial reporting.

Ensure that its supervisory committee (1) consists of members who are not employees of the corporate credit union; (2) supervises the IPA; and (3) ensures that audit engagement letters do not contain unsafe and unsound limitation of liability provisions.

NCUA has based many of these proposed revisions on part 363 of the FDIC's Rules, 12 CFR part 363. The FDIC has provided guidance, found in Appendices A and B to part 363, to assist managements of banks and thrifts in complying with a number of part 363 requirements. The NCUA Board has determined not to issue similar formal guidance in conjunction with the proposed revisions to part 704.

The NCUA Board also notes that part 363 only applies to banks and thrifts with assets of at least \$500 million. In contrast, most of these proposed provisions to part 704 would apply to all corporate credit unions, even those smaller corporates with under \$500 million in assets.⁴ The Board believes that because corporates provide services to NPCUs, smaller corporate credit unions may present systemic risks that smaller banks and thrifts do not. The Board requests comment, however, on whether certain of the proposed provisions should apply only to corporate credit unions with assets above a certain threshold. Commenters should specify which provisions and what the asset threshold or thresholds should be.

⁴ A few provisions in proposed 704.15 would apply only to corporates with assets of at least \$1 billion.

Paragraph 704.15(a), Annual Reporting Requirements

704.15(a)(1) Audited Financial Statements

Proposed paragraph (a)(1) restates the existing requirement that a corporate credit union prepare audited financial statements that conform with GAAP. To facilitate a more accurate picture of a corporate credit union's financial condition, the proposal also adds the requirement that the annual financial statements reflect all material correcting adjustments identified by the IPA as necessary to conform with GAAP.

704.15(a)(2) Management Report

Proposed paragraph (a)(2) requires the management of a corporate prepare an annual report that contains certain enumerated elements.

The Board is concerned that management in some corporate credit unions may have insufficient oversight over certain reporting, control, and compliance functions. The Board believes that requiring management to acknowledge its responsibilities in these areas will help the corporate credit union identify needed improvements in financial management. Accordingly, proposed paragraph (a)(2)(i) requires management reports contain a statement of management's responsibilities for preparing the corporate credit union's annual financial statements, for establishing and maintaining an adequate internal control structure and procedures for financial reporting, and for complying with certain laws and regulations relating to safety and soundness.

The proposed rule identifies the following five safety and soundness areas about which the NCUA Board is concerned: affiliate transactions, legal lending limits, loans to insiders, restrictions on capital and share dividends, and regulatory reporting that meets full and fair disclosure. When the FDIC issued a proposed rule implementing new audit, reporting, and internal control requirements for certain banks and thrifts, see 12 CFR part 363, it identified these five areas as presenting the greatest risks. See 57 FR 42516, Sept. 15, 1992.⁵ Corporate credit unions are structured differently from banks, however, and the Board seeks comment on whether the five identified areas are appropriate. The Board also seeks comment on whether the final regulation should specify the laws and rules and regulations covered by

⁵ Ultimately, the FDIC limited its compliance concerns to laws and regulations concerning insider lending and dividend restrictions. See 58 FR 31332, June 2, 1993.

proposed paragraph (a)(2), such as section 107(5)(A)(iv) and (v) of the Federal Credit Union Act, 12 U.S.C. 1757(5)(A)(iv) and (v), governing loans to directors and committee members, and § 704.7, governing corporate credit union lending.

Proposed paragraph (a)(2)(ii) requires management assess and report on the corporate credit union's compliance with those designated safety and soundness laws and regulations. This assessment requirement reinforces the importance of management's responsibility for complying with the rules by requiring disclosure of instances of noncompliance. Management should perform its own investigation and review of compliance with the rules and maintain records of its assessments until the next NCUA examination or such later date as specified by NCUA.

The NCUA Board has determined that corporate credit unions with \$1 billion or more in total assets present additional risks. Accordingly, proposed paragraph (a)(2)(iii) requires these larger corporate credit unions include in their management reports an assessment of the effectiveness of the internal control structure over financial reporting. Management must identify the internal control framework used to make its evaluation, include a statement that the evaluation included controls over the preparation of financial statements and regulatory reports, include a statement as to management's conclusion regarding the effectiveness of internal control over financial reporting, and disclose all material weaknesses identified by management. Management may not conclude that internal control over financial reporting is effective if there are any material weaknesses.

A suitable control framework is one established by a body of experts following widespread opportunity for comment, including the broad distribution of the framework for public comment. A framework is suitable only when it:

- Is free from bias;
 - Permits reasonably consistent qualitative and quantitative measurements of a corporate credit union's internal control over financial reporting;
 - Is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of a corporate credit union's internal control over financial reporting are not omitted; and
 - Is relevant to an evaluation of internal control over financial reporting.
- The *Internal Control—Integrated Framework* published by the Committee

of Sponsoring Organizations of the Treadway Commission (the "COSO Report") provides a suitable and recognized framework for purposes of a management assessment in the United States. Other suitable frameworks have been published in other countries, and still others may be developed in the future. Such other suitable frameworks may be used by management and the corporate credit union's IPA in assessments, attestations, and audits of internal control over financial reporting.

704.15(a)(3) Management Report Signatures

To ensure that management understands its ultimate responsibility for the corporate credit union's performance, proposed paragraph (a)(3) requires the chief executive officer and either the chief accounting officer or chief financial officer of the corporate credit union to sign the management report.

704.15(b)(1) Annual Audit of Financial Statements

Proposed paragraph (b) sets forth the requirements applicable to the corporate's IPA. Proposed paragraph (b)(1) clarifies the existing requirement that a corporate credit union have its annual financial statements audited by an IPA in accordance with generally accepted auditing standards. The IPA should be registered or licensed to practice as a public accountant, and be in good standing, under the laws of the State or other political subdivision of the United States in which the home office of the corporate credit union is located.

704.15(b)(2) Internal Control Over Financial Reporting

Proposed paragraph (b)(2) requires an IPA who audits a corporate credit union with assets of at least \$1 billion attest to management's assertions concerning the effectiveness of the corporate credit union's internal control structure and procedures for financial reporting. To ensure that an attestation report is sufficiently informative, the report must:

- Identify the internal control framework that the IPA used to make the evaluation (which must be the same as the internal control framework used by management);
- Include a statement that the IPA's evaluation included controls over the preparation of regulatory financial statements;
- Include a clear statement as to the IPA's conclusion regarding the effectiveness of internal control over financial reporting;

- Disclose all material weaknesses identified by the IPA that have not been remediated;

- Conclude that internal control is ineffective if there are any material weaknesses; and
- Be dated by the IPA on or after the date of management's report on its assessment of the effectiveness of internal control over financial reporting.

704.15(b)(3) Notice by Accountant of Termination of Services

In the interests of safety and soundness, and to ensure that NCUA is aware of potential conflicts between a corporate credit union and its IPA, proposed paragraph (b)(3) requires an IPA to notify NCUA if the IPA terminates work as the corporate credit union's auditor. The IPA's notice of termination under (b)(3) is similar to the notice of termination in proposed paragraph (c)(4) that the corporate credit union must provide to both NCUA and the IPA. In its (b)(3) notice, the IPA must state whether the IPA agrees with the corporate credit union's assertions contained in the (c)(4) notice and whether the IPA agrees that the (c)(4) notice discloses all relevant reasons for the IPA's termination.

704.15(b)(4) Communications With Supervisory Committee

The Board believes that communications between a corporate credit union's supervisory committee and its auditor are critical to proper oversight of the auditing function. Accordingly, proposed paragraph (b)(4) establishes certain communication requirements between the auditor and the committee. Under the proposal, an IPA must inform the supervisory committee on a timely basis about: (1) All critical accounting policies, (2) alternative accounting treatments discussed with management, and (3) written communications provided to management, such as a management letter or schedule of unadjusted differences. These requirements are minimum requirements—other communications beyond these requirements are encouraged.

704.15(b)(5) Retention of Working Papers

Consistent with best industry practices, proposed paragraph (b)(5) requires an IPA to retain the working papers related to its audit of a corporate credit union's financial statements for at least seven years. If the IPA has conducted an evaluation of internal control over financial reporting, the IPA must also retain those working papers for at least seven years.

704.15(b)(6) Independence

Proposed paragraph (b)(6) codifies existing industry self-governance requirements that auditors comply with the independence standards of the American Institute of Certified Public Accountants (AICPA).

704.15(b)(7) Peer Reviews

Proposed paragraph (b)(7) codifies existing industry self-governance requirements that auditors undergo periodic peer reviews. The proposal clarifies that acceptable peer reviews include those performed in accordance with the AICPA's Peer Review Standards and inspections conducted by the Public Company Accounting Oversight Board (PCAOB). This paragraph also requires a corporate credit union's IPA to file a copy of the peer review report, or the public portion of the PCAOB inspection report, with NCUA.

704.15(c)(1) Annual Reporting

Proposed paragraph 704.15(c) sets forth various reporting, filing, and notice requirements. The current regulation is silent on when a corporate credit union must provide a copy of its annual report to NCUA. To ensure timely filing and provide consistent application of the requirement, proposed paragraph (c)(1) provides that a corporate credit union must file a copy of its annual report to NCUA within 180 days after the end of the calendar year. The report must contain the audited financial statements, the IPA's report on those statements, a management report, and, if applicable, the IPA's attestation report on management's assessment of internal control over financial reporting.

704.15(c)(2) Public Availability

Proposed paragraph (c)(2) provides that NCUA will make a corporate credit union's annual report available for public inspection.

704.15(c)(3) IPA's Reports

Consistent with good corporate governance, proposed paragraph (c)(3) requires a corporate credit union to provide NCUA with a copy of any management letter or report issued by its IPA. The proposal includes examples of the types of reports covered.

704.15(c)(4) Notice of Engagement or Change of Accountants

In the interests of safety and soundness, and as discussed above, proposed paragraph (c)(4) requires a corporate to inform NCUA when the credit union engages an IPA or loses an IPA through dismissal or resignation. The corporate must include with the

notice a reasonably detailed statement of the reasons for any dismissal or resignation. The corporate must send a copy of the (c)(4) notice required to the IPA when the notice is filed with NCUA.

704.15(c)(5) Notification of Late Filing

Proposed paragraph (c)(5) requires the corporate provide a notice to NCUA of late filing of the annual report. The notice must specify the reasons for the inability to comply with the 180-day requirement and must also state the date by which the report will be filed.

704.15(c)(6) Report to Members

Paragraph (a) of the current § 704.15 requires a corporate credit union to submit a summary of its annual report to the membership. Recognizing that a corporate credit union may not have completed its annual report at the time of the annual meeting, proposed paragraph (c)(6) substitutes the word "preliminary" for "summary."

704.15(d)(1) Composition

Proposed paragraph 704.15(d) deals with the corporate's supervisory committee. Proposed paragraph (d)(1) discusses the composition of the supervisory committee, stating that its members may not be employees of the corporate credit union and must be independent of the corporate credit union. The employment prohibition codifies Article X, Section 1, of the Corporate Federal Credit Union Bylaws for all corporates. The NCUA Board believes that in the interests of sound governance this prohibition should be applied to all corporates.

The Board further believes that to avoid potential conflicts of interest, supervisory committee members should be independent of the corporate. Under the proposal, a committee member is independent if he or she does not have any family relationships or material business or professional relationships with the corporate credit union and has been free of such relationships for at least three years.

704.15(d)(2) Duties

As a general matter, the supervisory committee should perform all the duties required of it under the corporate's bylaws as determined by the corporate's board of directors. Proposed paragraph (d)(2) clarifies that the committee is also responsible for the appointment, compensation, and oversight of the IPA, and for reviewing with management and the IPA the basis for audit reports.

As the SEC noted when it adopted its final rule implementing a similar provision regarding the audit

committees of public companies, the auditing process may be compromised if a company's outside auditors incorrectly view their primary responsibility as serving the company's management rather than the company's full board of directors or audit committee. See 68 FR 18787, 18796, Apr. 16, 2003. The SEC went on to state that auditors may view management as the "employer" if management has the power to hire, fire, and set compensation and that under these circumstances the auditor may not have the appropriate incentive to raise concerns and conduct an objective review. *Id.* The SEC concluded that one way to promote auditor independence was for the auditor to be hired, evaluated, and, if necessary, terminated by the audit committee. *Id.* The NCUA Board believes it is critical that accountants who perform audit and attestation services for corporates have an appropriate incentive to conduct an objective review and identify potential concerns. In this regard, the Board believes it is a sound governance practice for a corporate's supervisory committee, rather than its management, to be responsible for the appointment, compensation, and oversight of the accountant.

704.15(d)(3) IPA Engagement Letters

In response to an observed increase in the types and frequency of provisions in financial institutions' external audit engagement letters that limit the auditors' liability, in February 2006 the Federal financial institution regulatory agencies, including NCUA, issued an Interagency Advisory on the Unsafe and Unsound Use of Limitation of Liability Provisions in External Audit Engagement Letters (Interagency Advisory).⁶ The Advisory states that such provisions may weaken the external auditors' objectivity, impartiality, and performance, which in turn may reduce the reliability of audits and consequently raise safety and soundness concerns. The agencies stated that a financial institution should not enter into any agreement that incorporates limitation of liability provisions with respect to audits.

Since a central purpose of this proposal is to increase the reliability of audits, proposed paragraph (d)(3)(i)(B) requires the supervisory committee ensure that audit engagement letters and any related agreements with the IPA for services to be performed under part 704 do not contain certain limitation of liability provisions. Prohibited provisions include any language that

⁶ 27 FR 6847, Feb. 9, 2006.

indemnifies the IPA against claims made by third parties; holds harmless or release the IPA from liability for claims or potential claims that might be asserted by the client corporate credit union, other than claims for punitive damages; or limits the remedies available to the client corporate credit union. Consistent with the Interagency Advisory, the proposal does not preclude the use of alternative dispute resolution agreements and jury trial waivers.

704.15(d)(4) Outside Counsel

Proposed paragraph (d)(4) provides that the supervisory committee must, when deemed necessary by the committee, have access to its own outside counsel. All counsel retained by a corporate, regardless of who at the corporate retained the counsel, owe the same fiduciary duties, that is, to provide advice in the best interests of the membership. Accordingly, in most circumstances the Board expects the supervisory committee, when seeking legal advice, would employ the services of the in-house counsel or other counsel under contract to the corporate. The Board believes, however, that in the interest of safety and soundness the supervisory committee must be able to retain counsel at its discretion without prior permission of the board of directors or management, particularly when the committee perceives that the in-house counsel or other counsel under contract to the corporate may be unable to provide unbiased advice.

704.15(e) Internal Audit

Paragraph (e) restates the internal audit requirements in the current paragraph (b).

704.21 Equitable Distribution of Corporate Credit Union Stabilization Expenses

Some of the recent corporate investment losses were absorbed directly by the members of the corporates in the form of capital depletion. Much of these losses, however, were absorbed by the NCUSIF as it made capital injections and launched liquidity and share guarantee programs designed to stabilize the corporate system and protect the system from collapse. The corporate losses absorbed by the NCUSIF—and subsequently transferred from the NCUSIF to the TCCUSF in June of 2009 and 2010—will be paid by all FICUs in the form of premium assessments now and over the next several years. The stabilization actions taken by NCUA to protect the corporate system benefitted every member of every corporate, both

FICU and non FICU.⁷ Without NCUA's stabilization actions, the entire corporate system would have been in danger of collapse. NCUA's actions protected both FICUs and non FICUs from potential losses in their uninsured shares and from other potential problems, such as interruptions in their payment systems. Unfortunately, however, not all corporate members have assumed their fair share of the expense of NCUA's corporate stabilization actions. In particular, non FICU members have not paid, and likely will not pay in the future without some encouragement, their fair share of the expenses associated with NCUA's stabilization actions. Accordingly, and as discussed below, this proposal seeks to encourage existing non FICU members to pay their fair share of such expenses.

The proposal adds a new § 704.21, *Equitable Distribution of Corporate Credit Union Stabilization Expenses*, to provide for the equitable sharing of TCCUSF expenses among all members of corporate credit unions. Proposed § 704.21 provides that when the NCUA Board assesses a TCCUSF premium on FICUs, NCUA will request existing non FICU members make voluntary payments to the TCCUSF. It requires that when the NCUA Board imposes a TCCUSF premium assessment on FICUs, a corporate credit union must furnish to NCUA information about all its non FICU members. NCUA will then request each of these non FICU members to make a voluntary premium payment to the TCCUSF in an amount calculated as a percentage of the non FICU member's previous year-end assets.⁸ In the event one or more of these non FICUs declines to make the requested payment, or makes a payment in an amount less than requested, the proposal requires the corporate conduct a member vote on whether to expel that non FICU. A paragraph-by-paragraph breakdown of § 704.21 follows.

When the Board acts to assess a premium on FICUs, paragraph (a) provides that each corporate credit union must prepare a list of all its members on the date of the assessment that are non FICUs, including the name and assets of each such member, with the address and contact information for

⁷ The term "non FICU" includes every corporate member that is not insured by the NCUSIF. Trade associations, CUSOs, non credit union cooperatives, banks, insurance companies, and privately insured credit unions are examples of entities that might be members of certain corporates and fall within the term "non FICU."

⁸ See 12 U.S.C. 1772a (authority of NCUA to accept gifts for carrying out any of its functions under the Act); and 12 U.S.C. 1789.

each such member. The assets of the non FICUs will be determined as of the previous year-end. The corporate should collect information from the member to support this asset calculation, such as an annual financial statement. If the member will not provide this information to the corporate, the corporate should simply make its best estimate of the asset size and inform NCUA of the basis for the estimate.

Paragraph (b) provides that within 14 days after the date of the assessment on FICUs, the corporate credit union must send the list of non FICU members to the NCUA Office of Corporate Credit Unions. A corporate that has no non FICU members must provide the Office of Corporate Credit Unions with a statement to that effect.

Paragraph (c) provides that within 60 days after the date of assessment on FICUs, the NCUA Chief Financial Officer will request each non FICU to make a voluntary payment to the TCCUSF. The amount of the requested payment will be the entity's assets times 0.815 times the percentage of insured shares that each FICU was assessed. The payment must be received by NCUA within 60 days after the date of the Chief Financial Officer's request.

NCUA determined the 0.815 factor by using the ratio of total aggregate FICU insured shares to aggregate FICU assets. NCUA calculated these ratios for year-end 2008 (ratio = 0.810)⁹ and year-end 2009 (ratio = 0.819)¹⁰ and then averaged the two ratios to obtain the factor 0.815. Accordingly, multiplying a non FICU's assets by 0.815 produces an amount approximating the entity's "insured shares" as if the entity were a Federally-insured credit union.

Paragraph (d) provides that if NCUA does not receive a full, timely payment of the TCCUSF contribution requested, NCUA will notify the corporate credit union of the failure. Paragraph (e) requires that no later than 90 days after receipt of the notice from NCUA, the corporate must call a special meeting of its members to determine whether each member that failed to make the full payment should be expelled from the corporate credit union. For Federally-chartered corporates, the expulsion vote will be conducted in accordance with § 118(a) of the Act, which provides that a member may be expelled by a two-thirds vote of the members present at a special meeting called for that purpose,

⁹ 2008: total shares \$658.9 billion; total assets \$813.4 billion. <http://www.ncua.gov/Resources/Reports/statistics/Yearend2008.pdf> (page 1, footnote 3).

¹⁰ 2009: total shares \$724.8 billion; total assets \$884.8 billion. <http://www.ncua.gov/Resources/Reports/statistics/Yearend2009.pdf> (page 1).

but only after an opportunity has been given to the member to be heard. 12 U.S.C. 1764(a); see Article III, § 5 of the Standard Federal Corporate Credit Union Bylaws. For State-chartered corporates, the expulsion vote will be conducted in accordance with the bylaws of the corporate and applicable State law.

Paragraph (f) permits the corporate to conduct the expulsion vote at an annual meeting, if that would coincide with the date of any special meeting called under paragraph (e).

Paragraph (g) provides that for non FICUs that belong to more than one corporate, NCUA will request only one voluntary payment from that non FICU in connection with each TCCUSF assessment. If NCUA does not receive full payment of the amount requested, however, NCUA will notify all corporates to which the non FICU belongs for purposes of conducting an expulsion vote.

As should be clear from the language of proposed § 704.21, NCUA does not ultimately make the determination of whether a non FICU should make a payment to the TCCUSF or the amount of the payment. The non FICU makes that determination. NCUA also does not make the determination of the adequacy of any payment. The members of the affected corporate make that determination when deciding whether or not to expel the non FICU member. It is these corporate members, and particularly the FICU corporate members, that have a vested financial interest in whether or not non FICU members are contributing equitably to cover losses in the corporate credit union system.

The Board does not intend at this time to apply § 704.21 retroactively. Section 704.21 would only apply to TCCUSF assessments made following the effective date of any final rule.

704.22 Enterprise Risk Management

Sound risk management is an integral part of running a corporate credit union, and corporates need to strengthen their enterprise risk management. A well-designed enterprise risk management process can help a corporate by providing a framework within which the board of directors and senior management can determine:

- Where all the corporate's risk exposures lie;
- The amount of risk the corporate has in each exposure and the maximum levels it is willing to accept;
- How the risk exposures are changing; and
- The appropriate risk controls to limit overall risk to targeted levels.

Accordingly, this proposal adds a new § 704.22, *Enterprise Risk Management*. This section requires corporates to develop and follow an enterprise risk management policy (paragraph (a)). The board of directors must establish an enterprise risk management committee that is responsible for overseeing the corporate's risk management practices and must report to at least annually to the board of directors (paragraph (b)). The committee must include at least one independent risk management expert with sufficient experience in identifying, assessing, and managing risk exposures (paragraph (c)).

The proposal defines *independent* to mean that the expert does not have any family relationships or any material business or professional relationships with the corporate that would affect his or her independence as a committee member, and has been free of any such relationships for at least three years (paragraph (d)). The risk management expert will have post-graduate education; an actuarial, accounting, economics, financial, or legal background; and at least five years experience in identifying, assessing, and managing risk exposures. The expert's experience must also be commensurate with the size of the corporate and the complexity of its operations. Proposed paragraph 704.22(e) clarifies that the risk management expert is not required to be a director of the corporate credit union. The board must hire this individual from outside the corporate.

Proposed paragraph 704.15(a)(2)(iii) requires management of a corporate with assets of at least \$1 billion assess the effectiveness of the corporate's internal control structure and procedures for financial reporting. Proposed paragraph 704.15(a)(3) requires the corporate's managers to sign the report. The Board requests comment on whether NCUA should add a corresponding requirement that management assess the effectiveness of the corporate's enterprise risk reporting and that the senior risk management official sign the management report.

704.23 Membership Fees

This proposal adds a new § 704.23, *Membership Fees*, permitting corporates the option of charging their members, as a mandatory requirement of membership, reasonable one-time or periodic membership fees. The fees must generally be proportional to the member's asset size, and a member must be given at least six months notice of any new fees, or any material change to an existing fee. Furthermore, a corporate can terminate the membership of any

credit union that fails to pay the fee fully and on time.

The September Rulemaking requires corporates to achieve certain minimum capital ratios, including, over time, certain minimum retained earnings ratios. NCUA is proposing this amendment to provide corporates with additional options in building up their retained earnings. Unlike a capital contribution, which will not flow to retained earnings, a membership fee flows directly to a corporate's retained earnings.

Paragraph (a) states that a corporate may charge its members a membership fee. The fees may be assessed on a periodic basis or as a one-time fee.

Paragraph (b) provides that the corporate must calculate the fee uniformly for all members and as a percentage of each member's assets. However, the corporate has the discretion to reduce the amount of the fee for members that have contributed capital to the corporate. Any such reduction must be proportional to the amount of the member's non-depleted contributed capital. Calculating the fee as a percentage of each member's assets is fairer to smaller natural person credit unions than a one-size-fits-all fee. In addition, NCUA wishes to give corporates the flexibility to reduce the size of the fee for those members that are contributing more capital to the corporate.

Paragraph (c) requires a corporate to give its members a minimum of six months notice of any new fee, including disclosure of its terms and conditions, before invoicing the fee. For a recurring fee, the corporate must also provide six months notice of any material change to the terms and condition of the fee. Corporate members should be given adequate time to look for alternatives to membership in the corporate should they find the fees too onerous. The Board believes that six months to find an alternative service provider should be appropriate.

Paragraph (d) permits a corporate to terminate the membership of any credit union that fails to pay the fee in full within 60 days of the invoice date. The Board believes this is a reasonable amount of time, given the advance notice required by paragraph (c).

Comment Period

The Board is putting this proposal out for a 30-day comment period in lieu of the standard 60-day comment period. The proposed rule is straightforward in its operation, and so does not require extensive time to consider. In addition, the Board desires, as much as possible, to coordinate the effective date of this

rulemaking with the effective dates of the September Rulemaking.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any proposed regulation may have on a substantial number of small entities (those under \$10 million in assets). For the most part, the proposal applies only to corporate credit unions, all of which have assets well in excess of \$10 million. The one provision that applies directly to natural person credit unions, which generally limits membership in one corporate at a time, will not affect many small credit unions because they generally do not belong to multiple corporates. Accordingly, the proposed amendments will not have a significant economic impact on a substantial number of small credit unions and, therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden. 44 U.S.C. 3507(d); 5 CFR part 1320. For purposes of the PRA, a paperwork burden may take the form of a reporting, recordkeeping, or disclosure requirement, each referred to as an information collection.

The proposed changes to part 704 in this proposal impose new information collection requirements. As required by the PRA, NCUA is submitting a copy of this proposal to OMB for its review and approval. Persons interested in submitting comments with respect to the information collection aspects of the proposed rule should submit them to OMB at the address noted below.

Estimated PRA Burden

The following discussion describes the new information collection requirements in the proposal:

1. Recorded director votes.

Proposed § 704.13(c)(8) revises existing § 704.13(c), *Board responsibilities*, to require corporates to conduct all board of directors votes by recorded vote, such that the minutes reporting the vote list the board members (by name) voting for or against the proposal, as well as, if applicable, board members who were absent or otherwise failed to vote, and board members who abstained from the vote. Proposed paragraph (c)(8) would apply to all 27 corporates. NCUA estimates that compliance with the requirement to

record all board votes and to include the votes of each director by name in the minutes will take about one hour. Corporates are required to hold a minimum of twelve meetings each year. 27 corporates × 12 meetings = 324 meetings per year. 324 meetings × 1 hour = 324 hours.

2. Equitable distribution of corporate credit union stabilization fund expenses.

When the NCUA Board assesses a premium on FICUs for the TCCUSF in accordance with proposed § 704.21, NCUA will ask current non FICU members of corporates to make voluntary contributions to the TCCUSF. Proposed § 704.21(e) requires a corporate hold an expulsion vote if a non FICU member does not make the requested payment. These provisions would apply to all 27 corporates. NCUA estimates that the NCUA Board may assess a premium on FICUs for the TCCUSF about once each year for the next several years.

Proposed paragraphs (a) and (b) of § 704.21 state that when a TCCUSF premium is assessed on FICUs, a corporate must immediately prepare a list of all its members that are non FICUs, including the name and asset size of each such member as of the end of the previous year, and the address and contact information of each such member, and forward the list to NCUA. NCUA estimates that it should take each corporate approximately 20 hours to collect the information, prepare the list, and submit the list to NCUA. 27 corporates × 20 hours = 540 hours.

Proposed paragraph (e) of § 704.21 provides that following receipt of a notice of non-payment from NCUA, the corporate must call a special meeting of its members to determine whether each non FICU member that failed to make the full payment to the TCCUSF should be expelled from membership in the corporate. The corporate must notify NCUA of the result of the member vote. NCUA estimates that approximately 27 corporates will be required to conduct a member vote on expulsion once each year. NCUA estimates the preparation and mailing of notices and ballots (if paper ballots are used), the collection of ballots (if paper ballots are used), and notifying NCUA of the result of the vote will take about 25 hours. 27 corporates × 25 hours = 675 hours.

3. Disclosure of dual employee compensation from corporate CUSOs.

The amendment to § 704.11 requires that each corporate CUSO disclose compensation of dual employees to the corporate credit unions that make loans to, or invest in, the CUSO. NCUA estimates that this requirement will

apply to five or fewer CUSOs, and that making these disclosures will take one hour per CUSO. 5 CUSOs × 1 hour = 5 hours.

4. Management report.

Proposed § 704.15(a)(2) requires each corporate credit union to prepare an annual management report that contains a statement of management's responsibilities for performing certain duties in the corporate credit union. The report must also contain an assessment of the corporate's compliance with certain laws and regulations. NCUA estimates that it should take each corporate approximately 4 hours to prepare its management report. 27 corporates × 4 hours = 108 hours.

5. Large corporate credit union management report.

Proposed § 704.15(a)(2)(iii) requires a corporate credit union with assets of \$1 billion or more to include in its management report an assessment by management of the effectiveness of the corporate credit union's internal control structure and procedures for financial reporting. Currently, there are 16 corporates with at least \$1 billion in assets. NCUA estimates that it should take a corporate credit union approximately 8 hours to prepare its assessment. 16 corporates × 8 hours = 128 hours.

6. Notice of engagement or change of accountants.

Proposed § 704.15(c)(4) requires a corporate credit union to notify NCUA when it engages an independent public accountant or loses an independent public accountant through dismissal or resignation. The corporate credit union must include with the notice a reasonably detailed statement of the reasons for any dismissal or resignation. NCUA estimates that no more than five corporate credit unions will change accountants each year and that it should take a corporate credit union about two hours to prepare the notice and submit it to NCUA. 5 corporates × 2 hours = 10 hours.

7. Notification of late filing.

Proposed § 704.15(c)(5) requires a corporate credit union that is unable to timely file its Annual Report to submit a written notice to NCUA. NCUA estimates that no more than five corporate credit unions will need to submit such notice and that it should take about one hour to prepare the notice and submit it to NCUA. 5 corporates × 1 hour = 5 hours.

B. Summary of Collection Burden

NCUA estimates the total information collection burden represented by the proposal, calculated on an annual basis, as follows:

Recorded director votes: 27 corporates × 12 meetings × 1 hour = 324 hours.

Preparation of list of non FICU members of a corporate and providing list to NCUA: 27 corporates × 20 hours = 540 hours.

Conducting special meeting of a corporate's members to expel a member and notifying NCUA of result of vote: 27 corporates × 25 hours = 675 hours.

Disclosure of dual employee compensation from corporate CUSOs: 5 CUSOs × 1 hour = 5 hours.

Management report: 27 corporates × 4 hours = 108 hours.

Large corporate credit union management report: 16 corporates × 8 hours = 128 hours.

Notice of engagement or change of accountants: 5 corporates × 2 hours = 10 hours.

Notification of late filing: 5 corporates × 1 hour = 5 hours.

Total Burden Hours: 1,795 hours.

The NCUA considers comments by the public on this proposed collection of information in:

Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the NCUA, including whether the information will have a practical use;

Evaluating the accuracy of the NCUA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

Enhancing the quality, usefulness, and clarity of the information to be collected; and

Minimizing the burden of 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.

The Paperwork Reduction Act requires OMB to make a decision concerning the collection of information contained in the proposed regulation between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to the NCUA on the proposed regulation.

Comments on the proposed information collection requirements should be sent to: Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, DC 20503; Attention: NCUA Desk Officer, with a copy to Mary Rupp, Secretary of the Board, National Credit

Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on State and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order.

The proposed rule would not have substantial direct effects on the States, on the connection between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this proposal does not constitute a policy that has federalism implications for purposes of the executive order.

The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105-277, 112 Stat. 2681 (1998).

List of Subjects

12 CFR Part 701

Credit unions, Reporting and recordkeeping requirements.

12 CFR Part 704

Credit unions, Corporate credit unions, Reporting and recordkeeping requirements.

12 CFR Part 741

Bank deposit insurance, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on November 18, 2010.

Mary F. Rupp,
Secretary of the Board.

For the reasons stated in the preamble, the National Credit Union Administration proposes to amend 12 CFR parts 701, 704, and 741 as set forth below:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1786, 1787, 1789.

2. Add a new § 701.5 to read as follows:

§ 701.5 Membership limited to one corporate credit union.

(a) A Federal credit union is prohibited from joining a corporate credit union if, after joining, the Federal credit union would be a member of three or more corporate credit unions.

(b) A Federal credit union is prohibited from joining a corporate credit union if, after joining, the Federal credit union would be a member of exactly two corporate credit unions. As an exception, a Federal credit union may join a second corporate credit union, but only if the Federal credit union intends to transfer its share and deposit account(s) from one corporate credit union to the other corporate credit union and has informed the former corporate credit union of its intent to resign its membership no later than six months after joining the latter corporate credit union.

(c) A Federal credit union is prohibited from making any investment, including a share or deposit account, a loan, or a capital investment, in a corporate credit union of which the Federal credit union is not also a member. This prohibition does not apply to investments made at a time when the Federal credit union was a member of the corporate.

PART 704—CORPORATE CREDIT UNIONS

3. The authority citation for part 704 continues to read as follows:

Authority: 12 U.S.C. 1762, 1766(a), 1772a, 1781, 1789, and 1795e.

4. In § 704.2, add the following new definitions:

* * * * *

Critical accounting policies means those policies that are most important to the portrayal of a corporate credit union's financial condition and results and that require management's most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

* * * * *

Enterprise risk management means the process of addressing risk on an entity-wide basis. The purpose of this process is not to eliminate risk but, rather, to provide the knowledge the board of directors and management need to effectively measure, monitor, and control risk and to then plan

appropriate strategies to achieve the entity's business objectives with a reasonable amount of risk taking.

Examination of internal control means an engagement of an independent public accountant to report directly on internal control or on management's assertions about internal control. An examination of internal control over financial reporting includes controls over the preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and NCUA regulatory reporting requirements.

* * * * *

Family, as it relates to a particular individual, means that individual's spouse, parents, children, and siblings, whether by blood, marriage, or adoption; and any other person residing in the individual's home.

* * * * *

Financial statements means the presentation of a corporate credit union's financial data, including accompanying notes, derived from accounting records of the credit union, and intended to disclose the credit union's economic resources or obligations at a point in time, or the changes therein for a period of time, in conformity with GAAP. Each of the following is considered to be a financial statement: A balance sheet or statement of financial condition; statement of income or statement of operations; statement of undivided earnings; statement of cash flows; statement of changes in members' equity; statement of revenue and expenses; and statement of cash receipts and disbursements.

Financial statement audit means an audit of the financial statements of a credit union performed in accordance with generally accepted auditing standards by an independent person who is licensed by the appropriate State or jurisdiction. The objective of a financial statement audit is to express an opinion as to whether those financial statements of the credit union present fairly, in all material respects, the financial position and the results of its operations and its cash flows in conformity with GAAP.

Generally accepted auditing standards (GAAS) means the standards approved and adopted by the American Institute of Certified Public Accountants which apply when an "independent, licensed certified public accountant" audits private company financial statements in the United States of America. Auditing standards differ from auditing procedures in that "procedures" address acts to be

performed, whereas "standards" measure the quality of the performance of those acts and the objectives to be achieved by use of the procedures undertaken. In addition, auditing standards address the auditor's professional qualifications as well as the judgment exercised in performing the audit and in preparing the report of the audit.

* * * * *

Independent public accountant (IPA) means a person who is licensed by the appropriate State or jurisdiction to practice public accounting. An IPA must be able to exercise fairness toward credit union officials, members, creditors and others who may rely upon the report of a supervisory committee audit and demonstrate the impartiality necessary to produce dependable findings. As used in this part, IPA is synonymous with the terms "auditor" or "accountant." The term IPA does not include a licensed person working in his or her capacity as an employee of an unlicensed entity and issuing an audit opinion in the unlicensed entity's name, e.g., a licensed league auditor or licensed retired examiner working for a non-licensed entity.

Internal control means the process, established by the credit union's board of directors, officers and employees, designed to provide reasonable assurance of reliable financial reporting and safeguarding of assets against unauthorized acquisition, use, or disposition. A credit union's internal control structure generally consists of five components: Control environment; risk assessment; control activities; information and communication; and monitoring. Reliable financial reporting refers to preparation of Call Reports that meet management's financial reporting objectives. Internal control over safeguarding of assets against unauthorized acquisition, use, or disposition refers to prevention or timely detection of transactions involving such unauthorized access, use, or disposition of assets which could result in a loss that is material to the financial statements.

Internal control framework means criteria such as that established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) or comparable, reasonable, and U.S. recognized criteria.

Internal control over financial reporting means a process effected by those charged with governance, management, and other personnel, designed to provide reasonable assurance regarding the preparation of

reliable financial statements in accordance with accounting principles generally accepted in the United States of America. A corporate credit union's internal control over financial reporting includes those policies and procedures that:

- (1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity;
- (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and those charged with governance; and
- (3) Provide reasonable assurance regarding prevention, or timely detection and correction of unauthorized acquisition, use, or disposition of the entity's assets that could have a material effect on the financial statements.

* * * * *

Supervisory committee means, for Federally chartered corporate credit unions, the supervisory committee as defined in Section 111(b) of the Federal Credit Union Act, 12 U.S.C. 1761(b). For State chartered corporate credit unions, the term supervisory committee refers to the audit committee, or similar committee, designated by State statute or regulation.

* * * * *

5. In § 704.11, revise paragraphs (g)(5) and (g)(6), and add a new paragraph (g)(7), to read as follows:

§ 704.11. Corporate Credit Union Service Organizations (Corporate CUSOs).

- * * * * *
- (g) * * *
- (5) Will allow the auditor, board of directors, and NCUA complete access to its personnel, facilities, equipment, books, records, and any other documentation that the auditor, directors, or NCUA deem pertinent;
 - (6) Will inform the corporate, at least quarterly, of all the compensation paid by the CUSO to its employees who are also employees of the corporate credit union; and
 - (7) Will comply with all the requirements of this section.
6. In § 704.13, revise paragraphs (c)(6) and (c)(7), and add a new paragraph (c)(8), to read as follows:

§ 704.13 Board responsibilities.

* * * * *

(c) * * *

(6) Financial performance is evaluated to ensure that the objectives of the corporate credit union and the responsibilities of management are met;

(7) Planning addresses the retention of external consultants, as appropriate, to review the adequacy of technical, human, and financial resources dedicated to support major risk areas; and

(8) All board of directors votes are conducted by recorded vote, such that the minutes reporting the vote list the board members (by name) voting for or against the proposal, as well as, if applicable, board members who were absent or otherwise failed to vote and board members who abstained from the vote.

7. Revise § 704.15 to read as follows:

§ 704.15 Audit and reporting requirements.

(a) *Annual reporting requirements—*

(1) *Audited financial statements.* A corporate credit union must prepare annual financial statements in accordance with generally accepted accounting principles (GAAP), which must be audited by an independent public accountant in accordance with generally accepted auditing standards. The annual financial statements and regulatory reports must reflect all material correcting adjustments necessary to conform with GAAP that were identified by the corporate credit union's independent public accountant.

(2) *Management report.* Each corporate credit union must prepare, as of the end of the previous calendar year, an annual management report that contains the following:

(i) A statement of management's responsibilities for preparing the corporate credit union's annual financial statements, for establishing and maintaining an adequate internal control structure and procedures for financial reporting, and for complying with laws and regulations relating to safety and soundness in the following areas: Affiliate transactions, legal lending limits, loans to insiders, restrictions on capital and share dividends, and regulatory reporting that meets full and fair disclosure;

(ii) An assessment by management of the corporate credit union's compliance with such laws and regulations during the past calendar year. The assessment must state management's conclusion as to whether the corporate credit union has complied with the designated safety and soundness laws and regulations during the calendar year and disclose any noncompliance with the laws and regulations; and

(iii) For a corporate credit union with consolidated total assets of \$1 billion or more as of the beginning of such calendar year, an assessment by management of the effectiveness of such internal control structure and procedures as of the end of such calendar year that must include the following:

(A) A statement identifying the internal control framework used by management to evaluate the effectiveness of the corporate credit union's internal control over financial reporting;

(B) A statement that the assessment included controls over the preparation of regulatory financial statements in accordance with regulatory reporting instructions including identification of such regulatory reporting instructions; and

(C) A statement expressing management's conclusion as to whether the corporate credit union's internal control over financial reporting is effective as of the end of the previous calendar year. Management must disclose all material weaknesses in internal control over financial reporting, if any, that it has identified that have not been remediated prior to the calendar year-end. Management may not conclude that the corporate credit union's internal control over financial reporting is effective if there are one or more material weaknesses.

(3) *Management report signatures.* The chief executive officer and either the chief accounting officer or chief financial officer of the corporate credit union must sign the management report.

(b) *Independent public accountant—*
(1) *Annual audit of financial statements.* Each corporate credit union must engage an independent public accountant to audit and report on its annual financial statements in accordance with generally accepted auditing standards. The scope of the audit engagement must be sufficient to permit such accountant to determine and report whether the financial statements are presented fairly and in accordance with GAAP. A corporate credit union must provide its independent public accountant with a copy of its most recent Call Report and NCUA examination report. It must also provide its independent public accountant with copies of any notice that its capital category is being changed or reclassified and any correspondence from NCUA regarding compliance with this section.

(2) *Internal control over financial reporting.* For each corporate credit union with total assets of \$1 billion or more at the beginning of the calendar

year, the independent public accountant who audits the corporate credit union's financial statements must examine, attest to, and report separately on the assertion of management concerning the effectiveness of the corporate credit union's internal control structure and procedures for financial reporting. The attestation and report must be made in accordance with generally accepted standards for attestation engagements. The accountant's report must not be dated prior to the date of the management report and management's assessment of the effectiveness of internal control over financial reporting. Notwithstanding the requirements set forth in applicable professional standards, the accountant's report must include the following:

(i) A statement identifying the internal control framework used by the independent public accountant, which must be the same as the internal control framework used by management, to evaluate the effectiveness of the corporate credit union's internal control over financial reporting;

(ii) A statement that the independent public accountant's evaluation included controls over the preparation of regulatory financial statements in accordance with regulatory reporting instructions including identification of such regulatory reporting instructions; and

(iii) A statement expressing the independent public accountant's conclusion as to whether the corporate credit union's internal control over financial reporting is effective as of the end of the previous calendar year. The report must disclose all material weaknesses in internal control over financial reporting that the independent public accountant has identified that have not been remediated prior to the calendar year-end. The independent public accountant may not conclude that the corporate credit union's internal control over financial reporting is effective if there are one or more material weaknesses.

(3) *Notice by accountant of termination of services.* An independent public accountant performing an audit under this part who ceases to be the accountant for a corporate credit union must notify NCUA in writing of such termination within 15 days after the occurrence of such event and set forth in reasonable detail the reasons for such termination.

(4) *Communications with supervisory committee.* In addition to the requirements for communications with audit committees set forth in applicable professional standards, the independent public accountant must report the

following on a timely basis to the supervisory committee:

(i) All critical accounting policies and practices to be used by the corporate credit union;

(ii) All alternative accounting treatments within GAAP for policies and practices related to material items that the independent public accountant has discussed with management, including the ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the independent public accountant; and

(iii) Other written communications the independent public accountant has provided to management, such as a management letter or schedule of unadjusted differences.

(5) *Retention of working papers.* The independent public accountant must retain the working papers related to the audit of the corporate credit union's financial statements and, if applicable, the evaluation of the corporate credit union's internal control over financial reporting for seven years from the report release date, unless a longer period of time is required by law.

(6) *Independence.* The independent public accountant must comply with the independence standards and interpretations of the American Institute of Certified Public Accountants (AICPA).

(7) *Peer reviews and inspection reports.* (i) Prior to commencing any services for a corporate credit union under this section, the independent public accountant must have received a peer review, or be enrolled in a peer review program, that meets acceptable guidelines. Acceptable peer reviews include peer reviews performed in accordance with the AICPA's Peer Review Standards and inspections conducted by the Public Company Accounting Oversight Board (PCAOB).

(ii) Within 15 days of receiving notification that the AICPA has accepted a peer review or the PCAOB has issued an inspection report, or before commencing any audit under this section, whichever is earlier, the independent public accountant must file a copy of the most recent peer review report and the public portion of the most recent PCAOB inspection report, if any, accompanied by any letters of comments, response, and acceptance, with NCUA if the report has not already been filed.

(iii) Within 15 days of the PCAOB making public a previously nonpublic portion of an inspection report, the independent public accountant must file a copy of the previously nonpublic

portion of the inspection report with NCUA.

(c) *Filing and notice requirements—*

(1) *Annual Report.* Each corporate credit union must, no later than 180 days after the end of the calendar year, file an Annual Report with NCUA consisting of the following documents:

(i) The audited comparative annual financial statements;

(ii) The independent public accountant's report on the audited financial statements;

(iii) The management report; and, if applicable,

(iv) The independent public accountant's attestation report on management's assessment concerning the corporate credit union's internal control structure and procedures for financial reporting.

(2) *Public availability.* The annual report in paragraph (c)(1) of this section will be made available for public inspection by NCUA.

(3) *Independent public accountant's letters and reports.* Each corporate credit union must file with NCUA a copy of any management letter or other report issued by its independent public accountant with respect to such corporate credit union and the services provided by such accountant pursuant to this part (except for the independent public accountant's reports that are included in the Annual Report) within 15 days after receipt by the corporate credit union. Such reports include, but are not limited to:

(i) Any written communication regarding matters that are required to be communicated to the supervisory committee (for example, critical accounting policies, alternative accounting treatments discussed with management, and any schedule of unadjusted differences); and

(ii) Any written communication of significant deficiencies and material weaknesses in internal control required by the AICPA's auditing standards.

(4) *Notice of engagement or change of accountants.* Each corporate credit union that engages an independent public accountant, or that loses an independent public accountant through dismissal or resignation, must notify NCUA within 15 days after the engagement, dismissal, or resignation. The corporate credit union must include with the notice a reasonably detailed statement of the reasons for any dismissal or resignation. The corporate credit union must also provide a copy of the notice to the independent public accountant at the same time the notice is filed with NCUA.

(5) *Notification of late filing.* A corporate credit union that is unable to

timely file any part of its Annual Report or any other report or notice required by this paragraph (c) must submit a written notice of late filing to NCUA. The notice must disclose the corporate credit union's inability to timely file all or specified portions of its Annual Report or other report or notice and the reasons therefore in reasonable detail. The late filing notice must also state the date by which the report or notice will be filed. The written notice must be filed with NCUA before the deadline for filing the Annual Report or any other report or notice, as appropriate. NCUA may take appropriate enforcement action for failure to timely file any report, or notice of late filing, required by this section.

(6) *Report to Members.* A corporate credit union must submit a preliminary Annual Report to the membership at the next calendar year's annual meeting.

(d) *Supervisory committees.* (1) *Composition.* Each corporate credit union must establish a supervisory committee. The members of the supervisory committee must not be employees of the corporate credit union and must be independent of the corporate credit union. A committee member is independent if:

(i) The committee member does not have any family relationships or any material business or professional relationships with the corporate credit union or its management that would affect his or her independence as a committee member, and

(ii) The committee member has not had any such relationships for at least three years preceding his or her appointment to the committee.

(2) *Duties.* In addition to any duties specified under the corporate credit union's bylaws and these regulations, the duties of the credit union's supervisory committee include the appointment, compensation, and oversight of the independent public accountant who performs services required under this section and reviewing with management and the independent public accountant the basis for all the reports prepared and issued under this section. The supervisory committee must submit the audited comparative annual financial statements and the independent public accountant's report on those statements to the corporate credit union's board of directors.

(3) *Independent public accountant engagement letters.* (i) In performing its duties with respect to the appointment of the corporate credit union's independent public accountant, the supervisory committee must ensure that engagement letters and/or any related

agreements with the independent public accountant for services to be performed under this section:

(A) Obligate the independent public accountant to comply with the requirements of paragraph (b) of this section (including, but not limited to, the notice of termination of services, communications with the supervisory committee, and notifications of peer reviews and inspection reports); and

(B) Do not contain any limitation of liability provisions that:

(1) Indemnify the independent public accountant against claims made by third parties;

(2) Hold harmless or release the independent public accountant from liability for claims or potential claims that might be asserted by the client corporate credit union, other than claims for punitive damages; or

(3) Limit the remedies available to the client corporate credit union.

(ii) Engagement letters may include alternative dispute resolution agreements and jury trial waiver provisions provided that the letters do not incorporate any limitation of liability provisions set forth in paragraph (e)(2)(i)(B) of this section.

(4) *Outside counsel.* The supervisory committee of any corporate credit union must, when deemed necessary by the committee, have access to its own outside counsel.

(e) *Internal audit.* A corporate credit union with average daily assets in excess of \$400 million for the preceding calendar year, or as ordered by NCUA, must employ or contract, on a full- or part-time basis, the services of an internal auditor. The internal auditor's responsibilities will, at a minimum, comply with the Standards and Professional Practices of Internal Auditing, as established by the Institute of Internal Auditors. The internal auditor will report directly to the chair of the corporate credit union's supervisory committee, who may delegate supervision of the internal auditor's daily activities to the chief executive officer of the corporate credit union. The internal auditor's reports, findings, and recommendations will be in writing and presented to the supervisory committee no less than quarterly, and will be provided upon request to the IPA and NCUA.

8. Revise the introductory text of paragraph (a) of § 704.19 to read as follows:

§ 704.19. Disclosure of executive and director compensation.

(a) Annual disclosure. A corporate credit union must annually prepare and maintain a disclosure of the dollar

amount of compensation paid to its most highly compensated employees, including compensation from any corporate CUSO in which the corporate has invested or made a loan, in accordance with the following schedule:

* * * * *

9. Add a new § 704.21 to read as follows:

§ 704.21 Equitable distribution of corporate credit union stabilization expenses.

When the NCUA Board acts to assess a premium on Federally-insured credit unions for the Temporary Corporate Credit Union Stabilization Fund (TCCUSF):

(a) A corporate credit union must immediately prepare a list of all its non-natural person members on the date of assessment that are not Federally-insured credit unions ("non-FICU members"), including the name of each such non-FICU member, the assets of each such non-FICU member as of the end of the previous year, and the address and contact information of each such non-FICU member.

(b) Within 14 days after the date of the assessment, the corporate credit union must forward the list described in paragraph (a) of this section to the Office of Corporate Credit Unions. A corporate credit union that has no non-FICU members must provide the Office of Corporate Credit Unions with a response indicating that it has no non-FICU members.

(c) Within 60 days after the date of assessment, the NCUA Chief Financial Officer will request each member on the list described in paragraph (a) of this section to make a voluntary payment to the TCCUSF. The amount of the requested payment will be the member's assets (as of the previous year-end) times 0.815 times the percentage of insured shares that NCUA assessed each Federally-insured credit union. If the member decides to make a payment the member must deliver the payment to NCUA no later than 60 days after the date of the NCUA Chief Financial Officer's request.

(d) If NCUA fails to receive a full, timely payment of the amount requested in paragraph (c) of this section, NCUA will notify the corporate credit union of the failure.

(e) No later than 90 days following receipt of the notice in paragraph (d) of this section, the corporate credit union must call a special meeting of its members to determine whether each non-FICU member that failed to make the full payment to the TCCUSF should be expelled from the corporate credit union. For a Federally-chartered

corporate credit union, the expulsion vote will be conducted in accordance with section 118(a) of the Federal Credit Union Act (12 U.S.C. 1764(a)) and the bylaws of the corporate credit union. For a State-chartered corporate credit union, the expulsion vote will be conducted in accordance with the bylaws of the corporate credit union and applicable State law. The corporate credit union must notify the Office of Corporate Credit Unions of the results of the member vote no later than 14 days following the date of the vote.

(f) If the corporate credit union's annual meeting falls within the timeframe specified in paragraph (e) of this section, the expulsion vote may be conducted at the annual meeting instead of a special meeting.

(g) For non-FICUs that belong to more than one corporate credit union, NCUA will request only one voluntary payment from that non-FICU in connection with each TCCUSF assessment. If NCUA fails to receive a full payment of the amount requested in paragraph (c) of this section, however, NCUA will notify all corporate credit unions to which the non-FICU belongs for purposes of conducting an expulsion vote.

10. Add a new § 704.22 to read as follows:

§ 704.22 Enterprise risk management.

(a) A corporate credit union must develop and follow an enterprise risk management policy.

(b) The board of directors of a corporate credit union must establish an enterprise risk management committee (ERMC) responsible for the oversight of the enterprise-wide risk management practices of the corporate credit union. The ERMC must report at least annually to the board of directors.

(c) The ERMC must include at least one independent risk management expert. The risk management expert will have post-graduate education: an actuarial, accounting, economics, financial, or legal background; and at least five years experience in identifying, assessing, and managing risk exposures. The risk management expert's experience must also be commensurate with the size of the corporate credit union and the complexity of its operations.

(d) An expert is independent if:

(1) He or she does not have any family relationships or any material business or professional relationships with the corporate credit union that would affect his or her independence as a committee member, and

(2) He or she has not had any such relationships for at least three years

preceding his or her appointment to the committee.

(e) The risk management expert is not required to be a director of the corporate credit union.

11. Add a new § 704.23 to read as follows:

§ 704.23 Membership fees.

(a) A corporate credit union may charge its members a membership fee. The fee may be one-time or periodic.

(b) The corporate credit union must calculate the fee uniformly for all members as a percentage of each member's assets, except that the corporate credit union may reduce the amount of the fee for members that have contributed capital to the corporate. Any reduction must be proportional to the amount of the member's nondepleted contributed capital.

(c) The corporate credit union must give its members at least six months advance notice of any initial or new fee, including terms and conditions, before invoicing the fee. For a recurring fee, the corporate credit union must also give six months notice of any material change to the terms and conditions of the fee.

(d) The corporate credit union may terminate the membership of any credit union that fails to pay the fee in full within 60 days of the invoice date.

PART 741—REQUIREMENTS FOR INSURANCE

12. The authority citation for part 741 continues to read as follows:

Authority: 12 U.S.C. 1757, 1766(a), 1781-1790, and 1790d; 31 U.S.C. 3717.

13. Add a new § 741.226 to read as follows:

§ 741.226 Membership in one corporate credit union.

Any credit union which is insured pursuant to Title II of the Act must adhere to the requirements stated in § 701.5 of this chapter.

[FR Doc. 2010-29546 Filed 11-26-10; 8:45 am]

BILLING CODE 7535-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 61

Notice of Public Meeting: Updating the Flight Instructor Renewal Process To Enhance Safety of Flight

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: The FAA announces a public meeting to receive industry input as to how to improve the Certificated Flight Instructor (CFI) biennial renewal process to enhance the safety of flight in the General Aviation (GA) community. This is an information gathering meeting.

DATES: The public meetings will be held on the following dates.

- December 6, 2010, from 9 a.m. until no later than 4 p.m., and
- December 7, 2010 from 9 p.m. until no later than 4 p.m.

ADDRESSES: The December 6 and 7, 2010, public meetings will be held at the FAA headquarters building B, located at 600 Independence Avenue, SW., Washington, DC 20591.

Because of limited capacity, we ask that all those who anticipate attending the meeting contact *Gregory.french@faa.gov* with written confirmation of attendance and the number of members in the attending party. If we find that we are nearing capacity, we may request that those who are planning on sending more than a single representative reduce the number in their party. If this is the case, respondents will be notified by e-mail and/or phone prior to the meeting date.

FOR FURTHER INFORMATION CONTACT: Requests to attend this public meeting, questions regarding the logistics of the meeting, and any technical questions should be directed to Inspector Gregory French, AFS-800, General Aviation and Commercial Division, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8212, facsimile (202) 267-5094, or, preferably, via e-mail at *Gregory.french@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA has been reviewing safety of flight data in the general aviation (GA) community over the last ten years. Even with the advent of new technologies to assist the GA pilot, there has been little improvement in the accident/incident rate among that community of aviators.

CFIs are responsible for ensuring that pilots are properly educated to operate safely within the National Airspace System (NAS). For CFIs to accomplish that mission effectively they must be provided the means and knowledge to do so, and there must be some objective method of measuring that information transfer and retention. The FAA has been reviewing indicators that suggest that the processes currently in place may lack sufficient effectiveness in ensuring that CFIs are being provided the best information in the most useful

manner. This meeting will elicit input from the community of authorized flight instructor renewal program operators so that the FAA can better analyze how to improve the process.

Purpose of the Public Meeting

The purpose of this public meeting is for the FAA to hear the public's views and obtain information relevant to improving the CFI biennial renewal process. The FAA will consider comments made at this public meeting before making decisions on any suggested changes to the current policy.

More specifically, the FAA seeks information on the following questions. The FAA requests that that all meeting participants provide written comments to support any positions they may express support for, or disagreement with.

- How effective have Flight Instructor Refresher Clinics been in transferring relevant information to flight instructors?
- What can be done to improve the effectiveness of flight instructor refresher clinics?
- How effective are the written tests provided at the conclusion of flight instructor refresher clinics?
- How can the effectiveness of flight instructor knowledge be better assessed?
- How effective have the online courses been?
- How do we effectively measure the success of knowledge transfer in online flight instructor renewal courses?
- Should there be changes to 14 CFR part 61.197?
- Are those non-FIRC methods of CFI biennial certificate renewal found in 14 CFR part 61.197 adequate and effective in ensuring that CFIs possess the most up to date information in terms of both proficiency and knowledge?
- What can the community conducting flight instructor recurrent training, the FIRC providers, do to contribute to enhancing safety of flight among the GA community at large?

Participation at the Public Meetings

Commenters who wish to present oral statements at the December 6 and 7, 2010, public meetings will be permitted to do so on an ad-hoc basis during the meeting.

The FAA will have available a projector and a computer capable of accommodating Word and PowerPoint presentations from a compact disk (CD) or USB memory device. Persons requiring any other kind of audiovisual equipment should notify the FAA prior to the meeting.

Sign and oral interpretation can be made available at the meeting, as well

as an assistive listening device, if requested 10 calendar days before the meeting.

Public Meeting Procedures

A panel of representatives from the FAA will be present. An FAA representative will facilitate the meetings in accordance with the following procedures:

(1) The meetings are designed to facilitate the public input on policies that directly affect them. The meetings will be informal and non-adversarial. No individual will be subject to cross-examination by any other participant. Government representatives on the panel may ask questions to clarify statements and to ensure an accurate record. Any statement made during the meetings by a panel member should not be construed as an official position of the government.

(2) There will be no admission fees or other charges to attend or to participate in the public meetings. The meetings will be open to all persons, subject to availability of space in the meeting room. The FAA will make every effort to accommodate all persons wishing to attend. The FAA asks that participants sign in at 9 a.m. on each day of the meeting being attended. The FAA will try to accommodate all speakers; however if available time does not allow this, speakers will be scheduled on a first-come-first-served basis. The FAA reserves the right to exclude some speakers, if necessary, to obtain balanced viewpoints. The meetings may adjourn early if scheduled speakers complete their statements in less time than is scheduled for the meetings.

(3) The FAA will prepare agendas of speakers and presenters and make the agendas available at the meetings.

(4) The meeting is intended to produce an environment conducive to an exchange of ideas. If speakers wish to give dedicated presentations, they may be limited to 5–10-minute statements. If possible, the FAA will notify speakers if additional time is available.

(5) The FAA will review and consider all material presented by participants at the public meetings. Position papers or materials presenting views or information related to the topics discussed may be accepted at the discretion of the presiding officer and will be subsequently placed in the public docket. If the attendees wish to provide written materials, the FAA requests that the presenters provide at least 10 copies of all materials for distribution to the panel members. Presenters may provide other copies to the audience at their discretion.

(6) Each person presenting comments is asked to submit data to support the comments. The FAA will protect from disclosure all proprietary data submitted in accordance with applicable laws.

Issued in Washington, DC on November 18, 2010.

Melvin O. Cintron,

Manager, General Aviation and Commercial Division.

[FR Doc. 2010–29921 Filed 11–26–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2010–0938; Airspace Docket No. 10–ANE–108]

Proposed Amendment of Class E Airspace; Newport, VT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E Airspace at Newport, VT, as the Newport Non-Directional Beacon (NDB) has been decommissioned and new Standard Instrument Approach Procedures (SIAPs) have been developed at Newport State Airport. This action would enhance the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective 0901 UTC. Comments must be received on or before January 13, 2011.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Ave., SE., Washington, DC 20590–0001; Telephone: 1–800–647–5527; Fax: 202–493–2251. You must identify the Docket Number FAA–2010–0938; Airspace Docket No. 10–ANE–108, at the beginning of your comments. You may also submit and review received comments through the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Melinda Giddens, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5610.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule 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–2010–0938; Airspace Docket No. 10–ANE–108) 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 Docket No. FAA–2010–0938; Airspace Docket No. 10–ANE–108.” The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. 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 from and comments submitted through <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 address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, room 210, 1701 Columbia Avenue, College Park, Georgia 30337.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A. Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace extending upward from 700 feet above the surface for new SIAPs developed at Newport State Airport, Newport, VT. Airspace reconfiguration is necessary due to the decommissioning of the Newport NDB and cancellation of the NDB approach. Controlled airspace is necessary for the safety and management of IFR operations.

Class E airspace designations are published in Paragraph 6005 of FAA order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this proposed 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that 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 United States Code. 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. This proposed 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 airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is

within the scope of that authority as it would amend Class E airspace at Newport State Airport, Newport, VT.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND CLASS E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 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 Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, effective September 15, 2010, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE VT E5 Newport, VT [AMENDED]

Newport State Airport, VT
(Lat. 44°53'20" N., long. 72°13'45" W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Newport State Airport and within 1.8 miles each side of the 159° bearing from the airport extending from the 6.4-mile radius to 10.9 miles south of Newport State Airport.

Issued in College Park, Georgia, on November 16, 2010.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2010-29898 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2010-0582; Airspace Docket No. 10-AEA-15]

Proposed Establishment of Class E Airspace; Kenbridge, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E Airspace at Kenbridge, VA, to accommodate the additional airspace needed for the Standard Instrument Approach Procedures (SIAPs) developed for Lunenburg County Airport. This action would enhance the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport.

DATES: 0901 UTC. Comments must be received on or before January 13, 2011.
ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12-140, 1200 New Jersey Ave., SE., Washington, DC 20590-0001; Telephone: 1-800-647-5527; Fax: 202-493-2251. You must identify the Docket Number FAA-2010-0582; Airspace Docket No. 10-AEA-15, at the beginning of your comments. You may also submit and review received comments through the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Richard Horrocks, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5588.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule 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-2010-0582; Airspace Docket No. 10-AEA-15) 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>.

Comments 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 Docket No. FAA-2010-0582; Airspace Docket No. 10-AEA-15." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. 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 from and comments submitted through <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_anendments/.

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 address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, room 210, 1701 Columbia Avenue, College Park, Georgia 30337.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace at Kenbridge, VA to provide controlled airspace required to support the SIAPs developed for Lunenburg County Airport. Class E airspace extending upward from 700 feet above the surface would be established for the safety and management of IFR operations.

Class E airspace designations are published in Paragraph 6005 of FAA order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that 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 United States Code. 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. This proposed 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 airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would establish Class E airspace at Lunenburg County Airport, Kenbridge, VA.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference. Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND CLASS E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 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 Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

AEA VA E5 Kenbridge, VA [NEW]

Lunenburg County Airport, VA
(Lat. 36°57'37" N., long. 78°11'06" W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Lunenburg County Airport.

Issued in College Park, Georgia, on November 16, 2010.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2010-29897 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-13-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2010-0816-201057; FRL-9233-6]

Approval and Promulgation of Implementation Plans; Georgia: Prevention of Significant Deterioration; Greenhouse Gas Tailoring Rule and Fine Particulate Matter Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a draft revision to the Georgia State Implementation Plan (SIP), submitted by the State of Georgia, through the Georgia Department of Natural Resources' Environmental Protection Division (EPD), to EPA on September 30, 2010, for parallel processing. The proposed revision makes two changes for which EPA is proposing approval in today's rulemaking. First, the proposed SIP revision modifies Georgia's New Source Review (NSR) Prevention of Significant Deterioration (PSD) program. Specifically, the proposed SIP revision establishes appropriate emission thresholds for determining which new stationary sources and modification projects become subject to Georgia's PSD permitting requirements for their greenhouse gas (GHG) emissions. Second, the proposed SIP revision incorporates provisions for implementing the PSD program for fine particulate matter (PM_{2.5}). The first component of this proposed SIP revision is necessary because without it, on January 2, 2011, PSD requirements would apply at the 100 or 250 tons per year (tpy) levels provided under the Clean Air Act (CAA or Act), which would overwhelm Georgia's permitting

resources. The second component of this proposed SIP revision (addressing the PM_{2.5} national ambient air quality standard (NAAQS)) is necessary to comply with Federal regulations related to PSD permitting. EPA is proposing approval of Georgia's September 30, 2010, SIP revision because the Agency has made the preliminary determination that this SIP revision is in accordance with the CAA and EPA regulations regarding PSD permitting for GHGs and the PM_{2.5} NAAQS.

DATES: Comments must be received on or before December 29, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2010-0816 by one of the following methods:

1. *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *E-mail: benjamin.lynora@epa.gov*.

3. *Fax: (404) 562-9019*.

4. *Mail: EPA-R04-OAR-2010-0816*, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960.

5. *Hand Delivery or Courier:* Ms. Lynora Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. "EPA-R04-OAR-2010-0816." 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 through *http://www.regulations.gov* or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity, or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://*

www.regulations.gov, your e-mail 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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 EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., 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 in *http://www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: For information regarding the Georgia SIP, contact Ms. Twunjala Bradley, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Ms. Bradley's telephone number is (404) 562-9352; e-mail address: *bradley.twunjala@epa.gov*. For information regarding the GHG Tailoring Rule and the PM_{2.5} NAAQS PSD requirements, contact Ms. Heather Abrams, Air Permits Section, at the same address above. Ms. Abrams' telephone number is (404) 562-9185; e-mail address: *abrams.heather@epa.gov*.
SUPPLEMENTARY INFORMATION:

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- I. What action is EPA proposing in today's Notice?
- II. What is the background for the action proposed by EPA in today's Notice regarding PSD Permitting Requirements for GHG-emitting sources?
- III. What is the relationship between today's proposed action and EPA's proposed GHG SIP Call and GHG FIP?
- IV. What is the background for the action proposed by EPA in today's Notice regarding the PSD Permitting Requirements for the PM_{2.5} NAAQS?
- V. What is EPA's analysis of Georgia's proposed SIP revision?
- VI. Proposed Action
- VII. Statutory and Executive Order Reviews

I. What action is EPA proposing in today's Notice?

On September 30, 2010,¹ EPD submitted a draft revision to EPA for approval into the Georgia SIP to establish appropriate emission thresholds for determining which new or modified stationary sources become subject to Georgia's PSD permitting requirements for GHG emissions. Final approval of Georgia's September 30, 2010, SIP revision will put in place the GHG emission thresholds for PSD applicability set forth in EPA's Tailoring Rule, ensuring that smaller GHG sources emitting less than these thresholds will not be subject to permitting requirements when these requirements begin applying to GHGs on January 2, 2011. Additionally, Georgia's September 30, 2010, SIP revision incorporates Federal requirements into Georgia's SIP for PSD permitting related to the PM_{2.5} NAAQS. Pursuant to section 110 of the CAA, EPA is proposing to approve these changes into the Georgia SIP.

Because this draft SIP revision is not yet State-effective, Georgia requested that EPA "parallel process" the SIP revision. Under this procedure, the EPA Regional Office works closely with the State while developing new or revised regulations. Generally, the State submits a copy of the proposed regulation or other revisions to EPA before conducting its public hearing. EPA reviews this proposed State action and prepares a notice of proposed rulemaking. EPA publishes this notice

¹ With respect to PM_{2.5}, Georgia's September 30, 2010, SIP revision only addresses PSD requirements. The nonattainment NSR provisions for Georgia for the PM_{2.5} NAAQS are still under development at the State level and are not due to EPA until May 16, 2011. Additionally, Georgia's submittal contains provisions at 391-3-1-.02(7)(a)(2)(iv)(I) and (II) of Georgia's PSD regulations that would render Georgia's regulation or a portion thereof automatically invalid in the wake of certain court decisions or other events. At this time, EPA is not proposing to approve this provision into the Georgia SIP.

of proposed rulemaking in the **Federal Register** and solicits public comment in approximately the same time frame during which the State is holding its public hearing. The State and EPA thus provide for public comment periods on both the State and the Federal actions in parallel.

After Georgia submits the formal State-effective SIP revision request (including a response to all public comments raised during the State's public participation process), EPA will prepare a final rulemaking notice for the SIP revision. If changes are made to the SIP revision after EPA's notice of proposed rulemaking, such changes must be acknowledged in EPA's final rulemaking action. If the changes are significant, then EPA may be obliged to re-propose the action. In addition, if the changes render the SIP revision not approvable, EPA's re-proposal of the action would be a disapproval of the revision.

In addition to changes to address PSD permitting requirements for GHGs and PM_{2.5}, Georgia's September 30, 2010, SIP revision also includes: (1) A provision that excludes facilities that produce ethanol through a natural fermentation process from the definition of "chemical process plants" in the major NSR source permitting program; and (2) a provision that incorporates by reference changes pursuant to EPA's Fugitive Emissions Rule, 73 FR 77882 (December 19, 2008).² In today's proposed rulemaking, EPA is not proposing to take action on Georgia's changes to its PSD regulations to exclude facilities that produce ethanol through a natural fermentation process from the definition of "chemical process plants" in the major NSR permitting program, nor is EPA proposing to take action on Georgia's changes to incorporate the provisions of the Fugitive Emission Rule.

II. What is the background for the action proposed by EPA in today's Notice regarding PSD permitting requirements for GHG-emitting sources?

Today's proposed action on the Georgia SIP primarily relates to EPA's "Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule," Final Rule (the Tailoring Rule).

² On March 31, 2010, EPA stayed the Fugitive Emissions Rule (73 FR 77882) for 18 months to October 3, 2011, to allow the Agency time to propose, take comment and issue a final action regarding the inclusion of fugitive emissions in NSR applicability determinations. Therefore, the 40 CFR part 51 and part 52 administrative regulations that were amended by the Fugitive Emissions Rule are stayed through October 3, 2011.

75 FR 31514. In the Tailoring Rule, EPA established appropriate GHG emission thresholds for determining the applicability of PSD requirements to GHG-emitting sources. These applicability thresholds were designed to ensure that smaller GHG sources will not be subject to GHG permitting requirements. While Georgia already has authority to issue PSD permits governing GHGs when PSD requirements begin applying to GHGs on January 2, 2011, Georgia needs to amend its SIP to incorporate the Tailoring Rule's applicability thresholds. Today's notice announces EPA's proposed approval of a revision to Georgia's SIP that would put these applicability thresholds in place.³

A. What are GHGs and their sources?

A detailed explanation of GHGs, climate change and the impact on health, society, and the environment is included in EPA's technical support document for EPA's GHG endangerment finding final rule (Document ID No. EPA-HQ-OAR-2009-0472-11292 at <http://www.regulations.gov>). The endangerment finding rulemaking is discussed later in this rulemaking. A summary of the nature and sources of GHGs is provided below.

GHGs trap the Earth's heat that would otherwise escape from the atmosphere into space and form the greenhouse effect that helps keep the Earth warm enough for life. GHGs are naturally present in the atmosphere and are also emitted by human activities. Human activities are intensifying the naturally occurring greenhouse effect by increasing the amount of GHGs in the atmosphere, which is changing the climate in a way that endangers human health, society, and the natural environment.

Some GHGs, such as carbon dioxide (CO₂), are emitted to the atmosphere through natural processes as well as human activities. Other gases, such as fluorinated gases, are created and emitted solely through human activities. The well-mixed GHGs of concern directly emitted by human activities include CO₂, methane (CH₄), nitrous oxide (N₂O), hydrofluorocarbons

³ On September 2, 2010, EPA proposed a "SIP Call" that would require those States with SIPs that do not authorize PSD permitting for GHGs to submit a SIP revision providing such authority. 75 FR 53892. In a companion rulemaking, EPA proposed a Federal Implementation Plan (FIP) that would apply in any State that is unable to submit the required SIP revision by its deadline. 75 FR 53883 (September 2, 2010). Because Georgia's SIP already authorizes Georgia to regulate GHGs once GHGs become subject to PSD requirements on January 2, 2011, Georgia is not subject to the proposed SIP Call or FIP.

(HFCs), perfluorocarbons (PFCs), and sulfur hexafluoride (SF₆), hereafter referred to collectively as "the six well-mixed GHG," or, simply, GHGs. Together these six well-mixed GHGs constitute the "air pollutant" upon which the GHG thresholds in EPA's Tailoring Rule are based. These six gases remain in the atmosphere for decades to centuries where they become well-mixed globally in the atmosphere. When they are emitted more quickly than natural processes can remove them from the atmosphere, their concentrations increase, thus increasing the greenhouse effect.

In the U.S., the combustion of fossil fuels (e.g., coal, oil, gas) is the largest source of CO₂ emissions and accounts for 80 percent of the total GHG emissions by mass. Anthropogenic CO₂ emissions released from a variety of sources, including through the use of fossil fuel combustion and cement production from geologically stored carbon (e.g., coal, oil, and natural gas) that is hundreds of millions of years old, as well as anthropogenic CO₂ emissions from land-use changes such as deforestation, perturb the atmospheric concentration of CO₂, and the distribution of carbon within different reservoirs readjusts. More than half of the energy-related emissions come from large stationary sources such as power plants, while about a third come from transportation. Of the six well-mixed GHGs, four (CO₂, CH₄, N₂O, and HFCs) are emitted by motor vehicles. In the U.S., industrial processes (such as the production of cement, steel, and aluminum), agriculture, forestry, other land use, and waste management are also important sources of GHGs.

Different GHGs have different heat-trapping capacities. The concept of Global Warming Potential (GWP) was developed to compare the heat-trapping capacity and atmospheric lifetime of one GHG to another. The definition of a GWP for a particular GHG is the ratio of heat trapped by one unit mass of the GHG to that of one unit mass of CO₂ over a specified time period. When quantities of the different GHGs are multiplied by their GWPs, the different GHGs can be summed and compared on a carbon dioxide equivalent (CO₂e) basis. For example, CH₄ has a GWP of 21, meaning each ton of CH₄ emissions would have 21 times as much impact on global warming over a 100-year time horizon as 1 ton of CO₂ emissions. Thus, on the basis of heat-trapping capability, 1 ton of CH₄ would equal 21 tons of CO₂e. The GWPs of the non-CO₂ GHG range from 21 (for CH₄) up to 23,900 (for SF₆). Aggregating all GHG on a CO₂e basis at the source level allows a facility

to evaluate its total GHG emissions contribution based on a single metric.

B. What are the general requirements of the PSD program?

1. Overview of the PSD Program

The PSD program is a preconstruction review and permitting program applicable to new major stationary sources and major modifications at existing stationary sources. The PSD program applies in areas that are designated "attainment" or "unclassifiable" for a national ambient air quality standard (NAAQS). The PSD program is contained in part C of title I of the CAA. The "nonattainment NSR" program applies in areas not in attainment of a NAAQS or in the Ozone Transport Region, and it is implemented under the requirements of part D of title I of the CAA. Collectively, EPA commonly refers to these two programs as the major NSR program. The governing EPA rules are contained in 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, Appendices S and W. There is no NAAQS for CO₂ or any of the other well-mixed GHGs, nor has EPA proposed any such NAAQS; therefore, unless and until EPA takes further such action, the nonattainment NSR program does not apply to GHGs.

The applicability of PSD to a particular source must be determined in advance of construction or modification and is pollutant-specific. The primary criterion in determining PSD applicability is whether the proposed project is sufficiently large (in terms of its emissions) to be a major stationary source or modification, both of which are described below. EPA has implemented these requirements in its regulations, which use somewhat different terminology than the CAA does, for determining PSD applicability.

a. Major Stationary Sources

Under PSD, a "major stationary source" is any source belonging to a specified list of 28 source categories that emits or has the potential to emit 100 tpy or more of any air pollutant subject to regulation under the CAA, or any other source type that emits or has the potential to emit such pollutants in amounts equal to or greater than 250 tpy. See, e.g., 40 CFR 52.21(b)(1). We refer to these levels as the 100/250-tpy thresholds. A new source with a potential to emit (PTE) at or above the applicable "major stationary source threshold" is subject to major NSR. These limits originate from section 169 of the CAA, which applies PSD to any "major emitting facility" and defines the term to include any source that emits or

has a PTE of 100 or 250 tpy, depending on the source category. Note that the major source definition incorporates the phrase "subject to regulation," which, as described later, will begin to include GHGs on January 2, 2011, under our interpretation of that phrase as discussed in the recent memorandum entitled, "EPA's Interpretation of Regulations that Determine Pollutants Covered by Federal Prevention of Significant Deterioration (PSD) Permit Program." 75 FR 17004 (April 2, 2010).

b. Major Modifications

PSD also applies to existing sources that undertake a "major modification," which occurs when: (1) There is a physical change in, or change in the method of operation of, a "major stationary source;" (2) the change results in a "significant" emissions increase of a pollutant subject to regulation (equal to or above the significance level that EPA has set for the pollutant in 40 CFR 52.21(b)(23)); and (3) there is a "significant net emissions increase" of a pollutant subject to regulation that is equal to or above the significance level (defined in 40 CFR 52.21(b)(23)). Significance levels, which EPA has promulgated for criteria pollutants and certain other pollutants, represent a de minimis contribution to air quality problems. When EPA has not set a significance level for a regulated NSR pollutant, PSD applies to an increase of the pollutant in any amount (that is, in effect, the significance level is treated as zero).

2. General Requirements for PSD

This section provides a very brief summary of the main requirements of the PSD program. One principal requirement is that a new major source or major modification must apply best available control technology (BACT), which is determined on a case-by-case basis taking into account, among other factors, the cost effectiveness of the control and energy and environmental impacts. EPA has developed a "top-down" approach for BACT review, which involves a decision process that includes identification of all available control technologies, elimination of technically infeasible options, ranking of remaining options by control and cost effectiveness, and then selection of BACT. Under PSD, once a source is determined to be major for any regulated NSR pollutant, a BACT review is performed for each attainment pollutant that exceeds its PSD significance level as part of new construction or for modification projects at the source, where there is a

significant increase and a significant net emissions increase of such pollutant.⁴

In addition to performing BACT, the source must analyze impacts on ambient air quality to assure that its emissions do not cause or contribute to violation of any NAAQS or PSD increments and must analyze impacts on soil, vegetation, and visibility. In addition, sources or modifications that would impact Class I areas (e.g., national parks) may be subject to additional requirements to protect air quality related values (AQRVs) that have been identified for such areas. Under PSD, if a source's proposed project impacts a Class I area, the Federal Land Manager is notified and is responsible for evaluating a source's projected impact on the AQRVs and recommending either approval or disapproval of the source's permit application based on anticipated impacts.

Because there are no NAAQS or PSD increments established for GHGs, the requirement to demonstrate that a source does not cause or contribute to a violation of the NAAQS is not applicable to GHGs. Furthermore, consistent with EPA's statement in the Tailoring Rule, EPA believes it is not necessary for applicants or permitting authorities to assess impacts from GHGs in the context of the additional impacts analysis or Class I area provisions of the PSD regulations for the following policy reasons. Although it is clear that GHG emissions contribute to global warming and other climate changes that result in impacts on the environment, including impacts on Class I areas and soils and vegetation, due to the global scope of the problem, climate change modeling and evaluations of risks and impacts of GHG emissions typically are conducted for emission changes orders of magnitude larger than the emissions from individual projects that might be analyzed in PSD permit reviews. Quantifying the exact impacts attributable to a specific GHG source obtaining a permit in specific places and points would not be possible with current climate change modeling. Given these considerations, GHG emissions would serve as the more appropriate and credible proxy for assessing the impact of a given facility. Thus, EPA believes that the most practical way to address the considerations reflected in the Class I area and additional impacts

⁴ EPA notes that the PSD program has historically operated in this fashion for all pollutants—when new sources or modifications are "major," PSD applies to all pollutants that are emitted in significant quantities from the source or project. This rule does not alter that for sources or modifications that are major due to their GHG emissions.

analysis is to focus on reducing GHG emissions to the maximum extent. In light of these analytical challenges, compliance with the BACT analysis is the best technique that can be employed at present to satisfy the additional impacts analysis and Class I area requirements of the rules related to GHGs.

However, if PSD is triggered for a GHG-emitting source, all regulated NSR pollutants that the source emits in significant amounts would be subject to PSD requirements. Therefore, if a facility triggers review for regulated NSR pollutants that are non-GHG pollutants for which there are established NAAQS or increments, the air quality, additional impacts, and Class I requirements must be satisfied for those pollutants and the applicant and permitting authority are required to conduct the necessary analysis.

Pursuant to existing PSD requirements, the permitting authority must provide notice of its preliminary decision on a source's application for a PSD permit and must provide an opportunity for comment by the public, industry, and other interested persons. After considering and responding to comments, the permitting authority must issue a final determination on the construction permit. Usually NSR permits are issued by a State or local air pollution control agency that has its own authority to issue PSD permits under a permit program that has been approved by EPA for inclusion in its SIP. In some areas, EPA has delegated its authority to issue PSD permits under Federal regulations to the State or local agency. In other areas, EPA issues the permits under its own authority.

C. What are the CAA requirements to include the PSD program in the SIP?

The CAA contemplates that the PSD program be implemented in the first instance by the States and requires that States include PSD requirements in their SIPs. CAA section 110(a)(2)(C) requires that—

Each implementation plan * * * shall * * * include a program to provide for * * * regulation of the modification and construction of any stationary source within the areas covered by the plan as necessary to assure that national ambient air quality standards are achieved, including a permit program as required in part (C) * * * of this subchapter.

CAA section 110(a)(2)(I) requires that—

Each implementation plan * * * shall * * * meet the applicable requirements of * * * part C of this subchapter (relating to significant deterioration of air quality and visibility protection).

CAA section 161 provides that—

[E]ach applicable implementation plan shall contain emission limitations and such other measures as may be necessary, as determined under regulations promulgated under this part (C), to prevent significant deterioration of air quality in each region * * * designated * * * as attainment or unclassifiable.

These provisions, read in conjunction with the PSD applicability provisions as well as other provisions such as the BACT provision under CAA Section 165(a)(4), mandate that SIPs include PSD programs that are applicable to, among other things, any air pollutant that is subject to regulation. As discussed below, this includes GHGs on and after January 2, 2011.⁵

A number of States do not have PSD programs approved into their SIPs. In those States, EPA's regulations at 40 CFR 52.21 govern, and either EPA or the State as EPA's delegatee acts as the permitting authority. However, most States have PSD programs that have been approved into their SIPs, and these States implement their PSD programs and act as the permitting authority. Georgia has a SIP-approved PSD program.

D. What actions has EPA taken concerning PSD requirements for GHG-emitting sources?

1. What are the Endangerment Finding, the Light Duty Vehicle Rule, and the Johnson Memo Reconsideration?

By notice dated December 15, 2009, and pursuant to CAA section 202(a), EPA issued two findings regarding GHGs that are commonly referred to as the "Endangerment Finding" and the "Cause or Contribute Finding." "Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act," 74 FR 66496. In the Endangerment Finding, the Administrator found that six long-lived and directly emitted GHGs—CO₂, CH₄, N₂O, HFCs, PFCs, and SF₆—may reasonably be anticipated to endanger public health and welfare. In the Cause or Contribute Finding, the Administrator "defin[ed] the air pollutant as the aggregate group of the same six * * * greenhouse gases," 74 FR at 66536, and found that the combined emissions of this air pollutant

⁵ In the Tailoring Rule, EPA noted that commenters argued, with some variations, that the PSD provisions applied only to NAAQS pollutants, and not GHG, and EPA responded that the PSD provisions apply to all pollutants subject to regulation, including GHG. See 75 FR at 31560–62. EPA maintains its position that the PSD provisions apply to all pollutants subject to regulation, and the Agency incorporates by reference the discussion of this issue in the Tailoring Rule.

from new motor vehicles and new motor vehicle engines contribute to the GHG air pollution that endangers public health and welfare.

By notice dated May 7, 2010, EPA published what is commonly referred to as the "Light-Duty Vehicle Rule" (LDVR), which for the first time established Federal controls on GHGs emitted from light-duty vehicles. "Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards; Final Rule," 75 FR 25324. In its applicability provisions, the LDVR specifies that it "contains standards and other regulations applicable to the emission * * * of six greenhouse gases," including CO₂, CH₄, N₂O, HFCs, PFCs, and SF₆. 75 FR at 25686 (40 CFR 86.1818–12(a)).

On December 18, 2008, EPA issued a memorandum, "EPA's Interpretation of Regulations that Determine Pollutants Covered by Federal Prevention of Significant Deterioration (PSD) Permit Program" (known as the "Johnson Memo" or the "PSD Interpretive Memo," and referred to in this preamble as the "Interpretive Memo"), that set forth EPA's interpretation regarding which EPA and State actions, with respect to a previously unregulated pollutant, cause that pollutant to become "subject to regulation" under the Act. Whether a pollutant is "subject to regulation" is important for the purposes of determining whether it is covered under the Federal PSD permitting program. The Interpretive Memo established that a pollutant is "subject to regulation" only if it is subject to either a provision in the CAA or regulation adopted by EPA under the CAA that requires actual control of emissions of that pollutant (referred to as the "actual control interpretation"). On February 17, 2009, EPA granted a petition for reconsideration on the Interpretive Memo and announced its intent to conduct a rulemaking to allow for public comment on the issues raised in the memorandum and on related issues. EPA also clarified that the Interpretive Memo would remain in effect pending reconsideration.

On April 2, 2010, EPA published a notice conveying its decision to continue applying (with one limited refinement) the Interpretive Memo's interpretation of "subject to regulation." "Reconsideration of Interpretation of Regulations that Determine Pollutants Covered by Clean Air Act Permitting Programs," 75 FR 17004. EPA concluded that the "actual control interpretation" is the most appropriate interpretation to apply given the policy implications. However, EPA refined the Agency's interpretation in one respect: EPA

established that PSD permitting requirements apply to a newly regulated pollutant at the time a regulatory requirement to control emissions of that pollutant "takes effect" (rather than upon promulgation or the legal effective date of the regulation containing such a requirement). In addition, based on the anticipated promulgation of the LDVR, EPA stated that the GHG requirements of the vehicle rule would take effect on January 2, 2011, because that is the earliest date that a 2012 model year vehicle may be introduced into commerce. In other words, the compliance obligation under the LDVR does not occur until a manufacturer may introduce into commerce vehicles that are required to comply with GHG standards, which will begin with model year 2012 and will not occur before January 2, 2011.

2. What is EPA's Tailoring Rule?

On June 3, 2010 (effective August 2, 2010), EPA promulgated a final rulemaking, the Tailoring Rule, for the purpose of relieving overwhelming permitting burdens that would, in the absence of the rule, fall on permitting authorities and sources. 75 FR 31514. EPA accomplished this by tailoring the applicability criteria that determine which GHG emission sources become subject to the PSD program⁶ of the CAA. In particular, EPA established in the Tailoring Rule a phase-in approach for PSD applicability and established the first two steps of the phase-in for the largest GHG-emitters. Additionally, EPA committed to certain follow-up actions regarding future steps beyond the first two, discussed in more detail later in this notice.

For the first step of the Tailoring Rule, which will begin on January 2, 2011, PSD requirements will apply to major stationary source GHG emissions only if the sources are subject to PSD anyway due to their emissions of non-GHG pollutants. Therefore, in the first step, EPA will not require sources or modifications to evaluate whether they are subject to PSD requirements solely on account of their GHG emissions. Specifically, for PSD, Step 1 requires that as of January 2, 2011, the applicable requirements of PSD, most notably, the BACT requirement, will apply to projects that increase net GHG emissions by at least 75,000 tpy CO₂e, but only if the project also significantly increases emissions of at least one non-GHG pollutant.

⁶The Tailoring Rule also applies to the title V program, which requires operating permits for existing sources. However, today's action does not affect Georgia's title V program.

The second step of the Tailoring Rule, beginning on July 1, 2011, will phase in additional large sources of GHG emissions. New sources that emit, or have the potential to emit, at least 100,000 tpy CO₂e will become subject to the PSD requirements. In addition, sources that emit or have the potential to emit at least 100,000 tpy CO₂e and that undertake a modification that increases net GHG emissions by at least 75,000 tpy CO₂e will also be subject to PSD requirements. For both steps, EPA notes that if sources or modifications exceed these CO₂e-adjusted GHG triggers, they are not covered by permitting requirements unless their GHG emissions also exceed the corresponding mass-based triggers in tpy.

EPA believes that the costs to the sources and the administrative burdens to the permitting authorities of PSD permitting will be manageable at the levels in these initial two steps and that it would be administratively infeasible to subject additional sources to PSD requirements at those times. However, EPA also intends to issue a supplemental notice of proposed rulemaking in 2011, in which the Agency will propose or solicit comment on a third step of the phase-in that would include more sources, beginning on July 1, 2013. In the Tailoring Rule, EPA established an enforceable commitment that the Agency will complete this rulemaking by July 1, 2012, which will allow for one year's notice before Step 3 would take effect.

In addition, EPA committed to explore streamlining techniques that may well make the permitting programs much more efficient to administer for GHG, and that therefore may allow their expansion to smaller sources. EPA expects that the initial streamlining techniques will take several years to develop and implement.

In the Tailoring Rule, EPA also included a provision that no source with emissions below 50,000 tpy CO₂e and no modification resulting in net GHG increases of less than 50,000 tpy CO₂e will be subject to PSD permitting before at least 6 years (*i.e.*, April 30, 2016). This is because EPA has concluded that at the present time, the administrative burdens that would accompany permitting sources below this level would be so great that even with the streamlining actions that EPA may be able to develop and implement in the next several years, and even with the increases in permitting resources that EPA can reasonably expect the permitting authorities to acquire, it would be impossible to administer the

permit programs for these sources until at least 2016.

As EPA explained in the Tailoring Rule, the threshold limitations are necessary because without them PSD would apply to all stationary sources that emit or have the potential to emit more than 100 or 250 tons of GHG per year beginning on January 2, 2011. This is the date when EPA's recently promulgated LDVR takes effect, imposing control requirements for the first time on CO₂ and other GHGs. If this January 2, 2011, date were to pass without the Tailoring Rule being in effect, PSD requirements would apply to GHG emissions at the 100/250 tpy applicability levels provided under a literal reading of the CAA as of that date. From that point forward, a source owner proposing to construct any new major source that emits at or higher than the applicability levels (and which therefore may be referred to as a "major" source) or modify any existing major source in a way that would increase GHG emissions would need to obtain a permit under the PSD program that addresses these emissions before construction or modification could begin.

Under these circumstances, many small sources would be burdened by the costs of the individualized PSD control technology requirements and permit applications that the PSD provisions, absent streamlining, require. Additionally, State and local permitting authorities would be burdened by the extraordinary number of these permit applications, which are orders of magnitude greater than the current inventory of permits and would vastly exceed the current administrative resources of the permitting authorities. Permit gridlock would result since the permitting authorities would likely be able to issue only a tiny fraction of the permits requested.

The Tailoring Rule's thresholds are based on CO₂e for the aggregate sum of six GHGs that constitute the pollutant that will be subject to regulation, which we refer to as GHG.⁷ These gases are CO₂, CH₄, N₂O, HFCs, PFCs, and SF₆. Thus, in EPA's Tailoring Rule, EPA provided that PSD applicability is based on the quantity that results when the mass emissions of each of these gases is multiplied by the GWP of that gas, and then summed for all six gases. However, EPA further provided that in order for a source's GHG emissions to trigger PSD requirements, the quantity of the GHG

⁷The term "greenhouse gases" is commonly used to refer generally to gases that have heat-trapping properties. However, in this notice, unless noted otherwise, we use it to refer specifically to the pollutant regulated in the LDVR.

emissions must equal or exceed both the applicability thresholds established in the Tailoring Rule on a CO_{2e} basis and the statutory thresholds of 100 or 250 tpy on a mass basis.⁸ Similarly, in order for a source to be subject to the PSD modification requirements, the source's net GHG emissions increase must exceed the applicable significance level on a CO_{2e} basis and must also result in a net mass increase of the constituent gases combined.

In the Tailoring Rule, EPA adopted regulatory language codifying the phase-in approach. As explained in that rulemaking, many State, local and Tribal area programs will likely be able to immediately implement the approach without rule or statutory changes by, for example, interpreting the term "subject to regulation" that is part of the applicability provisions for PSD permitting. EPA has requested permitting authorities to confirm that they will follow this implementation approach for their programs, and if they cannot, then EPA has requested that they notify the Agency so that we can take appropriate follow-up action to narrow Federal approval of their programs before GHGs become subject to PSD permitting on January 2, 2011.⁹ On August 2, 2010, Georgia provided a letter to EPA confirming that the State has the authority to issue PSD permits governing GHG emissions as of January 2, 2011, but explaining that Georgia needs to amend its SIP to enable it to implement the Tailoring Rule thresholds. See the docket for this proposed rulemaking for a copy of Georgia's letter.

3. What is the GHG SIP Call?

By **Federal Register** notice dated September 2, 2010, EPA proposed the GHG SIP Call. In that action, along with the companion GHG FIP rulemaking published at the same time, EPA took steps to ensure that in the 13 States that do not appear to have authority to issue PSD permits to GHG-emitting sources at

present, either the State or EPA will have the authority to issue such permits by January 2, 2011. EPA explained that although for most States either the State or EPA is already authorized to issue PSD permits for GHG-emitting sources as of that date, our preliminary information shows that these 13 States have EPA-approved PSD programs that do not appear to include GHG-emitting sources and therefore do not appear to authorize these States to issue PSD permits to such sources. Therefore, EPA proposed to find that these 13 States' SIPs are substantially inadequate to comply with CAA requirements and, accordingly, proposed to issue a SIP Call to require a SIP revision that applies their SIP PSD programs to GHG-emitting sources. In the companion GHG FIP rulemaking, EPA proposed a FIP that would give EPA authority to apply EPA's PSD program to GHG-emitting sources in any State that is unable to submit a corrective SIP revision by its deadline. Georgia was not one of the States for which EPA proposed a SIP Call.

III. What is the relationship between today's proposed action and EPA's proposed GHG SIP Call and GHG FIP?

As noted above, by notice dated September 2, 2010, EPA proposed the GHG SIP Call. At the same time, EPA proposed a FIP to apply in any State that is unable to submit, by its deadline, a SIP revision to ensure that the State has authority to issue PSD permits to GHG-emitting sources.¹⁰ As discussed in Section IV of this rulemaking, Georgia interprets its current PSD regulations as providing it with the authority to regulate GHGs, and as such, Georgia is not included on the list of areas for the proposed SIP call. Additionally, Georgia would not be subject to the FIP to implement GHG for PSD applicability. Georgia's September 30, 2010, proposed SIP revision (the subject of this rulemaking) merely modifies Georgia's SIP to establish appropriate thresholds for determining which stationary sources and modification projects become subject to permitting requirements for GHG emissions under the PSD program of the CAA.

¹⁰ As explained in the proposed GHG SIP Call (75 FR 53892, 53896), EPA intends to finalize its finding of substantial inadequacy and the SIP call for the 13 listed States by December 1, 2010. EPA requested that the States for which EPA is proposing a SIP call identify the deadline—between 3 weeks and 12 months from the date of signature of the final SIP Call—that they would accept for submitting their corrective SIP revision.

IV. What is the background for the action proposed by EPA in today's Notice regarding the PSD Permitting Requirements for the PM_{2.5} NAAQS?

Today's proposed action on the Georgia SIP also relates to EPA's "Implementation of the New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers (PM_{2.5})" Final Rule (the NSR PM_{2.5} Rule), 73 FR 28321 (May 16, 2008). In the NSR PM_{2.5} Rule, EPA finalized regulations to implement the NSR program for fine particulate matter. As a result of EPA's final NSR PM_{2.5} Rule, States are required to provide SIP submissions no later than May 16, 2011, to address those requirements for both the PSD and nonattainment NSR programs. Georgia's September 30, 2010, SIP revision addresses the PSD requirements for the PM_{2.5} NAAQS. Georgia will provide a subsequent SIP revision to address the nonattainment NSR requirements for the PM_{2.5} NAAQS. More detail on the NSR PM_{2.5} Rule can be found in EPA's May 16, 2008, final rule and is summarized below.

A. Fine Particulate Matter and the NAAQS for PM_{2.5}

Fine particles in the atmosphere are made up of a complex mixture of components. Common constituents include sulfate (SO₄); nitrate (NO₃); ammonium; elemental carbon; a great variety of organic compounds; and inorganic material (including metals, dust, sea salt, and other trace elements) generally referred to as "crustal" material, although it may contain material from other sources. Airborne particulate matter (PM) with a nominal aerodynamic diameter of 2.5 micrometers or less (a micrometer is one-millionth of a meter, and 2.5 micrometers is less than one-seventh the average width of a human hair) are considered to be "fine particles" and are also known as PM_{2.5}. "Primary" particles are emitted directly into the air as a solid or liquid particle (e.g., elemental carbon from diesel engines or fire activities, or condensable organic particles from gasoline engines). "Secondary" particles (e.g., sulfate and nitrate) form in the atmosphere as a result of various chemical reactions.

On July 18, 1997, EPA revised the NAAQS for PM to add new standards for fine particles, using PM_{2.5} as the indicator. (Previously EPA used PM₁₀ (inhalable particles smaller than, or equal to 10 micrometers in diameter) as the indicator for the PM NAAQS.) EPA established health-based (primary) annual and 24-hour standards for PM_{2.5},

⁸ The relevant thresholds are 100 tpy for title V, and 250 tpy for PSD, except for 28 categories listed in EPA regulations for which the PSD threshold is 100 tpy.

⁹ Narrowing EPA's approval will ensure that for Federal purposes, sources with GHG emissions that are less than the Tailoring Rule's emission thresholds will not be obligated under Federal law to obtain PSD permits during the gap between when GHG PSD requirements go into effect on January 2, 2011 and when either (1) EPA approves a SIP revision adopting EPA's tailoring approach, or (2) if a State opts to regulate smaller GHG-emitting sources, the State demonstrates to EPA that it has adequate resources to handle permitting for such sources. EPA expects to finalize the narrowing action prior to the January 2, 2011 deadline with respect to those States for which EPA will not have approved the Tailoring Rule thresholds in their SIPs by that time.

setting an annual standard at a level of 15 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) and a 24-hour standard at a level of 65 $\mu\text{g}/\text{m}^3$. 62 FR 38652. At the time the 1997 primary standards were established, EPA also established welfare-based (secondary) standards identical to the primary standards. The secondary standards are designed to protect against major environmental effects of $\text{PM}_{2.5}$, such as visibility impairment, soiling, and materials damage. On October 17, 2006, EPA revised the primary and secondary NAAQS for $\text{PM}_{2.5}$. In that rulemaking, EPA reduced the 24-hour NAAQS for $\text{PM}_{2.5}$ to 35 $\mu\text{g}/\text{m}^3$ and retained the existing annual $\text{PM}_{2.5}$ NAAQS of 15 $\mu\text{g}/\text{m}^3$. 71 FR 61144.

B. Implementation of NSR for the $\text{PM}_{2.5}$ NAAQS

After EPA promulgated the NAAQS for $\text{PM}_{2.5}$ in 1997, the Agency issued a guidance document entitled "Interim Implementation of New Source Review Requirements for $\text{PM}_{2.5}$." John S. Seitz, EPA, October 23, 1997 (the "Seitz memo").¹¹ The Seitz memo was designed to help States implement PSD requirements pertaining to the new $\text{PM}_{2.5}$ NAAQS in light of known technical difficulties posed by $\text{PM}_{2.5}$, including the lack of necessary tools to calculate the emissions of $\text{PM}_{2.5}$ and related precursors, the lack of adequate modeling techniques to project ambient impacts, and the lack of $\text{PM}_{2.5}$ monitoring sites. Specifically, the Seitz memo authorized sources to use implementation of a PM_{10} program as a surrogate for meeting $\text{PM}_{2.5}$ PSD requirements until EPA resolved these technical difficulties.

On May 16, 2008, EPA finalized a rule to implement the 1997 $\text{PM}_{2.5}$ NAAQS, including changes to the NSR program. See 73 FR 28321. The 2008 NSR $\text{PM}_{2.5}$

Rule revised the NSR program requirements to establish the framework for implementing preconstruction permit review for the $\text{PM}_{2.5}$ NAAQS in both attainment and nonattainment areas. In summary, the NSR $\text{PM}_{2.5}$ Rule: (1) Requires NSR permits to address directly emitted $\text{PM}_{2.5}$ and precursor pollutants (2) establishes significant emission rates for direct $\text{PM}_{2.5}$ and precursor pollutants; (3) allows interpollutant trading under the $\text{PM}_{2.5}$ nonattainment NSR program; and (4) requires States to address condensable PM in establishing enforceable emission limits. With two exceptions, the 2008 NSR $\text{PM}_{2.5}$ Rule requires that major stationary sources seeking permits must begin directly satisfying the $\text{PM}_{2.5}$ requirements as of the effective date of the rule, rather than relying on PM_{10} as a surrogate. The first exception is a "grandfathering" provision in the Federal PSD program at 40 CFR 52.21(i)(1)(xi). This grandfathering provision applied to sources that had applied for, but had not yet received, a final and effective PSD permit before the July 15, 2008 effective date of the May 2008 final rule. The second exception was that States with SIP-approved PSD programs could continue to implement the Seitz Memo's PM_{10} Surrogate Policy for up to three years (until May 2011) or until the individual revised State PSD programs for $\text{PM}_{2.5}$ are approved by EPA, whichever comes first. For additional information on the NSR $\text{PM}_{2.5}$ Rule, see 73 FR 28321.

On February 11, 2010, EPA proposed to repeal the grandfathering provision for $\text{PM}_{2.5}$ contained in the Federal PSD program at 40 CFR 52.21(i)(1)(xi), and to end early the PM_{10} Surrogate Policy applicable in States that have a SIP-approved PSD program. 75 FR 6827. In support of this proposal, EPA explained that the $\text{PM}_{2.5}$ implementation issues that led to the adoption of the PM_{10} Surrogate Policy in 1997 have been largely resolved to a degree sufficient for sources and permitting authorities to conduct meaningful permit-related $\text{PM}_{2.5}$ analyses. EPA has not yet taken final action on this proposal.¹²

Georgia's September 30, 2010, submittal addresses the PSD requirements related to EPA's May 16, 2008, NSR $\text{PM}_{2.5}$ Rule. Though EPA has not finalized a repeal of the $\text{PM}_{2.5}$ grandfathering provision at 40 CFR 52.21(i)(1)(xi), Georgia elected not to

include this provision in its SIP submittal.

V. What is EPA's analysis of Georgia's SIP revision?

On September 30, 2010, EPD provided a revision to Georgia's SIP to EPA for parallel processing and eventual approval. The proposed change pertaining to PSD permitting for GHGs is necessary because without it PSD requirements would apply for GHGs, as of January 2, 2011, at the 100- or 250-tpy levels provided under the CAA. This would greatly increase the number of required permits, imposing undue costs on small sources; which would overwhelm Georgia's permitting resources and severely impair the function of the program. The proposed change pertaining to PSD permitting for $\text{PM}_{2.5}$ is necessary to comply with Federal requirements. More detail regarding EPA's analysis of the proposed changes to Georgia's SIP (as provided in the September 30, 2010, submittal) is provided below.

A. Analysis Regarding Georgia's Changes To Incorporate the Tailoring Rule

The State of Georgia's September 30, 2010, proposed SIP revision establishes thresholds for determining which stationary sources and modification projects become subject to permitting requirements for GHG emissions under Georgia's PSD program. Specifically, Georgia's September 30, 2010, proposed SIP revision incorporates by reference the Federal Tailoring Rule provisions at 40 CFR 52.21 (as amended June 3, 2010, and effective August 2, 2010), into the Georgia SIP (Georgia's Regulation 391-3-1-.02(7)—*Prevention of Significant Deterioration of Air Quality*)¹³ to address the thresholds for GHG permitting applicability.

Georgia is currently a SIP-approved State for the PSD program, and has incorporated by reference EPA's 2002 NSR reform revisions for PSD at 40 CFR 52.21 into its SIP.¹⁴ The State has informed EPA that it interprets SIP Rule 391-3-1-.02(7), which includes the preconstruction review program required by Part C of title I of the CAA, as providing it with authority to issue

¹¹ EPA also issued a guidance document entitled "Implementation of New Source Review Requirements in $\text{PM}_{2.5}$ Nonattainment Areas" (the "2005 $\text{PM}_{2.5}$ Nonattainment NSR Guidance"), on April 5, 2005, the date that EPA's $\text{PM}_{2.5}$ nonattainment area designations became effective. This memorandum provides guidance on the implementation of the nonattainment major NSR provisions in $\text{PM}_{2.5}$ nonattainment areas in the interim period between the effective date of the $\text{PM}_{2.5}$ nonattainment area designations (April 5, 2005) and EPA's promulgation of final $\text{PM}_{2.5}$ nonattainment NSR regulations. Besides reaffirming the continuation of the PM_{10} Surrogate Policy for $\text{PM}_{2.5}$ attainment areas set forth in the Seitz memo, the 2005 $\text{PM}_{2.5}$ Nonattainment NSR Guidance recommended that until EPA promulgates the $\text{PM}_{2.5}$ major NSR regulations, States should use a PM_{10} nonattainment major NSR program as a surrogate to address the requirements of nonattainment major NSR for the $\text{PM}_{2.5}$ NAAQS. As mentioned earlier in this rulemaking, Georgia's September 30, 2010, SIP revision only relates to the PSD provisions for the $\text{PM}_{2.5}$ standard.

¹² Additional information on this issue can also be found in an August 12, 2009, final order on a title V petition describing the use of PM_{10} as a surrogate for $\text{PM}_{2.5}$. In the Matter of *Louisville Gas & Electric Company*, Petition No. IV-2008-3, Order on Petition (August 12, 2009).

¹³ Georgia's submittal also relates to title V provisions which are not included in the SIP. As such, EPA is not proposing to take action to approve Georgia's update to their title V regulations in this rulemaking.

¹⁴ On September 4, 2008, EPA proposed to approve Georgia's submittal related to the 2002 NSR reform rules. See 73 FR 51606. EPA considered the comments received on the September 4, 2008, proposal, and has addressed the comments in a final rulemaking that was signed on November 12, 2010.

PSD permits governing GHGs. Georgia's current PSD program incorporates by reference the Federal requirements, found at 40 CFR 52.21 (adopted prior to the promulgation of EPA's Tailoring Rule), into the State's major source PSD program (which applies to major stationary sources having the potential to emit at least 100-tpy or 250-tpy or more of a regulated NSR pollutant, depending on the type of source or modifications constructing in areas designated attainment or unclassifiable with respect to the NAAQS).

This current SIP revision to Georgia's Regulation 391-3-1-.02(7) (the subject of this proposed rulemaking) incorporates by reference the provisions at 40 CFR 52.21 as amended by the promulgation of the Tailoring Rule. Specifically, Georgia's September 30, 2010 revision updates its existing incorporation by reference of the Federal NSR program to include the relevant Federal Tailoring Rule provisions set forth at 40 CFR 52.21. EPA has preliminarily determined that Georgia's proposed SIP revision is consistent with the Tailoring Rule. Furthermore, EPA has preliminarily determined that this revision to Georgia's SIP is consistent with section 110 of the CAA. See, e.g., Tailoring Rule, 75 FR at 31561.

B. Analysis Regarding Georgia's Changes To Incorporate the NSR PM_{2.5} Requirements for PSD

Georgia's Regulation 391-3-1-.02(7) (the subject of this proposed rulemaking) also incorporates by reference the provisions at 40 CFR 52.21 as amended by the promulgation of the NSR PM_{2.5} Rule for PSD. Specifically, Georgia's September 30, 2010, revision updates its existing incorporation by reference of the Federal NSR program to include the relevant Federal NSR PM_{2.5} Rule provisions for PSD set forth at 40 CFR 52.21. However, in light of EPA's proposed rulemaking to repeal the PM_{2.5} "grandfathering" provision, as noted in section IV.B. above, Georgia's revision excludes adoption of the relevant Federal rule provision, 40 CFR 52.21(i)(1)(ix). EPA has preliminarily determined that Georgia's proposed SIP revision is consistent with the NSR PM_{2.5} Rule for PSD. Furthermore, EPA has preliminarily determined that this revision to Georgia's SIP is consistent with section 110 of the CAA.

VI. Proposed Action

EPA is proposing to approve Georgia's September 30, 2010, SIP revision, relating to PSD requirements for GHG-emitting sources and for the PM_{2.5} NAAQS. Specifically, Georgia's

September 30, 2010, proposed SIP revision establishes appropriate emissions thresholds for determining PSD applicability with respect to new and modified GHG-emitting sources in accordance with EPA's Tailoring Rule, and incorporates Federal requirements related to PSD for the PM_{2.5} NAAQS. EPA has made the preliminary determination that this SIP revision is approvable because it is in accordance with the CAA and EPA regulations regarding PSD permitting for GHGs and for the PM_{2.5} NAAQS.

VII. Statutory and Executive Order Reviews

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. Accordingly, this proposed action merely approves the State's law as meeting Federal requirements and does not impose additional requirements beyond those imposed by the State's 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 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 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 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.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, and Reporting and recordkeeping requirements.

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

Dated: November 18, 2010.

Gwendolyn Keyes Fleming,

Regional Administrator, Region 4.

[FR Doc. 2010-29951 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2010-0656; FRL-9232-1]

Approval and Promulgation of Air Quality Implementation Plans; Ohio; Ohio Portion of the Cincinnati-Hamilton Area; 8-Hour Ozone Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the maintenance plan for the Ohio portion of the Cincinnati-Hamilton, OH-KY-IN 8-hour ozone area. The Cincinnati-Hamilton area includes Butler, Clermont, Clinton, Hamilton, and Warren Counties in Ohio, Lawrenceburg Township in Dearborn County, Indiana, and Boone, Campbell, and Kenton Counties in Kentucky. The Ohio Environmental Protection Agency (Ohio EPA) submitted a maintenance plan revision on July 6, 2010. The submittal contained revisions to 2015 and 2020 NO_x point source emissions projections for Butler County to reflect modifications at a major source that will occur during the maintenance period.

DATES: Comments must be received on or before December 29, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-

OAR-2010-0656, by one of the following methods:

1. *http://www.regulations.gov*: Follow the online instructions for submitting comments.

2. *E-mail*: mooney.john@epa.gov.

3. *Fax*: (312) 692-2551.

4. *Mail*: John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery*: John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT:

Kathleen D'Agostino, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-1767, dagostino.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the maintenance plan revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an

adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: November 15, 2010.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2010-29785 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2009-0515; FRL-9232-4]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Clean Air Interstate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a request submitted by the Indiana Department of Environmental Management (IDEM) on June 29, 2009, to revise the Indiana State Implementation Plan (SIP) under the Clean Air Act (CAA). The State has submitted amendments to the Indiana Administrative Code (IAC), which supplement Indiana's Clean Air Interstate Rule (CAIR), for which EPA granted limited approval as an abbreviated SIP on October 22, 2007. The State's June 29, 2009, submittal includes elements that EPA deems necessary in order for EPA to fully approve Indiana's CAIR SIP. This will allow a transition from an abbreviated SIP with limited approval to a full SIP with full approval under which the various CAIR implementation provisions would be governed by State rules rather than Federal Implementation Plan (FIP) rules. This action results in the withdrawal of the Indiana CAIR FIP concerning sulfur dioxide (SO₂), nitrogen oxides (NO_x) annual, and NO_x ozone season emissions.

DATES: Comments must be received on or before December 29, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2009-0515, by one of the following methods:

1. *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *E-mail*: mooney.john@epa.gov.

3. *Fax*: (312) 692-2551.

4. *Mail*: John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J),

U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery*: John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Final Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT:

Andy Chang, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-0258, chang.andy@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we do not receive any adverse comments in response to this rule, we do not contemplate taking any further action. If EPA receives adverse comments, we will withdraw the direct final rule, and will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule, which is located in the Final Rules section of this **Federal Register**.

Dated: November 15, 2010.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2010-29789 Filed 11-26-10; 8:45 am]

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Notices

Federal Register

Vol. 75, No. 228

Monday, November 29, 2010

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

Commodity Credit Corporation

Cooperative Conservation Partnership Initiative and Wetlands Reserve Enhancement Program

AGENCY: Commodity Credit Corporation and Natural Resources Conservation Service, United States Department of Agriculture.

ACTION: Notice of request for proposals through the Mississippi River Basin Healthy Watersheds Initiative.

SUMMARY: The Natural Resources Conservation Service (NRCS) announces the availability of financial assistance funds in fiscal year (FY) 2011 for up to \$15 million in the Cooperative Conservation Partnership Initiative (CCPI) and up to \$25 million in the Wetlands Reserve Enhancement Program (WREP) through the Mississippi River Basin Healthy Watersheds Initiative (MRBI). These funding levels are available for new MRBI proposals only. However, CCPI and WREP will not be the only funding mechanisms for MRBI in FY 2011. The Chief of NRCS reserves discretion in

utilizing other NRCS conservation program funds and mechanisms in support of the objectives of MRBI.

Through agreements, partners and NRCS will provide assistance to eligible participants in the 43 designated focus areas (8-digit HUCs) in the following 13 States: Arkansas, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Ohio, Tennessee, South Dakota, and Wisconsin. The purpose of this notice is to solicit proposals from potential partners to enter into agreements with NRCS and to inform agricultural producers and landowners of the future availability of program funds through approved partnership projects. Proposals must be based on one or more 12-digit HUCs within the 43 designated focus areas. Partners who are currently involved in approved MRBI agreements through CCPI or WREP and want to work in other 12-digit watersheds must submit new proposals for a new project.

DATES: Eligible partners may submit proposals for MRBI-CCPI and/or MRBI-WREP via email or U.S. Postal Service; however, all proposals must be received on or before January 28, 2011.

ADDRESSES: Applicants are encouraged to submit proposals electronically to MRBI-CCPI@wdc.usda.gov for CCPI and MRBI-WREP@wdc.usda.gov for WREP. If submitting a paper proposal, the proposal may be mailed to: Troy Daniell, Initiatives Coordinator, Conservation Initiatives Team, Natural Resources Conservation Service, P.O. Box 2890, Washington, DC 20013.

Do not send submissions via registered or certified mail. Do not send

the same proposal both electronically and to the P.O. Box address; use only one method to submit a proposal. If submitting more than one project proposal, please submit each separately.

FOR FURTHER INFORMATION CONTACT: Troy Daniell, Initiatives Coordinator, Conservation Initiatives Team, Natural Resources Conservation Service; Telephone: (202) 690-2825; e-mail: Troy.Daniell@wdc.usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA TARGET Center at: (202) 720-2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Part A—General WREP and CCPI Proposal Information

Focus Area Watersheds

Forty-three focus area (8-digit hydrologic unit code (HUC)) watersheds have been selected by NRCS State Conservationists, with input from the State Technical Committees and State water quality agencies, to help improve water quality by reducing nitrogen and sediment levels in the watersheds of the Mississippi River Basin, as well as improve wildlife habitat and restore wetlands. The designated 8-digit HUC focus areas are listed below. A complete list of the smaller-scale, 12-digit HUC sub-watersheds within the designated 8-digit HUC focus areas can be found at: http://www.nrcs.usda.gov/programs/mrbi/unit_code_lists.html.

DESIGNATED FOCUS AREAS FOR THE MRBI FY 2011 (8-DIGIT HUCs)

State(s)	Watershed	Hydrologic Unit Code
Arkansas/Missouri	Cache	08020302
Arkansas	Lake Conway-Point Remove	11110203
Arkansas	L'Anguille	08020205
Arkansas/Missouri	Lower St. Francis	08020203
Illinois	Lower Illinois-Senachwine Lake	07130001
Illinois	Upper Illinois	07130005
Illinois	Vermillion (Upper Mississippi River sub-basin)	07130002
Illinois/Indiana	Vermillion (Upper Ohio River sub-basin)	05120109
Indiana	Eel	05120104
Indiana	Upper East Fork White	05120206
Indiana	Wildcat	05120107
Indiana/Ohio	Upper Wabash	05120101
Iowa	Boone	07100005
Iowa	Maquoketa	07060006
Iowa	North Raccoon	07100006
Iowa/Minnesota	Upper Cedar	07080201

DESIGNATED FOCUS AREAS FOR THE MRBI FY 2011 (8-DIGIT HUCs)—Continued

State(s)	Watershed	Hydrologic Unit Code
Kentucky/Tennessee	Bayou De Chien-Mayfield	08010201
Kentucky	Licking	05100101
Kentucky	Lower Green	05110005
Louisiana	Mermentau	08080202
Louisiana/Arkansas	Bayou Macon	08050002
Louisiana/Arkansas	Boeuf River	08050001
Minnesota	Middle Minnesota	07020007
Minnesota	Root	07040008
Minnesota	Sauk	07010202
Mississippi	Big Sunflower	08030207
Mississippi/Louisiana/Arkansas	Deer-Steele	08030209
Mississippi	Upper Yazoo	08030206
Missouri/Iowa	Lower Grand	10280103
Mississippi	Coldwater Creek	08030204
Missouri	North Fork Salt	07110005
Missouri	South Fork Salt	07110006
Missouri/Arkansas	Little River Ditches	08020204
Ohio/Indiana	Upper Great Miami	05080001
Ohio	Upper Scioto	05060001
Tennessee	Forked Deer	05010206
Tennessee/Kentucky	Obion	08010202
Tennessee	South Fork Obion	08010203
Tennessee/Kentucky	Red River	05130206
South Dakota/Minnesota	Upper Minnesota	07020001
Wisconsin/Illinois	Sugar	07090004
Wisconsin/Illinois	Upper Rock	07090001
Wisconsin/Illinois	Pecatonica	07090003

Under MRBI, NRCS works with partners through CCPI and WREP to help address conservation concerns and opportunities within the watershed of the Mississippi River Basin. In approved MRBI-CCPI project areas, NRCS will make Environmental Quality Incentives Program (EQIP), Conservation Stewardship Program (CSP), and Wildlife Habitat Incentive Program (WHIP) funds available to eligible producers consistent with the proposal design as much as possible. In approved MRBI-WREP project areas, funds are available through the Wetlands Reserve Program (WRP).

Proposal Submission, Review, and Notification

Potential partners are highly encouraged to submit proposals to the email address provided in the "Addresses" section of this notice. If the proposal is submitted in hard copy, the potential partner must submit two copies of the proposal, typewritten or printed on 8½" x 11" white paper. The entire project proposal, not including letters of support, cannot exceed 12 pages in length including a summary, responses to the information requested in this RFP, maps, and other supporting documents. The proposal must address, in sufficient detail, all the criteria outlined in the "Proposal Requirements" section of this notice in order to be considered.

MRBI-CCPI and MRBI-WREP proposals submitted to NRCS become the property of the agency for use in the administration of the program, may be filed or disposed of by the agency, and will not be returned to the potential partner. Once proposals have been submitted for review and ranking, there will be no further opportunity for the potential partner to change or re-submit the proposal; however, NRCS may request certain changes before finalizing the selection and approval of a project. Incomplete proposals or those that do not meet the requirements set forth in this notice will not be considered, and notification of elimination will be mailed to the applicant. Partner proposals may be withdrawn by written notice to Troy Daniell, Initiatives Coordinator, Conservation Initiatives Team, at any time prior to selection (see "Addresses" section in this notice).

NRCS will review, evaluate, and rank proposals based on the criteria set forth in the respective "Proposal Requirements" sections of this notice for both MRBI-CCPI and MRBI-WREP. Potential partners should recognize that the proposal is the only document NRCS will use in the evaluation process. The proposal must request NRCS program funds for obligation beginning in FY 2011 (October 1, 2010–September 30, 2011). Proposals which request funding with obligation starting after FY 2011 will not be evaluated or

considered under this request for proposals.

Partners whose proposals have been selected will receive an official letter of notification. Upon notification of selection, the partner should contact the appropriate State Conservationist(s) to develop the required partnership agreement and other project implementation requirements. Potential partners should note that, depending upon available funding and agency priorities, NRCS may offer a reduced amount of program financial assistance from what was requested in the proposal and may require adjustments to the proposal as a condition of approval to meet program or other requirements. Partner submissions of proposals that are not selected will also be notified by mail.

State Conservationist(s) Proposal Review

Once a project proposal is received, the agency will provide a copy of it to the appropriate State Conservationist(s). State Conservationist(s) will review the proposals to:

- Document potential duplication with other projects or existing programs;
- Ensure adherence to and consistency with program regulation, including requirements related to land and landowner eligibility and other program requirements;

(c) Address expected benefits for project implementation in their State(s);

(d) For multi-State proposals, coordinate with all State Conservationists involved in the proposal to verify there is concurrence and support for the project;

(e) Identify other issues or concerns that should be considered; and

(f) Provide a recommendation to the NRCS Chief for approval or disapproval of the project.

Waiver Authority

To assist in the implementation of approved WREP and CCPI projects, the Chief may waive the applicability of the Adjusted Gross Income Limitation, on a case-by-case basis, in accordance with 7 CFR part 1400. Such waiver requests must be submitted in writing from the program applicant, not the sponsoring partner, addressed to the Chief, and submitted through the local NRCS designated conservationist.

Part B—The Cooperative Conservation Partnership Initiative (CCPI) Component of MRBI

To improve the health of the watersheds within the Mississippi River Basin, NRCS and its partners will help producers to voluntarily implement conservation practices that avoid, control, and trap nutrient runoff; improve wildlife habitat; restore wetlands; and maintain agricultural productivity. These improvements will be accomplished through a conservation systems approach to address water quality, wetland, and wildlife related resource concerns. NRCS will provide producers assistance in implementing a suite of practices that will reduce the impacts of nutrients and sediment leaving agricultural fields.

Overview of the CCPI

The CCPI is a voluntary conservation initiative that enables the use of certain conservation programs, combined with resources from eligible partners, to provide financial and technical assistance to owners and operators of agricultural and nonindustrial private forest lands in order to enhance conservation outcomes and achieve resource conservation objectives. The functions of CCPI can best be described in two parts: CCPI partnerships and CCPI program participation.

CCPI Partnerships

Under CCPI, eligible potential partners may submit proposals addressing the criteria that are outlined in this request for proposals. Partners who may enter into partnership agreements with NRCS include federally

recognized Indian tribes, State and local units of government, producer associations, farmer cooperatives, institutions of higher education, and nongovernmental organizations with a history of working cooperatively with producers to effectively address conservation priorities related to agricultural production and nonindustrial private forest land. Individual agricultural producers are not an eligible partner entity and may not submit CCPI proposals. However, individual agricultural producers can participate by applying for program assistance in the approved proposal areas, through their local NRCS office.

Proposals will be evaluated through a competitive review process. After selection, the partners will enter into a partnership agreement with NRCS. The partnership agreement will not obligate funds, but will address the:

- (a) Role of the partner;
- (b) Role of NRCS;
- (c) Responsibilities of the partner as it relates to the monitoring and evaluation;
- (d) Frequency and duration of monitoring and evaluation to be completed by the partner;
- (e) Format and frequency of reports that are required as a condition of the partnership agreement;
- (f) Budget which includes other funding sources (if applicable) for financial and technical assistance;
- (g) Specified project schedule and timeframe; and
- (h) Other requirements deemed necessary by NRCS to further the purposes of MRBI.

Where flexibility is needed to meet project objectives, the partner may request that program adjustments be allowed, provided such adjustments are within the scope of the applicable programs' statutory and regulatory program authorities. An example of an adjustment may be to expedite the applicable program ranking process in a situation where a partner has identified the producers approved to participate in the project. Other examples of flexibilities are payments rates, or use of a single area-wide conservation plan of operations rather than individual conservation plans of operation. An example of an ineligible flexibility would be to request funds for activities that do not meet NRCS conservation practice standards.

CCPI is not a grant program, and all Federal funds made available through this request for proposals will be paid directly to producers through program contract agreements. If desired, producers may elect to have their payments assigned to another party. No technical assistance funding may be

provided to a partner through the CCPI partner agreement. However, if requested by a partner, the State Conservationist may consider development of a separate contribution agreement with a qualified partner to provide funding for delivery of technical services to producers participating in an approved CCPI project.

CCPI Program Participation

Once the agency approves and announces the selected partner projects, eligible agricultural producers located within the approved project areas may apply directly to NRCS for funding through one or more of the following programs: EQIP, CSP, or WHIP. CCPI uses the funds, policies, and processes of these programs to deliver assistance to eligible producers to implement approved core and supporting conservation practices, enhancements, and activities under MRBI. Producers interested in applying must meet the eligibility requirements of the program for which they are applying. Individual applications from eligible producers will be evaluated and ranked to ensure that producer applications selected for funding are most likely to achieve project objectives. Once applications are selected, the producers may enter into one or more contracts or cost-share agreements with NRCS within one or more of the programs offered under CCPI. During FY 2011, an objective of MRBI-CCPI is to deliver EQIP, CSP, and WHIP assistance to producers to achieve MRBI priority conservation objectives in geographic areas defined by the partner. Depending upon the program available in the project area, the assistance provided enables eligible producers to implement conservation practices and enhancements, including the development and adoption of innovative conservation practices and management approaches.

Availability of Funding

Effective on the publication date of this notice, the CCC announces the availability of up to \$9 million in EQIP and \$500,000 in WHIP financial assistance; and 278,000 acres in CSP for MRBI-CCPI during FY 2011.

Proposal Requirements

The proposal must include the following:

- (1) Proposal Cover and Summary:
 - (a) Project Title.
 - (b) Project director/manager name, telephone number, and mailing and email addresses.

(c) Name and contact information for lead partner entity submitting proposal and other collaborating partners.

(d) Short summary of project including:

- i. Project start and end dates (not to exceed a period of 4 years),
- ii. Designated 12-digit HUC, or contiguous multiple 12-digit HUCs sub-watersheds where the project is located, including the State(s) and county(s),
- iii. General project objectives and resource concerns to be addressed as they relate to MRBI priorities and objectives,
- iv. Total amount of CCPI financial assistance being requested by program, and

v. Whether the MRBI-CCPI proposal will be used in conjunction with a MRBI-WREP, MRBI-CIG, or other Federal programs to meet MRBI objectives. Include the name of that project and the associated Federal agency. (Note: Federal funds cannot be used as a match to the funds provided by NRCS.)

(2) Project Natural Resource Objectives and Concerns:

(a) Identify and provide detail about the project objectives. Objectives should be specific, measureable, achievable, and results-oriented.

(b) Identify and provide detail about the natural resource concern(s) to be addressed in this project. Include in this description how the proposal objectives will address the priority MRBI resource concerns of water quality, wetland restoration, and improved wildlife habitat. Potential partners will work with the State Conservationist(s) to ensure the priority resource concerns are addressed by utilizing approved conservation practices, enhancements and activities, and conservation program requirements. A list of NRCS approved natural resource concerns for MRBI may be found on the MRBI Web site at http://www.nrcs.usda.gov/programs/mrbi/mrbi_overview.html.

(3) Detailed Project Description:

(a) A detailed description of the geographic area covered by the proposal, including:

- i. Types of land uses to be treated, and
- ii. The location and size of the proposed project area and what 12-digit HUC sub-watershed(s) the project will be within.

(b) A detailed map showing the project area. Include on the map:

- i. Outlined areas that need conservation treatments,
- ii. Location where conservation treatments are needed, and
- iii. Priority order for the different areas to be treated.

(c) A description of the project timeline. Include:

i. Duration of the project, not to exceed 4 consecutive years in length beginning in FY 2011,

ii. Project implementation schedule that details when different objectives and conservation practices and enhancements will be completed,

iii. When partner and Federal resources will be used within the timeframe of the project. Include the total amount of financial assistance funds requested for each fiscal year of the project to be made available for producer contracts and cost-share agreements (for multi-State projects, provide the funds or acres by State as appropriate), and

iv. When the final project report will be submitted.

(d) A description of the plan for evaluating and reporting on progress made toward achieving the objectives of the agreement.

(e) Identify potential criteria to be used by NRCS to prioritize and rank agricultural producers' applications for EQIP, CSP, and WHIP in the project area. Potential partners should collaborate with NRCS to develop meaningful criteria that NRCS can use to evaluate and rank producer program applications. This will ensure that producer applications which will best accomplish MRBI objectives will be selected.

(f) An estimate of the percentage of producers, including nonindustrial private forest landowners, in the project area that may participate in the project along with an estimate of the total number of producers located in the project area. Provide details about additional information such as how the partner will encourage producer participation; does the project include any tribal producers, beginning farmers or ranchers, socially disadvantaged farmers or ranchers, or limited resource farmers or ranchers; and are there groups of producers who may submit joint applications to address resource issues of common interest and need.

(g) A listing and description of the approved MRBI-CCPI core conservation practices, conservation activity plans, enhancements, and partner activities to be implemented during the project timeframe and the general sequence of implementation of the project. Information about approved MRBI-CCPI EQIP, WHIP, and CSP practices, enhancements, and activities can be accessed at <http://nrcs.usda.gov/programs/mrbi/mrbi.html>. Only the conservation practices listed, which are available in the applicable State's Field Office Technical Guide, are eligible for use in MRBI. For each conservation practice, estimate the amount of practice

extent (feet, acres, number, etc.) the partner expects producers to implement and the amount of financial assistance requested to support implementation of each practice through producer contracts.

(h) Also address technical assistance efforts that will be made by the partner. Describe any activities that are innovative and include outcome-based performance measures, such as water quality monitoring, to be implemented by the partner.

(i) Indicate whether the project will address specific regulatory compliance and any other outcomes the partner expects to complete during the project period.

(j) A detailed description of any requested adjustments, by program, with an explanation of why the adjustment is needed in order to achieve the objectives of the project. Requested adjustments or flexibilities must comply with statutory and regulatory requirements.

(k) A science-based description of how the proposal's objectives also may provide additional benefits by addressing energy conservation or mitigating the effects of climate change, if applicable.

(l) A description of a plan to conduct water quality monitoring and evaluation and the reporting of progress made toward achieving MRBI objectives and desired outcomes. NRCS is especially interested in proposals that adopt a three-tiered monitoring and evaluation approach designed to assess environmental outcomes at the edge-of-field, in-stream, and at the 12-digit HUC level. Higher priority will be given to projects that adopt this three-tiered approach where the partner provides resources or technical services to carry it out. Higher priority will also be given to projects that utilize environmental indicators to assess water quality and evaluate effects of conservation systems and activities implemented through the project at the edge-of-field level in conjunction with in-stream and 12-digit HUC monitoring. Information concerning water quality monitoring and evaluation can be found at http://www.nrcs.usda.gov/programs/pdf_files/water_quality_monitoring_reference_material.pdf.

(4) Partner Description:

(a) A description of the partner(s) history of working with agricultural producers to address conservation priorities.

(b) A description of how the partner(s) will collaborate to achieve the objectives of the agreement. Include:

- i. The roles, responsibilities, and capabilities of the partner(s), and

ii. The financial or technical commitments of each of the partner(s) and how they will be leveraged by the Federal contribution through EQIP, WHIP, CSP, or a combination of the three. Include specifically what commitments will be used toward water quality monitoring needs. If partners who do not submit the proposal intend to commit resources, a letter or other documentation from these partners confirming a commitment of specified resources is required.

(c) A description of the resources (financial and technical assistance) requested from each of the applicable NRCS programs (EQIP, WHIP, and CSP) and the non-Federal resources provided by the partner that will be leveraged by the Federal contribution. Partners need to clearly state, by project objective, how they intend to leverage Federal funds along with partner resources. The funding and time contribution by agricultural producers to implement agreed-to conservation practices and enhancements in program contracts will not be considered any part of a match from the potential partner for purposes of CCPI.

(d) A description of how the partner will facilitate the submission of landowner applications.

(e) A description of how the partner will provide for outreach to beginning farmers or ranchers, limited resource farmers or ranchers, socially disadvantaged farmers or ranchers, and Indian tribes.

National Ranking Considerations

The agency will evaluate proposals using a national competitive process. A higher priority may be given to proposals that:

(a) Have a high percentage of producers actively farming or managing working agricultural or nonindustrial private forest lands included in the proposed project area;

(b) Significantly leverage non-Federal financial and technical resources and coordinate with other local, State, or Federal efforts. This includes resources committed to provide for water quality monitoring and evaluation of conservation practices;

(c) Integrate both WREP and CCPI within a project area;

(d) Deliver high percentages of applied conservation practices to address water quality, wildlife habitat, and wetland restoration;

(e) Provide innovation in approved conservation practices, conservation methods, and delivery, including outcome-based performance measures and methods such as adaptive management strategies;

(f) Complete the application of the conservation practices and activities on all of the covered program contracts or cost-share agreements in 4 years or less;

(g) Assist the participants in meeting local, State, and Federal regulatory requirements;

(h) Provide for environmental monitoring and evaluation of conservation practices, enhancements, and activities;

(i) Provide for outreach to, and participation of, beginning farmers or ranchers, socially disadvantaged farmers or ranchers, limited resource farmers or ranchers, and Indian tribes within the proposed project area;

(j) Have a high potential to achieve MRBI water quality objectives of nitrogen and sediment reductions leaving the field; and

(k) Identify other factors and criteria which best achieve the purposes of MRBI-CCPI.

Part C—The Wetlands Reserve Enhancement Program Component of MRBI

Availability of Funding

Effective upon publication of this notice, NRCS on behalf of CCC, announces that within the designated focus areas in the Mississippi River Basin Watersheds, up to \$25 million in financial assistance funds are available in FY 2011 for the WREP to eligible participants through approved partnership projects within the 43 designated 8-digit HUC focus area watersheds in the following states: Arkansas, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Ohio, Tennessee, South Dakota, and Wisconsin.

Under WREP, NRCS enters into multi-year agreements with eligible State and local governments, nongovernmental organizations, and Indian tribes to target and leverage resources to carry out high priority wetland protection, restoration, and enhancement activities; and improve water quality and wildlife habitat. Eligible partners should submit complete proposals to the addresses listed in this notice addressing the MRBI conservation objectives to be achieved in one or more 12-digit HUC watersheds within the 43 eligible 8-digit HUC focus area watersheds. Proposals that integrate a MRBI-WREP proposal with a MRBI-CCPI project in one or more 12-digit HUC watersheds will be given additional consideration in the selection process.

Overview

WREP is a voluntary conservation program which is a component of WRP.

WREP leverages resources of eligible partners to provide financial assistance to eligible landowners to protect, restore, and enhance high priority wetlands; improve wildlife habitat; and improve water quality. WREP partners are required to contribute a match as detailed in the proposal requirement section at 3(e). Proposals which include additional partner resources will be given higher priority consideration in the selection process.

WREP financial assistance is delivered to eligible landowners and partners in approved project areas through easement acquisition, conservation program contracts, cooperative agreements, contribution agreements, or Federal contracts. Restoration may be achieved through payments to other parties who conduct the restoration activities.

Only States and local units of government, Indian tribes, and nongovernmental organizations are eligible to submit a proposal and enter into agreements with NRCS. A nongovernmental organization is an organization described in section 501(c)(3) of the Internal Revenue Code of 1986. Individual landowners may not submit WREP proposals through this submission process. However, once a WREP project has been approved and announced, eligible landowners may apply for WREP through their local NRCS office. As part of the agreement, approved partners may also help facilitate the submission of landowner applications, provide additional technical or financial assistance to landowners, and provide other resources as defined in the agreement.

Written proposals are to be submitted by eligible partners, and project evaluation will be based upon a competitive process and the criteria established in this notice. Once NRCS selects a partner's proposal, landowners within the selected project area may submit an application directly to NRCS for participation in WREP. Individual landowner applications will be evaluated and ranked along with other applications in the watershed or geographic project area, when applicable, to ensure that the properties selected for funding will achieve project objectives.

Wetland restoration and enhancement actions will be designed to improve water quality, and maximize wildlife habitat benefits and wetland functions and values according to the WRP regulation, 7 CFR part 1467, and NRCS conservation practice standards. Additionally, the successful restoration of land and the resultant wetland values must take into consideration the cost of

such restoration, as required by the WRP statute and reflected in the WRP regulation at 7 CFR part 1467.4. Proposals must conform to the WRP guidelines for restoration and management of lands subject to a WRP easement.

Benefits to the partners in WREP agreements include:

- Involvement in wetland restorations in high priority MRBI focus areas;
- Ability to cost-share restoration or enhancement components beyond those required by NRCS;
- Ability to participate in management or monitoring of selected project locations; and
- Opportunity to utilize innovative restoration methods and practices.

Land Eligibility

The land eligibility criteria for WREP are the same as for WRP and are listed in 7 CFR § 1467.4.

Proposal Requirements

For consideration, the proposal must be in the following format and contain the information set forth below.

(1) *Proposal Cover and Summary.* The first few pages of the proposal must include—

- (a) Project Title.
- (b) Project Director/Manager name, telephone, and mailing and email address.
- (c) Name and contact information for lead partner submitting proposal and other collaborating partners.
- (d) Short general summary of project, including:
 - (i) Potential acres to be enrolled in the project area,
 - (ii) Designated 12-digit watershed(s) where the project is located, including the State(s), and county(s). Include a general location map,
 - (iii) Proposed project start and end dates that do not exceed 4 consecutive years including FY 2011,
 - (iv) The project objectives and resource concerns to be addressed, and
 - (v) Total amount of financial assistance being requested.

(2) *Project Natural Resource Objectives and Actions.* The proposal must—

- (a) Identify and provide detail about the wildlife and water quality concerns to be addressed and how the proposal's objectives will address those concerns. Objectives should be specific, measurable, achievable, results-oriented, and include a timeline for completion.
- (b) For each objective, identify the actions to be completed to achieve that objective and address the identified natural resource concern. Specify which

actions are to be addressed through this project using WREP assistance, and which are being addressed through alternate non-Federal funding sources or other resources provided.

(c) Identify the total acres that require wetland protection, restoration, and enhancement.

(3) *Detailed Project Description.* Information provided in the proposal must include—

(a) A description of the partner(s) history of working cooperatively with landowners on conservation easements.

(b) A description of the watershed characteristics within the designated focus area covered by the proposal including a detailed watershed map that indicates the project location. The description should include information related to land use types, vegetation, soils, hydrology, potential sources of water quality impairments, occurrences of at-risk species, proximity to other protected areas, and a summary of resource concerns. Proposals should state whether a MRBI-WREP proposal is integrated with a MRBI-CCPI proposed project and include the name of the proposed project.

(c) A description of the partner(s) and the roles, responsibilities, and capabilities of the partner(s). Proposals which include resources from partners other than the lead partner must include a letter or other documentation confirming the commitment of resources.

(d) A description of the project duration, plan of action, and project implementation schedule. Project proposals cannot exceed 4 years.

(e) A description of the financial assistance resources that are requested through WREP, and the non-Federal resources provided by the partner(s) that will be leveraged by the Federal contribution. WREP requires partners to contribute a match of:

- (i) In-kind only contributions of at least 20 percent of the restoration costs,
- (ii) Cash only contributions of at least 5 percent of the restoration costs, or
- (iii) A combination of in-kind and cash contributions of at least 20 percent of the restoration costs.

Proposals which include additional partner resources will be given additional consideration in the selection process. Contributions provided by the partners to achieve additional ranking points can be in the form of technical or financial assistance for the protection, restoration, and enhancement of the wetland. Contributions can also be in the form of assistance with management and monitoring activities. Contributions above the match requirement can be cash or in-kind equipment or services.

Partners may provide incentives to landowners to participate in WREP; however, incentive payments will not be considered part of the match requirement. Incentives include sign-up bonuses, practice incentive payments, or similar activities not funded through WRP.

(f) Total budget for the project including all partner resources which will be leveraged for the project and the amount of WREP financial assistance being requested for project broken out by fiscal year with totals. Include a description of the amount of funds needed annually for easement acquisition and wetland restoration and enhancement activities.

(g) A description of non-Federal resources that will be available for implementation of the proposal. Proposals which include additional non-Federal resources will be given higher consideration in the selection process. The partner needs to state clearly how they intend to leverage Federal funds along with partner resources. Landowner contributions in the implementation of agreed-to wetland restoration and enhancement practices may not be considered any part of a match from the potential partner for purposes of WREP. Partners will also be required to submit a plan for monitoring, evaluating, and reporting progress made toward achieving the objectives of the agreement.

(h) An estimate of the percentage of potential landowners, or estimate of the percentage of acres likely to be enrolled within the project area, compared to the total number of potential landowners or acres located in the project area. A statement on how the partner will encourage participation to guarantee success of the project. It is not necessary for a target area to involve multiple landowners to be selected. Projects will be evaluated based on the ecological merits of the proposal and contributions by the partners.

(i) A statement describing how the partner will provide outreach, especially to encourage participation by Indian tribes, beginning farmers or ranchers, socially disadvantaged farmers or ranchers, and limited resource farmers or ranchers.

(j) A description of the wetland protection, restoration, and enhancement activities to be implemented during the project timeframe, and the general sequence of implementation of the project. Activities may include those efforts undertaken by the partner and those that the partner requests NRCS to address through financial support.

National Ranking Considerations

The appropriate State Conservationist will evaluate proposals using a competitive process and forward recommended proposals to the Chief for review and selection. The Chief will give a higher priority to proposals that:

- (a) Have a high potential to achieve wetland restoration;
- (b) Have a high potential to significantly improve water quality;
- (c) Have a high potential to significantly improve wildlife habitat;
- (d) Significantly leverage non-Federal financial and technical resources and coordinate with other local, State, tribal, or Federal efforts;
- (e) Demonstrate the partner's history of working cooperatively with landowners on conservation easements;
- (f) Provide innovation in wetland protection, restoration, and enhancement methods and outcome-based performance measures and methods;
- (g) Provide evidence that wetland restoration and enhancement activities will be completed within 2 years of easement closing;
- (h) Provide for monitoring and evaluation of the effectiveness of the restoration activities on water quality;
- (i) Provide for matching financial or technical assistance funds to assist landowners with the implementation of the Wetlands Reserve Plan of Operations and associated contracts;
- (j) Facilitate the submission of landowner applications;
- (k) Provide for outreach to, and participation of, Indian tribes, beginning farmers or ranchers, socially disadvantaged farmers or ranchers, and limited resource farmers or ranchers within the area covered by the agreement; and
- (l) Integrate a MRBI-WREP proposal with a MRBI-CCPI proposed or approved project.

Partnership Agreements

Upon proposal selection, NRCS will enter an agreement with a partner as the mechanism for partner participation in WREP. At a minimum, the agreement will address:

- (a) The role of the partner;
- (b) The role of NRCS;
- (c) The format and frequency of reports that is required as a condition of the agreement;
- (d) The Plan of Work and budget to identify other funding sources (if applicable) for financial or technical assistance;
- (e) The specified project schedule and timeframe;
- (f) Whether the agreement will serve as an obligating document or whether

funds will be obligated under a separate agreement with the partner or with a third party; and

(g) Other requirements deemed necessary by NRCS to achieve purposes of the WRP.

Landowner Application

Landowners must meet the eligibility requirements of WRP, as published in 7 CFR part 1467. Landowners interested in participating may apply for designated WREP funds at their local service center after WREP proposals are selected. In FY 2011, NRCS will make WREP funds available to eligible landowners to enroll land under a permanent easement, a 30-year easement, a 30-year contract on acreage owned by Indian tribes, or through a Restoration Agreement.

NRCS and the partner may assist landowners in determining whether the application is appropriate for WREP depending on the wetland protection, restoration, and enhancement activities that the applicant seeks to install or perform.

Signed the 20th day of November, 2010, in Washington, DC.

Dave White,

Vice President, Commodity Credit Corporation and Chief, Natural Resources Conservation Service.

[FR Doc. 2010-29958 Filed 11-26-10; 8:45 am]

BILLING CODE 3410-16-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-549-502]

Circular Welded Carbon Steel Pipes and Tubes from Thailand: Amended Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 29, 2010.

FOR FURTHER INFORMATION CONTACT:

Myrna Lobo, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482-2371.

SUPPLEMENTARY INFORMATION: On October 13, 2010, the Department of Commerce (the Department) completed the final results of administrative review of the antidumping duty order on circular welded carbon steel pipes and tubes (pipes and tubes) from Thailand,

covering the period March 1, 2008 through February 28, 2009. The final results were subsequently released to all parties in the proceeding, and published in the **Federal Register** on October 20, 2010. See *Circular Welded Carbon Steel Pipes and Tubes From Thailand: Final Results of Antidumping Duty Administrative Review*, 75 FR 64696 (October 20, 2010).

The Department disclosed the calculations in connection with the final results as required under 19 CFR 351.224(b). On October 20, 2010, pursuant to 19 CFR 351.224(c)(2), we received a timely filed allegation from the respondent in this administrative review, Saha Thai Steel Pipe (Public) Company, Limited (Saha Thai), that the Department made a ministerial error with respect to the calculation of Saha Thai's dumping margin. See Letter from Saha Thai to the Department of Commerce, regarding "Ministerial Error in Final Results," dated October 20, 2010. For further details, see Memorandum from Myrna Lobo, Case Analyst, and Heidi Schriefer, Senior Accountant, to Barbara E. Tillman, Director, titled, "Ministerial Error Allegation—Final Results of the Antidumping Duty Administrative Review of Circular Welded Carbon Steel Pipes and Tubes from Thailand: Saha Thai Steel Pipe (Public) Company Ltd.," dated November 19, 2010 (*Ministerial Error Allegation Memorandum*). We did not receive comments on this allegation from any other interested parties.

A ministerial error, as defined at section 751(h) of the Tariff Act of 1930, as amended (the Act), includes "errors in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other type of unintentional error which the Department considers ministerial." See also 19 CFR 351.224(f). In its letter, Saha Thai alleges that the Department made a ministerial error by using Saha Thai's 2008 selling and administrative expenses to calculate Saha Thai's 2007 general and administrative (G&A) expense ratio. As stated in the final cost calculation memorandum accompanying the *Final Results*, we calculated the fiscal year 2007 G&A expense rate to use in the calculation of cost of production and constructed value for products with dates of sale prior to the POR (*i.e.*, the pre-POR quarters). See Memorandum from Heidi K. Schriefer, Senior Accountant to Neal M. Halper, Director, Office of Accounting "Cost of Production and Constructed Value Calculation Adjustments for the Final Results—Saha Thai Steel Pipe (Public) Company, Ltd.

("Saha Thai") dated October 13, 2010. The Department agrees that this constitutes a ministerial error within the meaning of section 751(h) of the Act and 19 CFR 351.224(f) because it inadvertently used the 2008 figure instead of the 2007 figure to calculate

the 2007 G&A expense ratio. Therefore, the Department has corrected this expense ratio and revised its margin calculations to reflect this correction. See *Ministerial Error Allegation Memorandum* at 2.

In accordance with section 751(h) of the Act and 19 CFR 351.224(e), we are

amending the final results in this antidumping duty administrative review of pipes and tubes from Thailand. As a result of correcting the ministerial error, the amended final weighted-average dumping margin is as follows:

Manufacturer/exporter	Final results weighted-average margin percentage	Amended final results weighted-average margin percentage
Saha Thai Steel Pipe (Public) Co. Ltd.	2.13 percent	1.76 percent

Assessment Rates

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. Pursuant to 19 CFR 351.212(b)(1), the Department calculates an assessment rate for each importer of the subject merchandise. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of these amended final results of review.

The Department clarified its "automatic assessment" regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the period of review produced by the company included in these amended final results of review for which the reviewed company 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 from the investigation if there is no rate for the intermediate company involved in the transaction. For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the amended final results of this administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these amended final results, as provided by section 751(a)(2)(C) of the Act: (1) For the company covered by this review, the cash deposit rate will be the rate listed above; (2) for merchandise exported by producers or exporters not covered in this review but covered in a previous segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published in the most recent final

results in which that producer or exporter participated; (3) if the exporter is not a firm covered in this review or in any previous segment of this proceeding, but the producer is, the cash deposit rate will be that established for the producer of the merchandise in these final results of review or in the most recent final results in which that producer participated; and (4) if neither the exporter nor the producer is a firm covered in this review or in any previous segment of this proceeding, the cash deposit rate will be 15.67 percent, the all-others rate established in the less than fair value investigation. See *Circular Welded Carbon Steel Pipes and Tubes From Thailand: Final Determination of Sales at Less Than Fair Value*, 51 FR 3384 (January 27, 1986):

Notification of Interested Parties

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 the antidumping duties occurred and the subsequent assessment of double antidumping duties.

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/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 that is subject to sanction.

We are issuing and publishing these amended final results of review and notice in accordance with sections 751(a), 751(h), and 777(i) of the Act, and 19 CFR 351.224(e).

Dated: November 19, 2010.

Ronald K. Lorentzen,
Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010-29962 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Application(s) for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, as amended by Pub. L. 106-36; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be postmarked on or before December 20, 2010. Address written comments to Statutory Import Programs Staff, Room 3720, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 a.m. and 5 p.m. at the U.S. Department of Commerce in Room 3720.

Docket Number: 10-065. *Applicant:* Vanderbilt University, 2201 West End Avenue, Nashville, TN 37235. *Instrument:* Electron Microscope. *Manufacturer:* FEI Company, Czech Republic. *Intended Use:* The instrument will be used to support general biological investigations into structure function relationships. Key capabilities of the instrument include extended

variable pressure capability, low kV and Schottky field emission source, secondary and backscatter detection, and a temperature control Peltier stage. **Justification for Duty-Free Entry:** There are no instruments of the same general category manufactured in the United States. **Application accepted by Commissioner of Customs:** October 27, 2010.

Docket Number: 10-066. **Applicant:** Vanderbilt University, 2201 West End Avenue, Nashville, TN 37235.

Instrument: Electron Microscope.

Manufacturer: JEOL Limited, Japan.

Intended Use: The instrument will be used to study cement-based composites, environmental materials, and geological samples for their microstructure, phase characteristics, and interfacial processes. This instrument can image and analyze samples that are completely wet while carrying the humidity and pressure in the specimen chamber. This instrument also offers a WetSTEM detector for imaging completely wet samples in both bright field (BF) and dark field (DF) modes without special sample handling/encapsulation.

Justification for Duty-Free Entry: There are no instruments of the same general category manufactured in the United States. **Application accepted by Commissioner of Customs:** October 27, 2010.

Dated: November 22, 2010.

Gregory Campbell,

Acting Director, IA Subsidies Enforcement Office.

[FR Doc. 2010-29967 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-405-803]

Purified Carboxymethylcellulose From Finland; Notice of Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On August 9, 2010, the Department of Commerce (the Department) published in the **Federal Register** the preliminary results of the administrative review of the antidumping duty order on purified carboxymethylcellulose from Finland. See *Purified Carboxymethylcellulose from Finland; Notice of Preliminary Results of Antidumping Duty Administrative Review*, 75 FR 47788 (August 9, 2010) (*Preliminary Results*).

We gave interested parties an opportunity to comment on the *Preliminary Results* and received no comments.

DATES: *Effective Date:* November 29, 2010.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold, or Robert James, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482-1121 or (202) 482-0649, respectively

SUPPLEMENTARY INFORMATION:

Background

On August 9, 2010, the Department published the preliminary results of administrative review of the antidumping duty order covering purified carboxymethylcellulose from Finland. See *Preliminary Results*. The parties subject to this review are CP Kelco Oy and CP Kelco U.S., Inc. (collectively, CP Kelco). The petitioner in this proceeding is the Aqualon Company, a division of Hercules Incorporated (Petitioner).

In the *Preliminary Results*, the Department stated that interested parties may submit case briefs within 30 days of publication of the *Preliminary Results* and rebuttal briefs within five days after the due date for filing case briefs. See *Preliminary Results* at 47794. No interested party submitted a case or rebuttal brief. Accordingly, we made no changes for the final results. See Memorandum from Tyler Weinhold, to the File, "Analysis of Data Submitted by CP Kelco Oy and CP Kelco U.S. Inc. (collectively, CP Kelco) in the *Preliminary Results* of the 2008-2009 Administrative Review of Purified Carboxymethylcellulose (CMC) from Finland," dated August 2, 2010; Memorandum from Tyler Weinhold, to the File, "Analysis of Data Submitted by CP Kelco Oy and CP Kelco U.S. Inc. (collectively, CP Kelco) in the 2008-2009 Administrative Review of Purified Carboxymethylcellulose (CMC) from Finland," and Memorandum from Sheikh M. Hannan, to the File, "Cost of Production and Constructed Value Calculation Adjustments for the *Preliminary Results*—CP Kelco Oy."

Period of Review

The period of review (POR) is July 1, 2008, through June 30, 2009.

Scope of the Order

The merchandise covered by this order is all purified carboxymethylcellulose (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 this order is 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.

Final Results of Review

The Department has determined that the following margin exists for the period July 1, 2008, through June 30, 2009:

Manufacturer	Weighted-average margin (percentage)
CP Kelco Oy	- 6.10

Assessment Rates

Pursuant to these final results, the Department has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions for CP Kelco to CBP 15 days after the date of publication of these final results. Pursuant to 19 CFR 351.212(b)(1), we calculated importer-specific (or customer-specific) *ad valorem* duty assessment rates based on the ratio of the total amount of the dumping margins calculated for the examined sales to the total entered value of those same sales. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific (or customer-specific) assessment rate calculated in the final results of this review are above *de minimis*.

The Department clarified its "automatic assessment" regulation on May 6, 2003. See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003) (*Assessment of Antidumping Duties*). This clarification will apply to entries of subject

merchandise during the POR produced by CP Kelco for which CP Kelco did not know the merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate un-reviewed entries at the 6.65 percent all-others rate from the LTFV investigation if there is no company-specific rate for an intermediary involved in the transaction. See *Notice of Antidumping Duty Orders: Purified Carboxymethylcellulose from Finland, Mexico, the Netherlands and Sweden*, 70 FR 39734 (July 11, 2005). See *Assessment of Antidumping Duties* for a full discussion of this clarification.

Cash Deposit Requirements

Furthermore, the following cash deposit requirements will be effective upon publication of these final results for all shipments of purified carboxymethylcellulose from Finland entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Tariff Act of 1930, as amended (the Act): (1) The cash deposit rate for CP Kelco will be the rate established in the final results of review; (2) if the exporter is not a firm covered in this review or 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 the merchandise; and (3) if neither the exporter nor the manufacturer is a firm covered in this or any previous review conducted by the Department, the cash deposit rate will be the all-others rate from the LTFV investigation. *Id.* These 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) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (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) of the Act.

Dated: November 15, 2010.

Ronald K. Lorentzen,
Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010-29961 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("the Department") has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews.

DATES: *Effective Date:* November 29, 2010.

FOR FURTHER INFORMATION CONTACT: Sheila E. Forbes, Office of AD/CVD Operations, Customs Unit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482-4697.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting date.

Notice of No Sales

Under 19 CFR 351.213(d)(3), the Department may rescind a review where

there are no exports, sales, or entries of subject merchandise during the respective period of review ("POR") listed below. If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the POR, it must notify the Department within 60 days of publication of this notice in the **Federal Register**. The Department will consider rescinding the review only if the producer or exporter, as appropriate, submits a properly filed and timely statement certifying that it had no exports, sales, or entries of subject merchandise during the period of review. All submissions must be made in accordance with 19 CFR 351.303 and are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended ("the Act"). Six copies of the submission should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room 1870, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230. Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy of each request must be served on every party on the Department's service list.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews, the Department intends to select respondents based on U.S. Customs and Border Protection ("CBP") data for U.S. imports during the period of review ("POR"). We intend to release the CBP data under Administrative Protective Order ("APO") to all parties having an APO within seven days of publication of this initiation notice and to make our decision regarding respondent selection within 21 days of publication of this **Federal Register** notice. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the applicable review.

Separate Rates

In proceedings involving non-market economy ("NME") countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China*, 56 FR 20588 (May 6, 1991), as amplified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China*, 59 FR 22585 (May 2, 1994). In accordance with the separate-rates criteria, the Department assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate-rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate-rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate-rate eligibility, the Department requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The

Separate Rate Certification form will be available on the Department's Web site at <http://www.trade.gov/ia> on the date of publication of this **Federal Register**. In responding to the certification, please follow the "Instructions for Filing the Certification" in the Separate Rate Certification. Separate Rate Certifications are due to the Department no later than 60 days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding¹ should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,² should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on the Department's Web site at <http://>

www.trade.gov/ia on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to the Department no later than 60 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate-rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with section 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than October 31, 2011.

	Period to be reviewed
Antidumping Duty Proceedings	
Mexico: Carbon and Certain Alloy Steel Wire Rod A-201-830	10/1/09-9/30/10.
Aceros San Luis S.A. de C.V. Altos Hornos de Mexico S.A. de C.V. Arcelor Mittal Las Truchas, S.A. de C.V. DeAcero de C.V. Siderurgica Lazaro Cadenas Las Truchas S.A. de C.V. (SICARTSA). Talleres y Aceros S.A. de C.V. Ternium Mexico S.A. de C.V. (formerly known as Hylsa S.A. de C.V. and Hylsa Puebla S.A. de C.V. (Hylsa))	
The People's Republic of China: Kitchen Appliance Shelving and Racks ^{3,4} A-570-941	3/5/09-8/31/10.
Asia Pacific CIS (Wuxi) Co., Ltd. Hengtong Hardware Manufacturing (Huizhou) Co., Ltd.	
The People's Republic of China: Steel Wire Garment Hangers ⁵ A-570-918	10/1/09-9/30/10.
Angang Clothes Rack Manufacture Company Limited. Bazhou Sanqiang Furniture Co., Ltd. Bestallied International Corp. Bestluck Enterprise Limited. Blue Mountain Imp Exp Co Ltd. Bon Voyage Logistics Inc. Butler Courtesy (Guilin) Inc. C Import and Export (Hong Kong) Co., Ltd. Century Distribution System (Shenzhen) Ltd. Changzhou Fortune Handicraft Co., Ltd. Changzhou MC Imp. & Exp. Co. Ltd. a/k/a Changzhou MC IE Co., Ltd. China Fujian Minhou Shenghua Handicrafts Co., Ltd. China Ningbo Wahfay Industrial (Group) Co., Ltd. CTN Limited Company	

¹ Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceedings (e.g., an ongoing administrative review, new

shipper review, etc.) and entities that lost their separate rate in the most recently complete segment of the proceeding in which they participated.

² Only changes to the official company name, rather than trade names, need to be addressed via

a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Application.

Period to be
reviewed

CTO International Co. Ltd.
 Eagle Brand Holdings Limited.
 Ecocom Crafts Co., Ltd. a/k/a Hangzhou Ecocom Crafts Co., Ltd.
 Eisho Co., Ltd. a/k/a Eisho Hanger Co., Ltd.
 Fujian Pucheng Breese Home Products, Inc.
 Good Wonder Limited.
 Guangdong Machinery Imp. & Exp. Co.
 Guangdong Provincial Taoyue Mfg. Co., Ltd.
 Guangxi Yikai Industry and Trade Co., Ltd.
 Guangzhou Haojin Motorcycle Company
 Guangzhou Zhoucheng Plastic Co., Ltd.
 Guilin Betterall Household Articles Co., Ltd.
 Guilin Harvest Co., Ltd.
 Guilin Jinlai Imp. & Exp. Co., Ltd.
 Guilin Yusense Home Collection Co., Ltd.
 Haimen Jinhang Business Trading Co.
 Haiyan Lianxiang Hardware Products Co.
 Hangzhou Dunli Import & Export Co.
 Hanji Metals and Plastics Crafts Co.
 HD Supply Shenzhen.
 Hezhou City Yaolong Trade Co Ltd.
 Jiahe International Trading Co.
 Jiangmen Masters Hardware Products.
 Jiangsu Y and S Inc.
 Jiangyin Hongji Metal Products Co., Ltd.
 Jiaying Boyi Medical Device Co.
 K.O.D Solutions Limited Dongguan Office.
 Kingtex Imp & Exp Co., Ltd.
 Laidlaw Company LLC.
 Mainfreight Int'l Logistics (Shanghai) Co. Ltd.
 Maxplus Industries Co., Ltd.
 Nanjing Feisike Import & Export Trading Co. Ltd.
 Ningbo Beilun Huafa Metal Products
 Ningbo Dasheng Hanger Ind. Co., Ltd.
 Ningbo Everun International Limited.
 Ningbo First Rank International Co.
 Ningbo Home-Dollar Imp. & Exp. Corp.
 Ningbo Hongdi Measuring Tape Co., Ltd.
 Ningbo Municipal Xinyu Imp. & Exp. Co.
 Ningbo Wellway Imp. & Exp. Co., Ltd.
 Overseas Int'l Group Corp.
 Plastic Intercon Co., Ltd.
 Pujiang County Command Metal Products Co., Ltd.
 Quiky Yanglei International Co., Ltd. a/k/a Quiky Group.
 Shandong Autjinrong Found-assembly Co., Ltd.
 Shanghai Cheertie Display Fixture.
 Shanghai Electric Imp. & Exp. Co., Ltd.
 Shanghai Hua Yue Packaging Products
 Shanghai International Trade Transportation Co., Ltd.
 Shanghai International Trade Yee Da Imp. & Ex. Co., Ltd.
 Shanghai New Union Textra Import & Export Co., Ltd.
 Shanghai Overseas Enterprises Co. Ltd.
 Shanghai Textile Raw Materials.
 Shanghai Wells Hanger Co., Ltd.
 Shanghai Wintex Import & Export Co., Ltd.
 Shangyu Baoxiang Metal Manufactured Co., Ltd.
 Shaoxing Amazon Prime Trade Co., Ltd.
 Shaoxing Andrew Metal Manufactured.
 Shaoxing Dingli Metal Clotheshorse Co., Ltd.
 Shaoxing Gangyuan Metal Manufacture.
 Shaoxing Guochao Metallic Products Co., Ltd.
 Shaoxing Kinglaw Metal Products Co., Ltd.
 Shaoxing Liangbao Metal Manufactured Co., Ltd.
 Shaoxing Meideli Metal Hanger Co., Ltd.
 Shaoxing Shunji Metal Clotheshorse Co., Ltd.
 Shaoxing Tongzhou Metal Manufactured Co., Ltd.
 Shaoxing Zhongbao Metal Manufactured Co., Ltd.
 Shenzhen He Zhenglong Imp. & Exp. Co. Ltd., a/k/a Shenzhen He Zhong Long Impx
 Shenzhen SED Industry Co., Ltd. a/k/a Shenzhen Sed Electronics Co.
 Sunny Metal Inc.
 Taishan Jinji Hangers Co., Ltd.
 Taizhou Huasheng Wooden Co., Ltd.
 Tianjin Tailai Imp & Exp Co., Ltd.

	Period to be reviewed
Transtek Automotive Products Co. Ltd. Tri-star Trading Co. Uasha Group International Shanghai Ltd. Universal Houseware (Dongguan) Wenzhou N. & A. Foreign Trade Corp. Wenzhou Pan Pacific Foreign Trade Co., Ltd. Wesken International (Kunshan) Co., Ltd. World Trading Service Limited. X&Y Papa-Fix Industry Limited. Yiwu Ao-Si Metal Products Co., Ltd. Zhangjiagang Maohua Coating & Adorn Zhejiang Arts and Crafts Import. Zhejiang Huamao International Co., Ltd. Zhejiang Lucky Cloud Hanger Co., Ltd. Zhejiang Wenzhou Packaging Imp. & Exp.	
Countervailing Duty Proceedings	
The People's Republic of China: Kitchen Appliance Shelving and Racks ⁶ C-570-942	1/7/09-12/31/09
Asia Pacific CIS (Wuxi) Co., Ltd. Hengtong Hardware Manufacturing (Huizhou) Co., Ltd.	
Suspension Agreements	
None.	

³ If one of the above named companies does not qualify for a separate rate, all other exporters of Kitchen Appliance Shelving and Racks from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

⁴ In the notice of initiation for September anniversary cases, published in the *Federal Register* on October 28, 2008 (75 FR 66349) and corrected on November 10, 2010 (75 FR 69054), the Department postponed initiation of five companies. We have determined to initiate on two of the companies (listed above). Regarding the three additional companies, the Department does not conduct administrative reviews to investigate transshipment allegations. See *Globe Metallurgical Inc. v. United States*, Slip Op. 10-100 (Ct. Int'l Trade Sept. 1, 2010). Petitioners (SSW Holding Company, Inc. and Nashville Wire Products, Inc.) have not provided any reason, other than potential transshipment of subject merchandise, for requesting a review of these three additional companies. Therefore, we are not initiating a review with respect to the following companies: Asia Pacific CIS (Thailand) Co., Ltd.; Taiwan Rail Company; and King Shan Wire Co., Ltd.

⁵ If one of the above-named companies does not qualify for a separate rate, all other exporters of Steel Wire Garment Hangers from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporter is a part.

⁶ In the notice of initiation for September anniversary cases, published in the *Federal Register* on October 28, 2008 (75 FR 66349) and corrected on November 10, 2010 (75 FR 69054), the Department postponed initiation of five companies. We have determined to initiate on two of the companies (listed above). Regarding the three additional companies, the Department does not conduct administrative reviews to investigate transshipment allegations. See *Globe Metallurgical Inc. v. United States*, Slip Op. 10-100 (Ct. Int'l Trade Sept. 1, 2010). Petitioners (SSW Holding Company, Inc. and Nashville Wire Products, Inc.) have not provided any reason, other than potential transshipment of subject merchandise, for requesting a review of these three additional companies. Therefore, we are not initiating a review with respect to the following companies: Asia

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under section 351.211 or a determination under section 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistent with *FAG Italia v. United States*, 291 F.3d 806 (Fed Cir. 2002), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures "gap" period, of the order, if such a gap period is applicable for the POR.

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings*:

Pacific CIS (Thailand) Co., Ltd.; Taiwan Rail Company; and King Shan Wire Co., Ltd.

Documents Submission Procedures; APO Procedures, 73 FR 3634 (January 22, 2008). Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (e.g., the filing of separate letters of appearance as discussed in 19 CFR 351.103(d)).

These initiations and this notice are in accordance with section 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)), and 19 CFR 351.221(c)(1)(i).

Dated: November 22, 2010.

Susan H. Kuhnach,
Acting Deputy Assistant Secretary for
Antidumping and Countervailing Duty
Operations.

[FR Doc. 2010-29970 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Renewable Energy and Energy Efficiency Advisory Committee (RE&EEAC)

November 22, 2010.

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of Open Meeting; Correction.

SUMMARY: The U.S. Department of Commerce published a document in the *Federal Register* of November 17, 2010 concerning a notification of an open

meeting of the Renewable Energy and Energy Efficiency Advisory Committee (RE&EEAC) on December 7, 2010. The document contained an incorrect e-mail address and an incorrect mailing address.

FOR FURTHER INFORMATION CONTACT:
Brian O'Hanlon, 202-482-3492.

Correction

In the *Federal Register* of November 17, 2010, in FR Doc. 75-70214 on page 70214 in the second column, correct the e-mail listed under "FOR FURTHER INFORMATION CONTACT" header to read:

FOR FURTHER INFORMATION CONTACT:
Brian O'Hanlon, Office of Energy and Environmental Industries, International Trade Administration, U.S. Department of Commerce at (202) 482-3492; e-mail: brian.ohanlon@trade.gov. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482-5225.

Correction

In the *Federal Register* of November 17, 2010, in FR Doc. 75-70214 on page 70214 in the third column, correct the address "Public Participation" to read:

Public Participation: The meeting is open to the public and the room is disabled-accessible. Public seating is limited and available on a first-come, first-served basis. Members of the public wishing to attend the meeting must notify Brian O'Hanlon at the contact information above by 5 p.m. EST on Thursday, December 2, in order to pre-register for clearance into the building. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted, but may be impossible to fill. A limited amount of time, from 3 p.m.-3:30 p.m., will be available for pertinent brief oral comments from members of the public attending the meeting.

Any member of the public may submit pertinent written comments concerning the RE&EEAC's affairs at any time before or after the meeting. Comments may be submitted to the Renewable Energy and Energy Efficiency Advisory Committee, C/O: Brian O'Hanlon, Office of Energy and Environmental Technologies, U.S. Department of Commerce, Mail Stop: 4053, 1401 Constitution Avenue, NW., Washington, DC 20230. To be considered during the meeting, written comments must be received no later than 5 p.m. EST on Thursday, December 2, 2010, to ensure transmission to the Committee prior to the meeting.

Comments received after that date will be distributed to the members but may not be considered at the meeting.

Edward A. O'Malley,
Director, Office of Energy and Environmental Industries.

[FR Doc. 2010-29882 Filed 11-26-10; 8:45 am]
BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-894]

Certain Tissue Paper Products From the People's Republic of China: Notice of Partial Rescission and Extension of Time Limit for Preliminary Results of 2009-2010 Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (the Department) is rescinding in part the administrative review of the antidumping duty order on certain tissue paper products from the People's Republic of China (PRC) for the period of review (POR) of March 1, 2009, to February 28, 2010, with respect to Max Fortune Industrial Limited (Max Fortune Industrial), Max Fortune (FZ) Paper Products Co., Ltd. (formerly known as Max Fortune (FETDE) Paper Products Co., Ltd.) (Max Fortune Fuzhou), and Fujian Provincial Shaowu City Huaguang Special Craft Co., Ltd. (Huaguang Special Craft). This partial rescission is based on the timely withdrawal of the requests for review by the only interested parties that requested the review of these companies. The Department is also fully extending the time limit for completion of the preliminary results of this administrative review with respect to Max Fortune (Vietnam) Paper Products Company Limited (Max Fortune Vietnam) to no later than March 31, 2011.

DATES: *Effective Date:* November 29, 2010.

FOR FURTHER INFORMATION CONTACT:
Brian Smith or Gemal Brangman, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482-1766 or (202) 482-3773, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2010, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on certain tissue paper products from the PRC. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 75 FR 9162 (March 1, 2010). In response, on March 31, 2010, the petitioner¹ timely requested an administrative review of the antidumping duty order on certain tissue paper products from the PRC for entries of the subject merchandise during the POR, from Max Fortune Industrial, Max Fortune Fuzhou, and Max Fortune Vietnam (*i.e.*, exporters of the subject merchandise). Similarly, in a letter dated March 31, 2010, Huaguang Special Craft (*i.e.*, an exporter of the subject merchandise) submitted a timely request for an administrative review of its entries of the subject merchandise during the POR. Therefore, on April 19, 2010, the Department initiated a review of Max Fortune Industrial, Max Fortune Fuzhou, Max Fortune Vietnam, and Huaguang Special Craft. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 75 FR 22107 (April 27, 2010).

In a letter dated July 6, 2010, Huaguang Special Craft informed the Department that it had withdrawn from this review and would no longer be participating in this segment of the proceeding. In a letter dated July 26, 2010, the petitioner withdrew its request for review of Max Fortune Industrial and Max Fortune Fuzhou, and requested that the Department rescind the review with respect to these companies. No other parties requested a review of Max Fortune Industrial, Max Fortune Fuzhou, or Huaguang Special Craft. The request for review of Max Fortune Vietnam was not withdrawn, and therefore, this administrative review will continue with respect to that company to examine its claim that it did not use PRC jumbo rolls or sheets of tissue paper in its shipments of tissue paper to the United States during the period of review. Max Fortune Vietnam is also a respondent in an ongoing anticircumvention inquiry and the Department intends to conduct verification of the above-mentioned claim in the context of that segment (see discussion below).

On March 29, 2010, the Department also initiated a circumvention inquiry on certain imports of tissue paper from

¹ The petitioner is Seaman Paper Company of Massachusetts, Inc.

Vietnam. See *Certain Tissue Paper Products from the People's Republic of China: Initiation of Anti-circumvention Inquiry*, 75 FR 17127 (April 5, 2010) (Initiation). In the Initiation notice, the Department stated that it would focus its analysis on the significance of the production process in Vietnam by Max Fortune Vietnam, the company the petitioner identified in its circumvention request (which is the same company on which the Department initiated an administrative review). In its June 28, 2010, response to the Department's April 23, 2010, questionnaire in the anticircumvention inquiry, Max Fortune Vietnam claimed that it did not export tissue paper to the United States produced from jumbo rolls imported from the PRC since January 2008. Likewise, in its August 17, 2010, response to the Department's May 7, 2010, questionnaire, in this review, Max Fortune Vietnam claimed that it did not export subject merchandise from the PRC or Vietnam.

Rescission, in Part, of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. Accordingly, the petitioner timely withdrew its request for review of Max Fortune Industrial and Max Fortune Fuzhou. In addition, Huaguang Special Craft withdrew its own request for review within the 90-day period. Because no other party requested a review of these companies' entries, we are rescinding this administrative review with respect to these companies in accordance with 19 CFR 351.213(d)(1).

Extension of Time Limits for Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to issue the preliminary results of an administrative review within 245 days after the last day of the anniversary month of the date of publication of an order for which a review is requested. If it is not practicable to complete the review within this time period, section 751(a)(3)(A) of the Act allows the Department to extend this deadline to a maximum of 365 days.

As noted above, Max Fortune Vietnam claimed that it made no shipments from Vietnam of tissue paper made from PRC-origin jumbo rolls or sheets to the U.S. market during the POR. Data on the record does indicate, however, that Max

Fortune Vietnam has exported tissue paper from Vietnam to the U.S. market during the period overlapping the administrative review POR. In response to the Department's questionnaire in the anticircumvention inquiry, Max Fortune Vietnam claimed that it has not exported to the United States tissue paper produced from jumbo rolls imported from the PRC since January 2008. Depending on the Department's finding in the anticircumvention segment, Max Fortune Vietnam may or may not continue to be a respondent in the administrative review. Because the Department intends to conduct verification of Max Fortune Vietnam's claims in the circumvention segment, the results of that verification will directly impact the administrative review segment of this proceeding. The Department, therefore, requires additional time in this review to make a preliminary finding on Max Fortune Vietnam's "no shipment" claim. For this reason, it is not practicable to complete this review within the original time limit. Thus, the Department is fully extending the time limit for completion of the preliminary results by 120 days to 365 days, in accordance with section 751(a)(3)(A) of the Act. The preliminary results are now due no later than March 31, 2011. The final results continue to be due 120 days after publication of the preliminary results.

Assessment

For the companies for which the Department is rescinding this review, the Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Therefore, for Max Fortune Industrial, Max Fortune Fuzhou, and Huaguang Special Craft, antidumping duties shall be assessed, if applicable, at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

Notification to Importers

This notice serves as a 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.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (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 or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is published in accordance with sections 751(a)(3)(A) and 777(i) of the Act, and 19 CFR 351.213(d)(4) and 351.213(h)(2).

Dated: November 19, 2010.

Susan H. Kuhbach,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010-29969 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-967]

Aluminum Extrusions From the People's Republic of China: Postponement of Final Determination of Sales at Less Than Fair Value

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 29, 2010.

FOR FURTHER INFORMATION CONTACT: Paul Stolz or Lori Apodaca, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-4474 and (202) 482-4551, respectively.

Postponement of Final Determination

The Department of Commerce ("Department") initiated the antidumping duty investigation of aluminum extrusions from the People's Republic of China ("PRC") on April 27, 2010.¹ On November 12, 2010, the Department published the *Preliminary*

¹ See *Aluminum Extrusions from the People's Republic of China: Initiation of Antidumping Duty Investigation*, 75 FR 22109 ("Initiation Notice").

Determination in the Federal Register.² The final determination of this antidumping duty investigation is currently due on January 10, 2011.

Section 735(a)(2) of the Tariff Act of 1930 ("the Act") provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by petitioner. In addition, 19 CFR 351.210(e)(2) requires that requests by respondents for postponement of a final determination be accompanied by a request for extension of provisional measures from a four-month period to not more than six months.

On November 1, 2010, Guang Ya Aluminium Industries Co., Ltd., Foshan Guangcheng Aluminium Co., Ltd., Kong Ah International Company Limited, and Guang Ya Aluminium Industries (Hong Kong) Limited, (collectively, "Guang Ya Group"), one of the entities comprising the sole active mandatory respondent in this investigation, requested an extension of the final determination and extension of the provisional measures.³ Thus, because the *Preliminary Determination* is affirmative, the respondent requesting extension of the final determination and extension of the provisional measures accounts for significant proportion of exports of the subject merchandise, and no compelling reasons for denial exist, we are extending the due date for the final determination in this investigation to no later than 135 days after the date of the publication of the preliminary determination.

For the reasons identified above, we are postponing the final determination until March 28, 2011.⁴

² See *Aluminum Extrusions from the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value, and Preliminary Determination of Targeted Dumping*, 75 FR 69403 (November 12, 2010) ("*Preliminary Determination*").

³ See *Aluminum Extrusions from the PRC: Request by Guang Ya Group for an Extension of the Final Determination* (November 1, 2010). See also *Preliminary Determination*, finding that Guang Ya Group, Zhaoqing New Zhongya Aluminium Co., Ltd., Zhongya Shaped Aluminium (HK) Holding Limited and Karlton Aluminium Company Ltd., and Xinya Aluminium & Stainless Steel Product Co., Ltd. should be considered a single entity for purposes of this investigation.

⁴ March 27, 2011, is 135 days after the date of the publication of the preliminary determination. However, because March 27, 2011, is a Sunday, we will postpone the due date to the next business day, Monday, March 28, 2011.

This notice is issued and published pursuant to sections 777(i) and 735(a)(2) of the Act and 19 CFR 351.210(g).

Dated: November 15, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010-29874 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-533-847]

1-Hydroxyethylidene-1, 1-Diphosphonic Acid From India: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a timely request by one manufacturer/exporter, Aquapharm Chemicals Pvt., Ltd. (Aquapharm), the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP) from India with respect to Aquapharm. The review covers the period April 23, 2009, through March 31, 2010. We preliminarily determine that Aquapharm did not make sales below normal value (NV).

If the preliminary results are adopted in our final results of the administrative review, we will issue appropriate assessment instructions to U.S. Customs and Border Protection (CBP).

FOR FURTHER INFORMATION CONTACT: David Goldberger or Brandon Custard, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC, 20230; telephone (202) 482-4136 or (202) 482-1823, respectively.

SUPPLEMENTARY INFORMATION:

Background

In response to a timely request by Aquapharm, on May 28, 2010, the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on HEDP from India with respect to Aquapharm covering the period April 23, 2009, through March 31, 2010. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 75 FR 29976 (May 28, 2010).

On June 11, 2010, we issued the antidumping duty questionnaire to Aquapharm. On July 19, 2010, we received a response to section A (*i.e.*, the section covering general information about the company), and on August 10, 2010, we received responses to sections B (*i.e.*, the section covering comparison-market sales) and C (*i.e.*, the section covering U.S. sales) of the antidumping duty questionnaire from Aquapharm.

On September 15, 2010, we issued to Aquapharm a supplemental questionnaire regarding its responses to sections A, B, and C of the original questionnaire, and received a response to this supplemental questionnaire on September 29, 2010.

Scope of the Order

The merchandise covered by this order includes all grades of aqueous, acidic (non-neutralized) concentrations of 1-hydroxyethylidene-1, 1-diphosphonic acid,¹ also referred to as hydroxyethylidenediphosphonic acid, hydroxyethanediphosphonic acid, acetodiphosphonic acid, and etidronic acid. The CAS (Chemical Abstract Service) registry number for HEDP is 2809-21-4. The merchandise subject to this order is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2931.00.9043. It may also enter under HTSUS subheading 2811.19.6090. While HTSUS subheadings are provided for convenience and customs purposes only, the written description of the scope of this order is dispositive.

Period of Review

The period of review (POR) is April 23, 2009, through March 31, 2010.

Comparisons to Normal Value

To determine whether Aquapharm's sales of HEDP from India to the United States were made at less than NV, we compared the export price (EP) or constructed export price (CEP) to NV, as described in the "Export Price and Constructed Export Price" and "Normal Value" sections of this notice.

Pursuant to section 777A(d)(2) of the Tariff Act of 1930, as amended (the Act), we compared the EPs and CEPs of individual U.S. transactions to the weighted-average NV of the foreign like product where there were sales made in the ordinary course of trade. See discussion below.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced by Aquapharm covered by the

¹ C₂H₅O-P₂ or C(CH₃)(OH)(PO₃H₂).

description in the "Scope of the Order" section, above, to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. Pursuant to 19 CFR 351.414(e)(2), we compared Aquapharm's U.S. sales of HEDP to its sales of HEDP made in the home market. Where there were no contemporaneous sales within the definition of 19 CFR 351.414(e)(2)(i), pursuant to 19 CFR 351.414(e)(2)(ii) and (iii), we compared sales within the contemporaneous window period, which extends from three months prior to the month of the U.S. sale until two months after the sale. In making the product comparisons, we matched foreign like products based on their aqueous concentration. Aquapharm reported that, pursuant to section 771(16)(A) of the Act, all of its U.S. sales during the POR were identical based on the product matching criterion (*i.e.*, aqueous concentration) to contemporaneous sales in the home market. Accordingly, in calculating Aquapharm's NV, we made product comparisons without having to account for cost differences associated with differences in the physical characteristics of the merchandise pursuant to section 773(a)(6)(C)(ii) of the Act.

Export Price and Constructed Export Price

In accordance with section 772(a) of the Act, we calculated EP for those sales where the subject merchandise was sold to the first unaffiliated purchaser in the United States prior to importation and CEP methodology was not otherwise warranted based on the facts of the record. We based EP on the packed delivered price to unaffiliated purchasers in the United States. Where appropriate, pursuant to 19 CFR 351.401(c), we adjusted the starting prices for billing adjustments. We made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act, which included, where appropriate, foreign inland freight from plant to the port of exportation, foreign brokerage and handling, U.S. brokerage and handling, international freight, U.S. inland freight to the customer, marine insurance, and U.S. customs duties (including harbor maintenance fees and merchandise processing fees).

Pursuant to section 772(b) of the Act, we calculated CEP for those sales where the subject merchandise was first sold or agreed to be sold in the United States before or after the date of importation by or for the account of the producer or exporter or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter.

We based CEP on the packed ex-U.S. warehouse prices to unaffiliated purchasers in the United States. Where appropriate, pursuant to 19 CFR 351.401(c), we adjusted the starting prices for billing adjustments. We made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act, which included, where appropriate, foreign inland freight from plant to the port of exportation, foreign brokerage and handling, U.S. brokerage and handling, international freight (inclusive of U.S. port to U.S. warehouse transportation), marine insurance, U.S. customs duties (including harbor maintenance fees and merchandise processing fees), and warehouse expenses. In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.*, credit expenses, commissions, and bank charges), and indirect selling expenses (including inventory carrying costs). We also deducted from CEP an amount for profit in accordance with section 772(d)(3) of the Act. In accordance with sections 772(f)(1) and (2)(C)(iii) of the Act, we calculated the CEP profit percentage using information from Aquapharm's audited financial statement. See Memorandum entitled "Aquapharm Preliminary Results Margin Calculation," dated contemporaneously with this notice, for further discussion of the CEP profit calculation.

Normal Value

A. Home Market Viability and Selection of Comparison Market

To determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV, we compared the volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(C) of the Act. Based on this comparison, we determined that, pursuant to 19 CFR 351.404(b), Aquapharm had a viable home market during the POR. Consequently, pursuant to section 773(a)(1)(B)(i) of the Act and 19 CFR 351.404(c)(i), we based NV on home market sales.

B. Level of Trade

Section 773(a)(1)(B)(i) of the Act states that, to the extent practicable, the Department will calculate NV based on sales of the foreign like product at the same level of trade (LOT) as the EP or CEP. Sales are made at different LOTS

if they are made at different marketing stages (or their equivalent). See 19 CFR 351.412(c)(2). Substantial differences in selling activities are a necessary, but not sufficient condition for determining that there is a difference in the stages of marketing. See *id.*; see also *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From South Africa*, 62 FR 61731, 61732 (November 19, 1997) (*Plate from South Africa*). To determine whether the comparison-market sales were at different stages in the marketing process than the U.S. sales, we reviewed the distribution system in each market (*i.e.*, the chain of distribution), including selling functions, class of customer (customer category), and the level of selling expenses for each type of sale.

Pursuant to section 773(a)(1)(B)(i) of the Act, in identifying LOTS for EP and comparison-market sales (*i.e.*, where NV is based on either home market or third country prices),² we consider the starting prices before any adjustments. For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. See *Micron Technology, Inc. v. United States*, 243 F. 3d 1301, 1314–16 (Fed. Cir. 2001). When the Department is unable to match U.S. sales of the foreign like product in the comparison market at the same LOT as the EP or CEP, the Department may compare the U.S. sales to sales at a different LOT in the comparison market. In comparing EP or CEP sales at a different LOT in the comparison market, where available data make it practicable, we make an LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales only, if the NV LOT is at a more advanced stage of distribution than the LOT of the CEP and there is no basis for determining whether the difference in LOTS between NV and CEP affects price comparability (*i.e.*, no LOT adjustment was practicable), the Department shall grant a CEP offset, as provided in section 773(a)(7)(B) of the Act. See *Plate from South Africa*, 62 FR at 61732–33.

In this administrative review, we obtained information from Aquapharm regarding the marketing stages involved in making its reported home market and U.S. sales, including a description of the selling activities performed by Aquapharm for each channel of distribution.

² Where NV is based on constructed value (CV), we determine the NV LOT based on the LOT of the sales from which we derive selling expenses, general and administrative (G&A) expenses, and profit for CV, where possible.

Aquapharm reported that during the POR it sold HEDP to end-users, distributors, and end-users/distributors through three channels of distribution in the United States, and to end-users and traders through two channels of distribution in the home market.

Aquapharm made CEP sales in the U.S. market through one channel of distribution: sales through an unaffiliated U.S. selling agent to an unaffiliated U.S. distributor of HEDP maintained in inventory at an unaffiliated U.S. warehouse (Channel 1). In addition, Aquapharm made EP sales in the U.S. market through two channels of distribution: Direct sales/shippments to unaffiliated U.S. end-users (Channel 2); and direct sales/shippments to unaffiliated U.S. distributors (Channel 3).

We examined the selling activities performed for the three U.S. sales channels and found that Aquapharm performed the following selling functions for each channel: sales forecasting, order input/processing, direct sales personnel, packing, freight and delivery services, inventory maintenance, technical assistance, warranty service, and after-sales service. These selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery; (3) warehousing and inventory; and (4) warranty and technical support. Accordingly, based on the four selling function categories, we find that Aquapharm performed primarily sales and marketing, freight and delivery services, and warranty and technical services for U.S. sales. Although Aquapharm performed additional freight and delivery functions, (such as repacking) and warehousing functions for its U.S. sales through Channel 1, we did not find these differences to be material selling function distinctions which are significant enough to warrant a separate LOT in the U.S. market. Therefore, we preliminarily determine that there is one LOT in the U.S. market because Aquapharm performed essentially the same selling functions for all U.S. sales.

With respect to the home market, Aquapharm made sales through the following channels of distribution: (1) Sales to unaffiliated end-users (Channel 1); and sales to unaffiliated traders (Channel 2). We examined the selling activities performed for each home market sales channel and found that Aquapharm performed the following selling functions for sales made through both channels: Sales forecasting, order input/processing, advertising, direct sales personnel, sales/marketing

support, market research, packing, freight and delivery services, inventory maintenance, technical assistance, and warranty service. Accordingly, based on the four selling function categories described above, we find that Aquapharm performed primarily sales and marketing, freight and delivery services, and warranty and technical services for home market sales. Moreover, we did not find any significant distinctions between the selling functions Aquapharm performed for each home market channel to warrant a separate LOT in the home market. Therefore, we preliminarily determine that there is one LOT in the home market because Aquapharm performed essentially the same selling functions for all home market sales.

Finally, we compared the U.S. LOT to the home market LOT and found that the selling functions performed for home market sales are either performed at the same degree of intensity as, or vary only slightly from, the selling functions performed for U.S. sales. Specifically, we found that with respect to the four selling function categories, there are only slight differences in the level of intensity between the home and U.S. markets, and have preliminarily determined that these slight differences do not provide a sufficient basis to find separate LOTs between the two markets. Therefore, we find that the single home market LOT and single U.S. LOT are the same and, as a result, no LOT adjustment or CEP offset is warranted. Accordingly, we matched U.S. and home market sales at the same LOT.

C. Calculation of Normal Value Based on Comparison-Market Prices

We based NV for Aquapharm on delivered prices to unaffiliated customers in the home market. We made deductions, where appropriate, from the starting price for discounts, inland freight expenses and inland insurance expenses, under section 773(a)(6)(B)(ii) of the Act. Where appropriate, we also added freight and insurance revenue to the starting price, and capped it by the amount of freight and insurance expenses incurred, in accordance with our practice. *See, e.g., Certain Orange Juice from Brazil: Final Results of Antidumping Duty Administrative Review and Notice of Intent Not To Revoke Antidumping Duty Order in Part*, 75 FR 50999 (August 18, 2010), and accompanying Issues and Decision Memorandum at Comment 2.

Pursuant to section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410(b), we made, where appropriate, circumstance-of-sale adjustments for imputed credit expenses and bank charges. We also

made adjustments in accordance with 19 CFR 351.410(e) for indirect selling expenses incurred on comparison market or U.S. sales where commissions were granted on sales in one market but not the other. Specifically, where commissions were granted in the U.S. market but not in the comparison market, we made a downward adjustment to NV for the lesser of: (1) The amount of the commission paid in the U.S. market; or (2) the amount of the indirect selling expenses incurred in the comparison market. We also deducted home market packing costs and added U.S. packing costs, in accordance with sections 773(a)(6)(A) and (B) of the Act.

Currency Conversion

We made currency conversions into U.S. dollars in accordance with section 773A of the Act and 19 CFR 351.415, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Preliminary Results of the Review

We preliminarily determine that the following weighted-average dumping margin exists for Aquapharm for the period April 23, 2009, through March 31, 2010:

Manufacturer/exporter	Percent margin
Aquapharm Chemicals Pvt., Ltd.	0.00

Disclosure and Public Hearing

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). Pursuant to 19 CFR 351.309, 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 not later than five days after the date for filing case briefs. Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties who wish to request a hearing or to participate if one is requested must submit a written request to the Assistant Secretary for Import Administration, Room 1870, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *See* 19 CFR 351.310(c). Issues raised in

the hearing will be limited to those raised in the respective case briefs.

The Department will issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of the administrative review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212. The Department intends to issue appropriate appraisement instructions for the company subject to this review directly to CBP 15 days after the date of publication of the final results of this review.

Where the respondent reported entered value for its U.S. sales, we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales for that importer.

Where the respondent did not report entered value for its U.S. sales, we will calculate importer-specific per-unit duty assessment rates by aggregating the total amount of antidumping duties calculated for the examined sales and dividing this amount by the total quantity of those sales. To determine whether the duty assessment rates are *de minimis*, in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we will calculate importer-specific *ad valorem* ratios based on the estimated entered value.

We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *de minimis* (i.e., at or above 0.50 percent). Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis* (i.e., less than 0.50 percent). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

The Department clarified its "automatic assessment" regulation on May 6, 2003. See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*). This clarification will

apply to entries of subject merchandise during the POR produced by the company included in these final results of review for which the reviewed company did not know that the merchandise it sold to the intermediary (e.g., a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate effective during the POR if there is no rate for the intermediary involved in the transaction. See *Assessment Policy Notice* for a full discussion of this clarification.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not participating 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 review or the original 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 the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 3.10 percent, the all-others rate made effective by the LTFV investigation. See *1-Hydroxyethylidene-1, 1-Diphosphonic Acid from India: Notice of Final Determination of Sales at Less Than Fair Value*, 74 FR 10543 (March 11, 2009). These requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) 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.

This administrative review and notice are published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221.

Dated: November 19, 2010.

Ronald K. Lorentzen,
Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010-29963 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-896]

Magnesium Metal From the People's Republic of China: Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: November 29, 2010.

SUMMARY: On May 28, 2010, the U.S. Department of Commerce ("the Department") published a notice of initiation of an administrative review of the antidumping duty order on magnesium metal from the People's Republic of China ("PRC").¹ The review covers one manufacturer/exporter of subject merchandise from the PRC, Tianjin Magnesium International Co., Ltd. ("TMI"). The period of review ("POR") is April 1, 2009, through March 31, 2010. Following the receipt of a certification of no shipments from TMI, we notified all interested parties of the Department's intent to rescind this review and provided an opportunity to comment on the rescission.² We received no comments. Therefore, we are rescinding this administrative review.

FOR FURTHER INFORMATION CONTACT: Laurel LaGivita, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-4243.

SUPPLEMENTARY INFORMATION:

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 75 FR 29976 (May 28, 2010) ("Initiation").

² See Memorandum to the File, "Magnesium Metal from the People's Republic of China: Intent to Rescind the 2009-2010 Antidumping Duty Administrative Review of Magnesium Metal from the People's Republic of China—A-570-896," dated November 1, 2010 ("Intent to Rescind Memorandum").

Background

On April 1, 2010, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on magnesium metal from the PRC for the period April 1, 2009, through March 31, 2010.³ On April 30, 2010, U.S. Magnesium LLC ("U.S. Magnesium"), a domestic producer and Petitioner in the underlying investigation of this case, made a timely request that the Department conduct an administrative review of TMI.⁴ On May 28, 2010, in accordance with section 751(a) of the Tariff Act of 1930, as amended ("the Act"), the Department published in the *Federal Register* a notice of initiation of this antidumping duty administrative review.⁵ On June 28, 2010, TMI submitted a letter to the Department certifying that it did not export magnesium metal for consumption in the United States during the POR.

On June 30, 2010, the Department placed on the record information obtained in response to the Department's query to U.S. Customs and Border Protection ("CBP") concerning imports into the United States of subject merchandise during the POR. This data indicates that TMI made an entry of merchandise during the POR under the tariff item that includes magnesium metal.⁶

On July 14, 2010, TMI explained that it correctly classified the merchandise in question using the same Harmonized Tariff System ("HTS") category as magnesium metal.⁷ However, TMI noted that the merchandise in question is covered by the scope of the antidumping duty order on pure magnesium from the PRC.⁸ Moreover, TMI maintained that it reported, and the Department reviewed and verified, the merchandise at issue during the 2008–2009 review of pure magnesium from the PRC.⁹

³ See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 75 FR 16426 (April 1, 2010).

⁴ See letter from TMI, "Magnesium Metal from China: Request for Administrative Review," dated April 30, 2010.

⁵ See *Initiation*, 75 FR at 29983.

⁶ See Memorandum to the File, "Magnesium Metal from the People's Republic of China; Transmittal of U.S. Customs and Border Protection Information to the File," dated June 30, 2010, at Attachment I; see also letter from TMI, "Magnesium Metal from the People's Republic of China: A-570-896; Supplemental Information of No Sales by Tianjin Magnesium International Co., Ltd.," dated July 14, 2010 ("TMI's Supplemental No Shipments Letter"), at 1.

⁷ *Id.* at 3.

⁸ *Id.*

⁹ *Id.* at 4.

On October 19, 2010, the Department placed on the record of this review, copies of the entry documents received from CBP.¹⁰ These documents indicate that the merchandise at issue does not consist of subject merchandise.¹¹ Rather, this merchandise is included in the scope of the order or pure magnesium, which states in relevant part:¹²

(3) Products that contain 50% or greater, but less than 99.8% primary magnesium, by weight, and that do not conform to ASTM specifications for alloy magnesium (generally referred to as "off-specification pure" magnesium).

"Off-specification pure" magnesium is pure primary magnesium containing magnesium scrap, secondary magnesium, oxidized magnesium or impurities (whether or not intentionally added) that cause the primary magnesium content to fall below 99.8% by weight. It generally does not contain, individually or in combination, 1.5% or more, by weight, of the following alloying elements: aluminum, manganese, zinc, silicon, thorium, zirconium and rare earths.

On November 1, 2010, the Department notified interested parties of its intent to rescind this administrative review and gave parties until November 8, 2010, to provide comments. We did not receive any comments.

Scope of the Order

The product covered by this antidumping duty order is magnesium metal, which includes primary and secondary alloy magnesium metal, regardless of chemistry, raw material source, form, shape, or size. Magnesium is a metal or alloy containing by weight primarily the element magnesium. Primary magnesium is produced by decomposing raw materials into magnesium metal. Secondary magnesium is produced by recycling magnesium-based scrap into magnesium metal. The magnesium covered by this order includes blends of primary and secondary magnesium.

The subject merchandise includes the following alloy magnesium metal products made from primary and/or secondary magnesium including, without limitation, magnesium cast into ingots, slabs, rounds, billets, and other shapes, and magnesium ground,

¹⁰ See Memorandum to the File, "Magnesium Metal from the People's Republic of China: Release of U.S. Entry Documents from the Department's August 17, 2010 Request—A-570-896," ("Release of Entry Documents") dated October 19, 2010.

¹¹ See Release of Entry Documents at Attachment I.

¹² See *Notice of Antidumping Duty Orders: Pure Magnesium From the People's Republic of China, the Russian Federation and Ukraine; Notice of Amended Final Determination of Sales of Less Than Fair Value: Antidumping Duty Investigation of Pure Magnesium From the Russian Federation*, 60 FR 25691 (May 12, 1995).

chipped, crushed, or machined into raspings, granules, turnings, chips, powder, briquettes, and other shapes: Products that contain 50 percent or greater, but less than 99.8 percent, magnesium, by weight, and that have been entered into the United States as conforming to an "ASTM Specification for Magnesium Alloy"¹³ and thus are outside the scope of the existing antidumping orders on magnesium from the PRC (generally referred to as "alloy" magnesium).

The scope of this order excludes: (1) All forms of pure magnesium, including chemical combinations of magnesium and other material(s) in which the pure magnesium content is 50 percent or greater, but less than 99.8 percent, by weight, that do not conform to an "ASTM Specification for Magnesium Alloy"¹⁴; (2) magnesium that is in liquid or molten form; and (3) mixtures containing 90 percent or less magnesium in granular or powder form by weight and one or more of certain non-magnesium granular materials to make magnesium-based reagent mixtures, including lime, calcium metal, calcium silicon, calcium carbide, calcium carbonate, carbon, slag coagulants, fluorspar, nepheline syenite, feldspar, alumina (Al₂O₃), calcium aluminate, soda ash, hydrocarbons, graphite, coke, silicon, rare earth metals/mischmetal, cryolite, silica/fly ash, magnesium oxide, periclase, ferroalloys, dolomite lime, and colemanite.¹⁵

The merchandise subject to this order is classifiable under items 8104.19.00, and 8104.30.00 of the Harmonized Tariff Schedule of the United States

¹³ The meaning of this term is the same as that used by the American Society for Testing and Materials in its *Annual Book of ASTM Standards: Volume 01.02 Aluminum and Magnesium Alloys*.

¹⁴ This material is already covered by existing antidumping orders. See *Notice of Antidumping Duty Orders: Pure Magnesium from the People's Republic of China, the Russian Federation and Ukraine; Notice of Amended Final Determination of Sales of Less Than Fair Value: Antidumping Duty Investigation of Pure Magnesium from the Russian Federation*, 60 FR 25691 (May 12, 1995); and *Antidumping Duty Order: Pure Magnesium in Granular Form from the People's Republic of China*, 66 FR 57936 (Nov. 19, 2001).

¹⁵ This third exclusion for magnesium-based reagent mixtures is based on the exclusion for reagent mixtures in the 2000–2001 investigations of magnesium from China, Israel, and Russia. See *Final Determination of Sales of Less Than Fair Value: Pure Magnesium From the People's Republic of China*, 66 FR 49345 (September 27, 2001); *Final Determination of Sales of Less Than Fair Value: Pure Magnesium From Israel*, 66 FR 49349 (September 27, 2001); *Final Determination of Sales of Not Less Than Fair Value: Pure Magnesium From the Russian Federation*, 66 FR 49347 (September 27, 2001). These mixtures are not magnesium alloys, because they are not chemically combined in liquid form and cast into the same ingot.

("HTSUS"). Although the HTSUS items are provided for convenience and customs purposes, the written description of the merchandise is descriptive.

Rescission of the Administrative Review

Based upon the certifications and the evidence on the record, the Department finds TM's claim of no shipments of subject merchandise to the United States during the POR to be substantiated. Pursuant to 19 CFR 351.213(d)(3), the Department may rescind an administrative review, in whole or with respect to a particular exporter or producer, if the Secretary concludes that, during the period covered by the review, there were no entries, exports, or sales of the subject merchandise. Therefore, the Department is rescinding this review in accordance with 19 CFR 351.213(d)(3). The Department intends to instruct CBP fifteen days after the publication of this notice to liquidate such entries.

Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(2).

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213(d)(4).

Dated: November 19, 2010.

Susan H. Kuhbach,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010-29965 Filed 11-26-10; 8:45 am]

BILLING CODE 3510-DS-P

to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information for CPSC-sponsored prize competitions or contests.

DATES: Submit written or electronic comments on the collection of information by January 28, 2011.

ADDRESSES: You may submit comments, identified by Docket No. [CPSC 2010-0112], by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail), except through <http://www.regulations.gov>.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Glatz, Division of Policy and Planning, Office of Information Technology, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, 301-504-7671, lglatz@cpsc.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 before submitting the collection to the OMB for approval. To comply with this requirement, the CPSC is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, the CPSC invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility; (2) the accuracy of the CPSC'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.

Consistent with the OMB Memorandum on the Use of Challenges and Prizes to Promote Open Government (M-10-11, March 8, 2010), the CPSC intends to establish contests and give awards to members of the public to further the mission of the CPSC. The purposes of the proposed contests and awards range from increasing the knowledge and awareness of schoolchildren of certain safety hazards, such as carbon monoxide poisoning, to recognizing outstanding consumer product safety accomplishments of scientists, business leaders, entrepreneurs, and others who have demonstrated support of the CPSC's product safety mission. The CPSC awards and contests will highlight excellence in consumer product safety to motivate, inspire, and guide others, including companies across the supply chain; to increase the number and diversity of the individuals, organizations, and teams that are addressing consumer product safety issues; to educate children and consumers about safety hazards; and to attract more public interest and attention to the issues involving consumer product hazards and safety.

The CPSC is seeking OMB approval for a generic clearance for CPSC's contests and awards. The information to be collected from contestants and award

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC 2010-0112]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prize Competitions and Contests

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission ("CPSC" or "Commission") 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 and

nominees or nominators includes contact and background information necessary to conduct a contest or award program. Limited background or biographical information similar to data found on a resume, such as a nominee's education and work experience, may be requested for some contests or awards. Additionally, the substantive entries that are the subject of the contests or awards, such as essays, posters, drawings, and videos, descriptions of products, services, or invention descriptions, and statistics on product or service performance or impact, may be requested from contestants and award nominees.

We estimate the burden of this collection of information as follows. The CPSC estimates up to 500 contest or award participants each year. The estimated time to complete a contest or award submission is five hours. In addition, approximately 20 applicants may be asked to provide additional information, a task that may take up to two additional hours to complete. Therefore, the total estimated burden on respondents is 2,540 hours ((500 participants × 5 hours/participant) + (20 applicants × 2 hours/participant) = 2,500 hours + 40 hours = 2,540 hours). The estimated total annual cost of the burden to all respondents is \$75,463. This estimate is based on the total estimated burden on respondents (2,540 hours) multiplied against an hourly civilian rate of \$29.71 per hour as specified by the Bureau of Labor Statistics, March 2010, All Workers, resulting in a total of \$75,463.40 which we have rounded down to \$75,463.

We estimate the total annual costs to the Federal government as follows. Ten staff members would support the contest or award activities annually. The CPSC tentatively estimates that each staff member will spend approximately six hours per work week for six months on such contest or award activities. Of the ten staff members, the CPSC tentatively believes that seven will be General Schedule (GS) employees and three will be Senior Executive Service (SES) employees. Accordingly, for seven GS employees, the estimated total annual cost to the Federal government is determined as follows: Seven employees × (six hours/week/employee × 24 weeks) = 1,008 hours. Assuming the employees are at the GS-15, Step 5 level, the hourly rate for such an employee located in the Washington, DC area is \$67.21/hour; thus \$67.21/hour × 1,008 hours = \$67,747.68. For the SES employees three employees × (six hours/week/employee × 24 weeks) = 432 hours. Assuming the employees are at the

Level III level for SES employees, the hourly rate for such an employee is approximately \$79.47/hour; thus \$79.47/hour × 432 hours = \$34,331.04. The estimated total annual cost to the Federal government is \$67,747.68 + \$34,331.04 = \$102,078.72, which we have rounded up to \$102,079.

Dated: November 22, 2010.

Alberta E. Mills,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2010-29833 Filed 11-26-10; 8:45 am]

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

Notice of Meeting of Chronic Hazard Advisory Panel on Phthalates and Phthalate Substitutes

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of meeting.

SUMMARY: The Commission announces the third meeting of the Chronic Hazard Advisory Panel (CHAP) on phthalates and phthalate substitutes. The Commission appointed this CHAP to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles, pursuant to section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) (Pub. L. 110-314).

DATES: The meeting will be held Thursday, December 2, and Friday, December 3, 2010. The meeting will begin at approximately 8 a.m. both days. It will end at approximately 5 p.m. on Thursday and approximately 3 p.m. on Friday.

ADDRESSES: The meeting will be held in the fourth floor hearing room in the Commission's offices at 4330 East West Highway, Bethesda, Maryland.

Registration and Webcast: Members of the public who wish to attend the meeting may register on the day of the meeting. This meeting will also be available live via Webcast December 2 and 3, 2010, at <http://www.cpsc.gov/Webcast>. Registration is not necessary to view the Webcast. There will not be any opportunity for public participation at this meeting.

FOR FURTHER INFORMATION CONTACT: Michael Babich, Directorate for Health Sciences, Consumer Product Safety Commission, Bethesda, MD 20814; telephone (301) 504-7253; e-mail mbabich@cpsc.gov.

SUPPLEMENTARY INFORMATION: Section 108 of the CPSIA permanently prohibits the sale of any "children's toy or child

care article" containing more than 0.1 percent of each of three specified phthalates: Di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP). Section 108 of the CPSIA also prohibits, on an interim basis, the sale of any "children's toy that can be placed in a child's mouth" or "child care article" containing more than 0.1 percent of each of three additional phthalates: diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP).

Moreover, section 108 of the CPSIA requires the Commission to convene a CHAP "to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles." The CPSIA requires the CHAP to complete an examination of the full range of phthalates that are used in products for children and:

- Examine all of the potential health effects (including endocrine disrupting effects) of the full range of phthalates;
- Consider the potential health effects of each of these phthalates, both in isolation and in combination with other phthalates;

- Examine the likely levels of children's, pregnant women's, and others' exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of such products;

- Consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources, such as personal care products;

- Review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies of these phthalates and phthalate alternatives that employ objective data collection practices or employ other objective methods;

- Consider the health effects of phthalates not only from ingestion but also as a result of dermal, hand-to-mouth, or other exposure;

- Consider the level at which there is a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals and their offspring, considering the best available science, and using sufficient safety factors to account for uncertainties regarding exposure and susceptibility of children, pregnant women, and other potentially susceptible individuals; and
- Consider possible similar health effects of phthalate alternatives used in children's toys and child care articles.

The CHAP's examination must be conducted *de novo*, and the CPSIA contemplates completion of the CHAP's examination within 18 months of the CHAP's appointment. The CHAP must

review prior work on phthalates by the Commission, but it is not to be considered determinative.

The CHAP must make recommendations to the Commission regarding any phthalates (or combinations of phthalates) in addition to those identified in section 108 of the CPSIA or phthalate alternatives that the panel determines should be prohibited from use in children's toys or child care articles or otherwise restricted. The CHAP members were selected by the Commission from scientists nominated by the National Academy of Sciences. See 15 U.S.C. 2077, 2030(b).

The CHAP met previously on April 14–15, 2010, and July 26–28, 2010. The CHAP heard public comments at the July meeting. The December 2–3 meeting will include discussion of possible risk assessment approaches. The analysis of biomonitoring data will also be discussed. There will not be any opportunity for public comment at the December 2–3 meeting.

Dated: November 19, 2010.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2010–29868 Filed 11–26–10; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment Request.

SUMMARY: The Department of Education (the Department), 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 and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 28, 2011.

ADDRESSES: Comments regarding burden and/or the collection activity

requirements should be electronically mailed to ICDocketMgr@ed.gov or mailed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. 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.

Dated: November 23, 2010.

Darrin A. King,

Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Office of the Secretary

Type of Review: Extension.

Title of Collection: U.S. Department of Education Grant Performance Report Form (ED 524B)

OMB Control Number: 1894–0003.

Agency Form Number(s): ED 524 B Form.

Frequency of Responses: Annually.

Affected Public: State, Local, or Tribal Government, State Educational Agencies or Local Educational Agencies.

Total Estimated Number of Annual Responses: 5,900.

Total Estimated Number of Annual Burden Hours: 132,300.

Abstract: The ED 524B form and instructions are used in order for grantees to meet Department of Education (ED) deadline dates for submission of performance reports for ED discretionary grant programs. Recipients of multi-year discretionary grants must submit an annual performance report for each year funding has been approved in order to

receive a continuation award. The annual performance report should demonstrate whether substantial progress has been made toward meeting the approved goals and objectives of the project. ED program offices may also require recipients of “forward funded” grants that are awarded funds for their entire multi-year project up-front in a single grant award to submit the ED 524B on an annual basis. In addition, ED program offices may also require recipients to use the ED 524B to submit their final performance reports to demonstrate project success, impact and outcomes. In both the annual and final performance reports, grantees are required to provide data on established performance measures for the grant program (e.g., Government Performance and Results Act measures) and on project performance measures that were included in the grantee's approved grant application. The ED 524B also contains a number of questions related to project financial data such as Federal and non-Federal expenditures and indirect cost information. Performance reporting requirements are found in 34 CFR 74.51, 75.118, 75.253, 75.590 and 80.40 of the Education Department General Administrative Regulations.

Requests for copies of the proposed information collection request may be accessed from <http://edicsweb.ed.gov>, by selecting the “Browse Pending Collections” link and by clicking on link number 4421. When you access the information collection, click on “Download Attachments” to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to ICDocketMgr@ed.gov or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2010–29924 Filed 11–26–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education Overview Information; College Assistance Migrant Program (CAMP); Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011

Catalog of Federal Domestic Assistance (CFDA) Number: 84.149A.

DATES: *Applications Available:* November 29, 2010.

Deadline for Transmittal of Applications: January 19, 2011.

Deadline for Intergovernmental Review: March 21, 2011.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of CAMP is to provide academic and financial support to help migrant and seasonal farmworkers and their children complete their first year of college and continue in postsecondary education.

Priorities: This competition includes four priorities. In accordance with 34 CFR 75.105(b)(2)(ii), the competitive preference priority for being a "novice applicant" is from the Education Department General Administrative Regulations (EDGAR) (34 CFR 75.225). In accordance with 34 CFR 75.105(b)(2)(iv), the competitive preference priority for "prior experience of service delivery" is from section 418A(e) of the Higher Education Act of 1965, as amended by the Higher Education Opportunity Act (20 U.S.C. 1070d-2(e)). The third priority is an invitational priority for applications that promote science, technology, engineering, and mathematics (STEM) education. The fourth priority is an invitational priority for applications that propose to engage faith-based and community organizations in the delivery of services under this program.

Competitive Preference Priorities: For FY 2011 these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award: (1) An additional five points to an application that meets the "novice applicant" competitive preference priority; and (2) up to a maximum of 15 additional points to an application, depending on how well the applicant meets the "prior experience of service delivery" competitive preference priority.

These priorities are:

Novice Applicant: The applicant must be a "novice applicant" as defined in 34 CFR 75.225(a). A novice applicant is defined as one who has: (i) Never received a grant or a subgrant under the CAMP program; (ii) never been a member of a group application,

submitted in accordance with 34 CFR 75.127-75.129, that received a grant under the CAMP program; and (iii) not had an active discretionary grant from the Federal government in the five (5) years before the deadline date of receiving applications.

Prior Experience of Service Delivery: For applicants with an expiring CAMP project, the Secretary will consider the applicant's prior experience in implementing its expiring CAMP project, based on information contained in documents previously provided to the Department, such as annual performance reports, project evaluation reports, site visit reports, and the previously approved CAMP application.

Under this competition, we also are particularly interested in applications that address the following priorities.

Invitational Priorities: For FY 2011, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1), we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:
Invitational Priority 1—Science, Technology, Engineering and Mathematics (STEM) Education:

Projects that are designed to address one or more of the following priority areas:

(a) Providing students with increased access to rigorous and engaging coursework in STEM.

(b) Increasing the number and proportion of students prepared for postsecondary or graduate study and careers in STEM, with a specific focus on an increase in the number and proportion of students so prepared who are from groups traditionally underrepresented in STEM careers, including minorities, individuals with disabilities, and women.

Note: Applicants could consider increasing participants' access to studies in STEM through such activities as counseling and tutoring of participants in ways that motivate them to pursue postsecondary education in the areas of STEM. Similarly, applicants could consider increasing students' preparedness for study and careers in STEM through activities such as referrals to STEM-oriented work study, exposure to academic programs and careers in STEM-related fields, and providing support services, such as services to improve participants' academic skills and content knowledge, so that they may pursue studies and careers in STEM-related fields.

Invitational Priority 2—Faith-Based and Community Organizations: Applications that propose to engage faith-based and community organizations in the delivery of services under this program.

Program Authority: 20 U.S.C. 1070d-2.

Applicable Regulations: (a) The Education Department General Education Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 82, 84, 85, 86, 97, 98, and 99. (b) The regulations in 34 CFR part 206. (c) The definitions of a *migratory agricultural worker* in 34 CFR 200.81(d), *migratory child* in 34 CFR 200.81(e), and *migratory fisher* in 34 CFR 200.81(f). (d) The regulations in 20 CFR 669.110 and 669.320.

Note: The regulations in 34 CFR part 86 apply to institutes of higher education (IHEs) only.

Note: The Department published final regulations updating the program regulations in accordance with the changes enacted by the HEOA in the Federal Register on October 26, 2010 (75 FR 65711). These revised regulations will be effective on December 27, 2010. The application package identifies any provisions in part 206 that have been superseded by enactment of the HEOA.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested \$2,841,000 for new awards for this program for FY 2011. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Awards: \$180,000-\$425,000.

Estimated Average Size of Awards: \$410,000.

Maximum Award: We will reject any application that proposes a CAMP award exceeding \$425,000 for any of the five single budget periods of 12 months. The Assistant Secretary for Elementary and Secondary Education may change the maximum amount through a notice published in the **Federal Register**.

Minimum Award: We will reject any application that proposes a CAMP award that is less than \$180,000 for any of the five single budget periods of 12 months. The Assistant Secretary for Elementary and Secondary Education may change the minimum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 7.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. Eligible Applicants: IHEs or private non-profit organizations (including faith-based organizations) that plan their projects in cooperation with an IHE and

propose to operate some aspects of the project with the facilities of the IHE.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching. However, consistent with 34 CFR 75.700, which requires an applicant to comply with its approved application, an applicant that proposes non-Federal matching funds and is awarded a grant must provide those funds for each year that the funds are proposed.

3. *Annual Meeting Attendance:* Projects funded under this competition are encouraged to budget for a two-day Office of Migrant Education Annual Meeting for CAMP Directors in the Washington, DC area during each year of the project period.

IV. Application and Submission Information

1. *Address to Request Application Package:* David De Soto, U.S. Department of Education, Office of Migrant Education, 400 Maryland Avenue, SW., room 3E344, Washington, DC 20202-6135. Telephone: (202) 260-8103 or by e-mail: david.de.soto@ed.gov.

The application package content also can be viewed electronically at the following address: <http://www.ed.gov/programs/camp/applicant.html>.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. Content and Form of Application Submission:

Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Panel readers will award points only for an applicant's response to a given selection criterion that is contained within the section of the application designated to address that particular selection criterion. Readers will not review, or award points for responses to a given selection criterion that are in any other section of the application or appendices. You must limit the application narrative to no more than 25 pages, using the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.

- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space all text in charts, tables, figures, and graphs. Charts, tables, figures, and graphs presented in the application narrative count toward the page limit.

- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch) throughout the entire application package.

- Appendices must be limited to 20 pages and must include the following: Resumes, job descriptions of key personnel. Job descriptions must include duties and minimum qualifications. Items in the appendices will only be used by the program office for the purpose of approving any future personnel changes.

The 25-page limit for the project narrative does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; and the one-page abstract. However, the page limit does apply to all of the application narrative section.

Our reviewers will not read any pages of your application that exceed the page limit.

3. *Submission Dates and Times:*
Applications Available: November 29, 2010.

Deadline for Transmittal of Applications: January 19, 2011.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other

requirements and limitations in this notice. Deadline for Intergovernmental Review: March 21, 2011.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

- a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

- b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

- c. Provide your DUNS number and TIN on your application; and

- d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2-5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see <http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf>).

7. *Other Submission Requirements:* Applications for grants under this

competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the College Assistance Migrant Program, CFDA number 84.149A must be submitted electronically using the Governmentwide Grants.gov Apply site at <http://www.Grants.gov>. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the College Assistance Migrant Program at <http://www.Grants.gov>. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.149, not 84.149A).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time

stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at <http://www.G5.gov>.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must attach any narrative sections of your application as files in a .PDF (Portable Document) format only. If you upload a file type other than .PDF or submit a password-protected file, we will not review that material.

- Your electronic application must comply with any page-limit requirements described in this notice.

- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal

holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: David De Soto, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E344, LBJ, Washington, DC 20202-6135. FAX: (202) 205-0089.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.149A, LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.149A, 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

V. Application Review Information

1. **Selection Criteria:** The selection criteria for this competition are from 34 CFR 75.210 of EDGAR and are listed in the application package.

2. **Review and Selection Process:** We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. **Special Conditions:** Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if

the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. **Award Notices:** If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. Administrative and National Policy Requirements:

We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. **Reporting:** (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary in 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

4. **Performance Measures:** Under the Government Performance and Results Act of 1993 (GPRA), the Department developed the following performance measures to evaluate the overall effectiveness of the CAMP: (1) The percentage of CAMP participants completing the first academic year of their postsecondary program, and (2) the percentage of CAMP participants, after completing the first academic year of

college, continue their postsecondary education.

Applicants must propose annual targets for these measures in their applications. The national target for GPRA 1 for FY 2011 is that 86 percent of CAMP participants will complete the first academic year of their postsecondary program. The national target for GPRA 2 for 2011 is that 85 percent of CAMP participants after completing the first academic year of college, continue their postsecondary education. The national targets for subsequent years may be adjusted based on additional baseline data. The panel readers will score related selection criteria on the basis of how well an applicant addresses these GPRA measures. Therefore, applicants will want to consider how they will make demonstration of a sound capacity to provide reliable data on GPRA measures, including the project's annual performance targets for addressing the GPRA performance measures, as is required by the OMB approved annual performance report that is included in the application package. All grantees will be required to submit, as part of their annual performance report, information with respect to these performance measures.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made "substantial progress toward meeting the objectives in its approved application." This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT:

David De Soto, U.S. Department of Education, Office of Migrant Education, 400 Maryland Avenue, SW., room 3E344, Washington, DC 20202-6135. Telephone Number: (202) 260-8103, or by e-mail: david.de.soto@ed.gov, or Tara Ramsey, U.S. Department of Education, Office of Migrant Education, 400 Maryland Avenue, SW., room 3E342,

Washington, DC 20202-6135. Telephone Number: (202) 260-2063, or by e-mail: tara.ramsey@ed.gov.

If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: 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) on the Internet at the following site: <http://www.ed.gov/news/fedregister>. To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: 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 on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: November 23, 2010.

Thelma Meléndez de Santa Ana,
Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2010-29987 Filed 11-26-10; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education; Overview Information; High School Equivalency Program (HEP); Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011

Catalog of Federal Domestic Assistance (CFDA) Number: 84.141A.

DATES: Applications Available: November 29, 2010.

Deadline for Transmittal of Applications: January 19, 2011.

Deadline for Intergovernmental Review: March 21, 2011.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of HEP is to help migrant and seasonal farmworkers and members of their immediate family obtain a general education diploma (GED) that meets the guidelines for high school equivalency established by the State in which the

HEP project is conducted, and to help them gain employment or be placed in an institution of higher education (IHE) or other postsecondary education or training.

Priorities: This competition includes four priorities. In accordance with 34 CFR 75.105(b)(2)(ii), the competitive preference priority for being a "novice applicant" is from the Education Department General Administrative Regulations (EDGAR) (34 CFR 75.225). In accordance with 34 CFR 75.105(b)(2)(iv), the competitive preference priority for "prior experience of service delivery" is from section 418A(e) of the Higher Education Act of 1965, as amended by section 408(3) of the Higher Education Opportunity Act (20 U.S.C. 1070d-2(e)). The third priority is an invitational priority for applications that promote science, technology, engineering and mathematics (STEM) education. The fourth priority is an invitational priority for applications that propose to engage faith-based and community organizations in the delivery of services under this program.

Competitive Preference Priorities: For FY 2011 these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award: (1) An additional five points to an application that meets the "novice applicant" competitive preference priority; and (2) up to a maximum of 15 additional points to an application, depending on how well the applicant meets the "prior experience of service delivery" competitive preference priority.

These priorities are:

Novice Applicant

The applicant must be a "novice applicant," as defined in 34 CFR 75.225(a). A novice applicant is defined as one who has: (i) Never received a grant or a subgrant under the HEP program; (ii) never been a member of a group application, submitted in accordance with 34 CFR 75.127-75.129, that received a grant under the HEP program; and (iii) not had an active discretionary grant from the Federal government in the five (5) years before the deadline date of receiving applications.

Prior Experience of Service Delivery

For applicants with an expiring HEP project, the Secretary will consider the applicant's prior experience in implementing its expiring HEP project, based on information contained in documents previously provided to the Department, such as annual performance reports, project evaluation

reports, site visit reports, and the previously approved HEP application.

Under this competition, we also are particularly interested in applications that address the following priorities.

Invitational Priorities: For FY 2011, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority 1—Science, Technology, Engineering and Mathematics (STEM) Education

Projects that are designed to address one or more of the following priority areas:

(a) Providing students with increased access to rigorous and engaging coursework in STEM.

(b) Increasing the opportunities for high-quality preparation of, or professional development for, teachers or other educators of STEM subjects.

Note: Applicants could consider activities to better prepare program participants to transition into postsecondary education, such as preparing students to successfully pass the sections of college entrance examinations in STEM-related subjects, or activities such as counseling and tutoring services that are designed to motivate participants to pursue postsecondary education in STEM-related fields. Similarly, for demonstrating professional development, applicants could propose how they intend to increase the opportunities for high-quality professional development in the area of mathematics instruction and related GED instruction among their project instructors. Opportunities for increasing professional development of GED instructors of STEM-related subjects could include, for example, these instructors' participation in training on intensive science teaching techniques presented by a professionally credentialed expert in science education.

Invitational Priority 2—Faith-Based and Community Organizations

Applications that propose to engage faith-based and community organizations in the delivery of services under this program.

Program Authority: 20 U.S.C. 1070d-2.

Applicable Regulations: (a) The Education Department General Education Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 82, 84, 85, 86, 97, and 99. (b) The regulations in 34 CFR part 206. (c) The definitions in 34 CFR 200.81. (d) The regulations in 20 CFR 669.110 and 669.320. **Note:** The regulations in 34 CFR part 86 apply to IHEs only.

Note: The Department published final regulations updating the program regulations

in accordance with the changes enacted by the HEOA in the **Federal Register** on October 26, 2010 (75 FR 65711). These revised regulations will be effective on December 27, 2010. The application package identifies any provisions in part 206 that have been superseded by enactment of the HEOA.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested \$4,629,000 for new awards for this program for FY 2011. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Awards: \$180,000–\$475,000.

Estimated Average Size of Awards: \$432,000.

Maximum Award: We will reject any application that proposes a HEP award exceeding \$475,000 for any of the five single budget periods of 12 months. The Assistant Secretary for Elementary and Secondary Education may change the maximum amount through a notice published in the **Federal Register**.

Minimum Award: We will reject any application that proposes a HEP award that is less than \$180,000 for any of the five single budget periods of 12 months. The Assistant Secretary for Elementary and Secondary Education may change the minimum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 11.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. **Eligible Applicants:** IHEs or private non-profit organizations (including faith-based organizations) that plan their projects in cooperation with an IHE and propose to operate some aspects of the project with the facilities of the IHE.

2. **Cost Sharing or Matching:** This program does not require cost sharing or matching. However, consistent with 34 CFR 75.700, which requires an applicant to comply with its approved application, an applicant that proposes non-Federal matching funds and is awarded a grant must provide those funds for each year that the funds are proposed.

3. **Annual Meeting Attendance:** Projects funded under this competition are encouraged to budget for a two-day Annual Meeting for IHEP Directors in the Washington, DC area during each year of the project period.

IV. Application and Submission Information

1. Address to Request Application Package:

David De Soto, U.S. Department of Education, Office of Migrant Education, 400 Maryland Avenue, SW., room 3E344, Washington, DC 20202-6135. Telephone: (202) 260-8103 or by e-mail:

david.de.soto@ed.gov.

The application package content also can be viewed electronically at the following address: <http://www.ed.gov/programs/hep/applicant.html>.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., Braille, large print, audiotope, or computer diskette) by contacting the program contact person listed in this section.

2. Content and Form of Application Submission:

Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. **Page Limit:** The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Panel readers will award points only for an applicant's response to a given selection criterion that is contained within the section of the application designated to address that particular selection criterion. Readers will not review, or award points for responses to a given selection criterion that is located in any other section of the application or the appendices. You must limit the application narrative to no more than 25 pages, using the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space all text in charts, tables, figures, and graphs. Charts, tables, figures, and graphs presented in the application narrative count toward the page limit.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch) throughout the entire application package.
- Appendices must be limited to 20 pages and must include the following: Resumes and job descriptions of key personnel. Job descriptions must include duties and minimum

qualifications. Items in the appendices will only be used by the program office for the purpose of approving any future personnel changes.

The 25-page limit for the project narrative does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract. However, the page limit does apply to all of the application narrative section.

Our reviewers will not read any pages of your application that exceed the page limit.

3. Submission Dates and Times:

Applications Available: November 29, 2010.

Deadline for Transmittal of Applications: January 19, 2011.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: March 21, 2011.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see <http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf>).

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the High School Equivalency Program, CFDA number 84.141A, must be submitted electronically using the Governmentwide Grants.gov Apply site at <http://www.Grants.gov>. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for HEP at <http://www.Grants.gov>. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.141, not 84.141A).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures

pertaining to Grants.gov under News and Events on the Department's G5 system home page at <http://www.G5.gov>.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must attach any narrative sections of your application as files in a .PDF (Portable Document) format only. If you upload a file type other than .PDF or submit a password-protected file, we will not review that material.

- Your electronic application must comply with any page-limit requirements described in this notice.

- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from, electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing

instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: David De Soto, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E344, LBJ, Washington, DC 20202-6135. FAX: (202) 205-0089.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail.

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.141A, LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

- (1) A legibly dated U.S. Postal Service postmark.
- (2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
- (3) A dated shipping label, invoice, or receipt from a commercial carrier.
- (4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

- (1) A private metered postmark.
- (2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery.

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.141A, 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 of EDGAR and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other

requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department developed the following performance measures to evaluate the overall effectiveness of HEP: (1) The percentage of HEP program exiters receiving a General Education Diploma (GED) (GPRA 1), and (2) the percentage of HEP GED recipients who enter postsecondary education or training programs, upgraded employment, or the military (GPRA 2).

Applicants must propose annual targets for these measures in their applications. The national target for GPRA 1 for FY 2011 is that 69 percent of HEP program exiters will receive a GED credential. The national target for GPRA 2 for FY 2011 is that 80 percent of HEP GED recipients will enter postsecondary education or training programs, upgraded employment, or the military. The national targets for subsequent years may be adjusted based on additional baseline data. The panel readers will score related selection criteria for applicants, in part, on the basis of how well an applicant addresses these GPRA measures. Therefore, applicants should consider how they will demonstrate their capacity to provide reliable data on these measures, including the project's

annual performance targets for the GPRA measures, as required by the OMB approved annual performance report that is included in the application package. All grantees will be required to submit, as part of their annual performance report, information with respect to these GPRA measures.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made "substantial progress toward meeting the objectives in its approved application." This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: David De Soto, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E344, LBJ, Washington, DC 20202-6135. Telephone: (202) 260-8103 or by e-mail: david.de.soto@ed.gov, or Tara Ramsey, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E342, LBJ, Washington, DC 20202-6135. Telephone: (202) 260-2063 or by e-mail: tara.ramsey@ed.gov.

If you use a TDD, call the Federal Relay Service, FRS, toll free, at 1-800-877-8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) on request to the program contact persons listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: 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) on the Internet at the following site: <http://www.ed.gov/news/fedregister>. To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: 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 on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: November 23, 2010.

Thelma Meléndez de Santa Ana,
Assistant Secretary for Elementary and
Secondary Education.

[FR Doc. 2010-29993 Filed 11-26-10; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Discretionary Grant Programs

AGENCY: Department of Education.

ACTION: Notice announcing additional requirement for applicants and grantees.

SUMMARY: The Department of Education announces an additional requirement affecting applicants and grantees. We are taking this action to conform our requirements with final guidance issued by the Office of Management and Budget (OMB) on September 14, 2010 (Financial Assistance Use of Universal Identifier and Central Contractor Registration). The new guidance affects an applicant's or grantee's registration of its Dun and Bradstreet Data Universal Numbering System (DUNS) Number and its Taxpayer Identification Number (TIN) with the Central Contractor Registration (CCR) database.

FOR FURTHER INFORMATION CONTACT: Greg Vick, U.S. Department of Education, 400 Maryland Avenue, SW., Washington, DC 20202-0170. Telephone: (202) 245-6147 or by e-mail: gregory.vick@ed.gov.

SUPPLEMENTARY INFORMATION: In each notice inviting applications for grant awards, we include requirements governing an applicant's DUNS Number and TIN and specify that to do business with the Department, an applicant must register those numbers with the CCR, the Government's primary registrant database.

In its final guidance issued under 2 CFR Part 25 and published in the **Federal Register** on September 14, 2010 (75 FR 55671), OMB added a requirement that an entity doing business with the Department must maintain an active CCR registration with current information while its application is under review and, if it is awarded a grant, during the project period.

The final guidance took effect on October 1, 2010, which made it applicable to every grant competition with an application deadline date on or after October 1, 2010. However, on or

before the effective date, we had published a number of notices inviting applications that had application deadline dates on or after October 1, 2010, but that did not include the new requirement with regard to maintaining an active CCR registration:

This notice serves to inform applicants and potential applicants under those affected competitions that the new requirement applies to them, and each such potential applicant must, therefore, maintain an active CCR registration during the time its application is under review and, if funded, during the project period. However, this requirement does not affect the submission of their applications and does not require any applicant to amend, withdraw, or resubmit its application.

The affected competitions and the publication date in the **Federal Register** of each notice inviting applications are shown below in order of Catalog of Federal Domestic Assistance (CFDA) Number. Questions about the applicability of this notice to any application submitted under these programs should be directed to the program contact identified for each program.

CFDA No. 84.019A—Office of Postsecondary Education; Overview Information; Fulbright-Hays Faculty Research Abroad Fellowship Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011. Published October 1, 2010 (75 FR 60740). *Program contact:* Cynthia Dudzinski, 202-502-7589.

CFDA No. 84.021A—Office of Postsecondary Education; Overview Information; Fulbright-Hays Group Projects Abroad Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011. Published September 24, 2010 (75 FR 59051). *Program contact:* Michelle Guilfoil, 202-502-7625.

CFDA No. 84.022A—Office of Postsecondary Education; Overview Information; Fulbright-Hays Doctoral Dissertation Research Abroad (DDRA) Fellowship Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011. Published September 17, 2010 (75 FR 57000). *Program contact:* Amy Wilson, 202-502-7689.

CFDA No. 84.327J—Office of Special Education and Rehabilitative Services; Overview Information; Technology and Media Services for Individuals with Disabilities—Video Description Research and Development Center; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011. Published August 12, 2010 (75 FR

48957). *Program contact:* Jo Ann McCann, 202-245-7434.

CFDA No. 84.327W—Office of Special Education and Rehabilitative Services; Overview Information; Technology and Media Services for Individuals with Disabilities—The Accessible Instructional Materials (AIM) Personnel Development Center; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011. Published September 28, 2010 (75 FR 59699). *Program contact:* Glinda Hill, 202-245-7376.

CFDA No. 84.330B—Office of Elementary and Secondary Education; Overview Information; Advanced Placement (AP) Test Fee Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011. Published September 1, 2010 (75 FR 53681). *Program contact:* Francisco Ramirez, 202-260-1541.

Electronic Access to This Document: 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) on the Internet at the following site: <http://www.ed.gov/news/fedregister>. To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: 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 on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: November 23, 2010.

Thomas P. Skelly,
Delegated Authority to Perform the Functions
of the Chief Financial Officer.

[FR Doc. 2010-29990 Filed 11-26-10; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Record of Decision and Floodplain Statement of Findings for the Cushman Hydroelectric Project, Mason County, Washington, Environmental Impact Statement (DOE/EIS-0456)

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy (DOE).

ACTION: Record of Decision (ROD) and Floodplain Statement of Findings.

SUMMARY: DOE announces its decision to provide approximately \$4.6 million appropriated under the American Recovery and Reinvestment Act, Public Law 111-5 (Recovery Act), to the City

of Tacoma, Washington (Tacoma), for the design and construction of certain components of the Cushman Hydroelectric Project in Mason County, Washington. These components include a new 3.6 megawatt (MW) powerhouse on the North Fork of the Skokomish River, an integral fish collection, handling, and sorting facility, and related transmission infrastructure.

The environmental impacts from the proposed action were analyzed in the Federal Energy Regulatory Commission's (FERC's) 1996 *Final Environmental Impact Statement for the Cushman Hydroelectric Project* (FERC Project No. 460) (1996 FEIS). In a July 15, 2010, Order¹ (FERC's 2010 Order), FERC lifted a stay on a 1998 license for the Cushman Hydroelectric Project and amended the license to include *inter alia* conditions for fish passage facilities and authorization to construct the powerhouse. FERC's 2010 Order includes the components of the Cushman Hydroelectric Project that DOE proposes to fund. FERC relied on the 1996 FEIS to fulfill its National Environmental Policy Act (NEPA) obligations for the 1998 license as amended on July 15, 2010. DOE has adopted the 1996 FEIS and 2010 Order, together, as a final DOE EIS (DOE/EIS-0456).

ADDRESSES: DOE's final EIS, this ROD, and other project information are available on the DOE NEPA Web site at <http://nepa.energy.gov>. In addition, copies of this ROD may be requested by contacting Ms. Jane Summerson, NEPA Document Manager, Office of Energy Efficiency and Renewable Energy Department of Energy at jane.summerson@ee.doe.gov. Ms. Summerson can be reached at the U.S. Department of Energy, 1000 Independence Ave, SW., EE-4a, Washington, DC 20585, phone (202) 287-6188 or fax (202) 586-8177.

FOR FURTHER INFORMATION CONTACT: For further information about this project, contact Ms. Summerson as indicated in the **ADDRESSES** section above. For information about DOE's NEPA process, contact Ms. Carol M. Borgstrom, Director, NEPA Policy and Compliance, GC-54, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, telephone (202) 586-4600, or leave a message at (800) 472-2756.

SUPPLEMENTARY INFORMATION:

¹ *City of Tacoma, Washington* 132 FERC ¶ 61,037. (Order on Remand and an Offer of Settlement, Amending License, Authorizing New Powerhouse, and Lifting Stay).

Background

DOE is providing approximately \$4.6 million to Tacoma, for the design and construction of certain components of the Cushman Hydroelectric Project in Mason County, Washington. These components include a new 3.6 MW powerhouse on the North Fork of the Skokomish River, an integral fish collection and sorting facility, and related transmission infrastructure.²

Tacoma applied for this funding in response to DOE Solicitation (FOA-0000120), entitled "Hydroelectric Facility Modernization," pursuant to the Wind and Water Technologies Program. The goal of the Solicitation is to provide funding for industry members who propose to develop, deploy, and test hydropower projects that would modernize the existing hydropower infrastructure in the U.S. and increase the quantity, value, and environmental performance of hydropower generation. Because the funds are appropriated by the Recovery Act, the projects must stimulate the economy and create and retain jobs.

The background on the relicensing of the Cushman Project spans several decades and includes administrative and judicial litigation and multiple stays with interim operating requirements. To fully understand the history of the relicensing process, please refer to FERC's 2010 Order, the 1998 license,³ and the 1996 FEIS. What follows is a brief summary setting forth those aspects of the Cushman Project and relicensing process relevant to this ROD.

In 1924, Tacoma obtained a license from the Federal Power Commission (predecessor to FERC) to flood 8.8 acres of national forest land by damming the North Fork of the Skokomish River at Lake Cushman on the Olympic Peninsula. This license was designated a "minor part license" because it covered only a small part of Tacoma's much larger hydroelectric project (Cushman Project). At that time, the Federal Power Commission interpreted its licensing authority narrowly, and the 1924 minor part license gave Tacoma the authority it needed to proceed with the Cushman Project.

The 131 MW Cushman Project is located on the North Fork of the Skokomish River (North Fork) in Mason County, Washington, and occupies U.S.

² The "Cushman Project" refers to the entire project that FERC licensed in its 2010 Order. The scope of the Cushman Project is broader than the project that DOE is funding, and is defined in this section of this ROD.

³ *City of Tacoma, Washington* 84 FERC ¶ 61107 (1998).

lands within the Olympic National Forest and the Skokomish Indian Reservation. Tacoma built two dams across the Skokomish River. Dam No. 1, which was completed in 1926, impounds Lake Cushman and supplies water for electricity generation at a powerhouse with a capacity of 50 MW, located downstream of that dam. Dam No. 2, which was completed in 1930, impounds Lake Kokanee, a much smaller reservoir than Lake Cushman. Water leaving Dam No. 2 passes through a tunnel to a second powerhouse with 81 MW capacity and does not return to the North Fork. Historically, the Cushman Project diverted nearly all of the flow of the North Fork out of the river basin, leading to controversy regarding the total amount of flow diverted from the river, its environmental effects, and the appropriate level of minimum flows that should be required to return water to the North Fork. The Cushman Project is currently operated to provide load-following power and to meet peak-demand period needs.

In 1963, the Federal Power Commission determined that its hydroelectric licensing jurisdiction extends to whole projects, not just to the parts of those projects that occupy or use Federal land. As required by Title I of the Federal Power Act, Tacoma filed for a "major project license" for the Cushman Project on November 5, 1974. Tacoma continued to operate the Cushman Project under the terms of its 1924 minor part license, and FERC issued annual renewals of Tacoma's existing license during the application review period.

FERC's 1996 FEIS

Subsequent to Tacoma's application for a major part license, FERC decided to prepare an environmental impact statement to analyze the impacts from the Cushman Project and alternatives to it. FERC issued a Notice of Intent to prepare a Draft EIS for the Cushman Project on November 12, 1992 (57 FR 53727). FERC held two rounds of scoping, in December 1992 and April 1993, and issued a final Scoping Document in February 1994. FERC issued the Draft EIS in November 1995 and held three public meetings in January and February 1996 to receive public comments on the Draft EIS (61 FR 1375). The comment period closed on February 13, 1996. FERC issued the 1996 FEIS on November 15, 1996 (61 FR 59435).

After a lengthy relicensing proceeding, FERC issued a new license for the Cushman Project on July 30,

1998,⁴ and issued an order on rehearing on March 30, 1999.⁵ The license then became the subject of judicial and administrative review, in which the principal plaintiff was the Skokomish Tribe (Tribe), and concerns about endangered and threatened species and minimum flow were at the center of the dispute. The relicensing was stayed in part for most of the following decade, and FERC, at various times, amended the license with conditions for interim operation of the Cushman Project.

As required by Section 7 of the Endangered Species Act, the Fish and Wildlife Service (FWS) filed a biological opinion for protection of listed fish in 2004. On January 21, 2009, the City of Tacoma and other parties to the litigation, including the Tribe, filed a comprehensive offer of settlement that includes conditions for protection of the Skokomish Indian Reservation, fish passage facilities, and measures for fish and wildlife protection. The National Marine Fisheries Service (NMFS) and FWS filed revised biological opinions in 2010.

FERC's 2010 Order

In its July 15, 2010, Order, FERC lifted a stay on a 1998 license for the Cushman Project and amended the license to include conditions for fish passage facilities and authorization to construct the 3.6 MW powerhouse. FERC relied on the 1996 FEIS to fulfill its NEPA obligations for the 1998 license, as amended in FERC's 2010 Order. The amended license includes license articles consistent with the settlement, extends the license expiration date to June 20, 2048, and authorizes construction of a new 3.6 MW powerhouse that will increase the Cushman Project's authorized capacity to 134.6 MW.

As stated above, FERC's license authorizes all activities that DOE is funding through this decision. In FERC's 2010 Order, FERC found that the activities it authorized, including the proposed powerhouse, were within the range of alternatives examined in the 1996 FEIS and that a supplemental EIS would not be needed for the activities.

Alternatives Analyzed in FERC's 1996 EIS

In the 1996 FEIS, FERC analyzed Tacoma's proposal, which included replacing turbine runners at the second powerhouse; installing a 1.3 MW powerhouse at the base of Dam No. 2;

implementing major environmental enhancements such as increasing instream flows into the North Fork; removing resident fish passage barriers in project reservoir tributaries; and executing a land exchange to remove lands within Olympic National Forest. FERC also analyzed four other alternatives:

- (1) No Action Alternative;
- (2) Alternative adapted from resource agencies' and Tribe's recommended alternatives to Tacoma's proposal. Under this alternative, Tacoma would build a new powerhouse with a generating capacity of 16 MW at the base of Dam No. 2, and the project would operate with full river flows. Tacoma would remove certain dikes, enhance more than 15,000 acres of land for wildlife, and stop diverting water from the North Fork;
- (3) Alternative intended to achieve, to the extent practicable, important elements of each objective: under this alternative, Tacoma would manage flow levels through an instream flow schedule to balance the competing demands on North Fork water; build a new 3 MW powerhouse near the base of Dam No. 2; and implement a staff-formulated wildlife habitat enhancement plan covering 5,981 acres of land for wildlife; and
- (4) Decommissioning Alternative.

Environmentally Preferred Alternative

FERC identified Alternative (2) as the environmentally preferred alternative in the 1996 FEIS because, among other things, it maximizes river flows and enhances the greatest area of land for wildlife in comparison to the other alternatives.

Alternatives Available to DOE

DOE's two alternatives are to (1) provide funding for certain components of the Cushman Project as defined and conditioned in FERC's 2010 Order and which were analyzed in substantive part in Alternative 2 of the 1996 EIS, or (2) not provide funding (No Action Alternative). Under either alternative, Tacoma would construct and operate the Cushman Project consistent with FERC's 2010 Order and related settlement agreements.

Consultation

FERC is the lead Federal agency for complying with Section 106 of the National Historic Preservation Act (NHPA) and Tribal Consultation for all components of the Cushman Project. The Tribe and others originally opposed Tacoma's Cultural Resource Summary Report, and cultural resource protection became a contested issue. On May 13,

2010, however, FERC entered into a Memorandum of Agreement (MOA) with the Washington State Historic Preservation Officer (SHPO) and the Tribe, and other interested parties concurred in the MOA. The MOA includes a Treatment Plan that Tacoma must follow to protect cultural resources during the construction of the new powerhouse. On June 8, 2010, the Advisory Council on Historic Preservation (ACHP) acknowledged receipt of the MOA and stated that FERC had completed its requirements under Section 106 of the NHPA.

DOE hereby concurs with the May 13, 2010, MOA and, in so doing, completes its own consultation requirements under Section 106 of the NHPA. DOE's proposed action is to fund elements of the Cushman Project that were already the subject of extensive Section 106 consultations.

FERC is also the lead Federal agency for complying with Section 7 of the Endangered Species Act (16 U.S.C. 1536) (ESA). FERC consulted extensively with both NMFS and FWS regarding impacts from the Cushman Project on listed species and critical habitat. These agencies concluded consultation when NMFS and FWS issued Biological Opinions finding that the Cushman Project is not likely to result in jeopardy to listed species or destruction or adverse modification of critical habitat. FERC and Tacoma agreed to implement certain mitigation measures (2010 Order at 148).

DOE finds that, either with or without DOE funding, Tacoma will manage the Cushman Project in compliance with the terms of FERC's relicense and the settlement agreement, which include terms that mitigate impacts to listed species. Thus, DOE's proposed action will have no effect on listed species or critical habitat and DOE has fulfilled its obligations under Section 7 of the ESA.

EIS Adoption

DOE has independently reviewed the 1996 FEIS and FERC's 2010 Order and has concluded that, together, the 1996 FEIS and FERC's 2010 Order meet the standards for an adequate environmental impact statement under the Council on Environmental Quality's and DOE's NEPA regulations, which can be found at 40 CFR Parts 1500-1508 and 10 CFR Part 1021, respectively. In addition, DOE has determined that the Cushman Project is within the range of alternatives analyzed in the 1996 FEIS.

The only difference between the project that DOE is funding and the actions analyzed under the 1996 FEIS is the placement of a transmission line. In the 1996 FEIS, FERC analyzed an

⁴ *City of Tacoma, Washington* 84 FERC ¶ 61107 (1998).

⁵ *City of Tacoma, Washington* 86 FERC ¶ 61311 (1999).

aboveground transmission line. Tacoma is now planning to bury the line underground to mitigate environmental impacts. This mitigation measure is not a substantial change in the proposed action relevant to environmental concerns, within the meaning of 40 CFR 1502.9(c), warranting a supplement to the FEIS. Accordingly, DOE adopted FERC's 1996 FEIS and 2010 Order as a final DOE EIS (DOE/EIS-0456).

Because DOE did not participate as a cooperating agency in preparation of FERC's 1996 FEIS, DOE recirculated the adopted document as a DOE final EIS and filed it with the Environmental Protection Agency (EPA). EPA published a notice of availability in the **Federal Register** on October 8, 2010 (75 FR 62386). DOE did not receive any comments on the final EIS.

Floodplain Statement of Findings

In accordance with DOE regulations at 10 CFR Part 1022 (*Compliance with Floodplain and Wetland Environmental Review Requirements*), DOE considered the potential impacts of the Cushman Project on floodplains. These findings are based on the assessment of environmental impacts in the final EIS. The location of the Cushman Project and the alternatives considered are discussed in detail in the final EIS. The differences among the alternatives, including the original proposal from Tacoma, are summarized above.

DOE finds that no practicable alternative to locating the Cushman Project in a floodplain is available. The nature of the existing Cushman Dam site and the process of generating electricity from water pressure require that the proposed powerhouse be constructed downstream of the dam; therefore the proposed construction will necessarily be within a floodplain.

FERC's 2010 Order establishes numerous requirements that Tacoma must follow in constructing and operating the proposed new facilities to minimize potential harm to or within the floodplain, including measures to reduce flooding hazards while protecting water quality and fish habitat. For example, Article 403 of FERC's 2010 Order requires Tacoma to implement measures to enhance the channel conveyance capacity of the mainstem Skokomish River for the reduction of risks to human health and welfare from flooding, including, among other things, providing funds to the U.S. Army Corps of Engineers for a *Skokomish River Basin Ecosystem Restoration and Flood Damage Reduction General Investigation*; the preparation, under certain conditions, of a *Mainstem Channel Restoration Plan* in

consultation with NMFS, FWS, the Bureau of Indian Affairs (BIA) and including the comments of the Federal Emergency Management Agency, EPA, and Mason County; and, under certain conditions, providing funds for a *Channel Restoration Account*.

In addition, under Articles 406 and 407 of FERC's 2010 Order, Tacoma must prepare and implement an *Operational and Flow Monitoring Plan* to improve fish habitat, address lake water use changes, improve sediment transport and stream flow, and improve flood control and forecasting. This plan must be submitted to and approved by NMFS, FWS, and BIA. Under certain conditions, Tacoma would be required to develop a *Flood Damage and Mitigation Plan* and provide funding to implement the plan.

Mitigation

In addition to adopting the measures addressing floodplain impacts, described above, DOE adopts and incorporates by reference all other mitigation measures documented in FERC's 2010 Order. These other measures include but are not limited to:

- Monitoring water use, which provides a feedback mechanism to help ensure that adequate flows will be available to meet the needs of anadromous fish at different times of the year, support aquatic habitats, maintain improvements to the channel capacity of the river, and provide some assurances that the flows released will benefit these resources.

- A variety of fish habitat protection, mitigation and enhancement measures such as habitat enhancement and restoration work that benefits anadromous fish by improving channel habitat and removing instream barriers.

- The use of a floating surface collector for downstream fish passage. Tacoma will use a trap and haul system for upstream fish passage.

- Implementation of a resident fishery, which will include anadromous fish hatcheries.

Decision

DOE has decided to provide funding, appropriated by the Recovery Act, to Tacoma for the design and construction of certain components of the Cushman Project in Mason County, Washington. These components include a new 3.6 MW powerhouse on the North Fork of the Skokomish River, an integral fish collection and sorting facility, and related transmission infrastructure.

DOE incorporates by reference all mitigation measures and other conditions identified in FERC's 2010 Order. DOE expects that Tacoma will

execute the Cushman Project in compliance with FERC's 2010 Order. Thus, all practicable means to avoid or minimize environmental harm have been adopted.

Basis for Decision

DOE's decision enables it to meet the objectives set forth in the Solicitation, namely, to provide financial assistance for industry members and industry-led partnerships who propose to develop, deploy, and test hydropower projects to modernize the existing hydropower infrastructure in the U.S. and increase the quantity, value, and environmental performance of hydropower generation.

DOE did not select the No Action alternative because it would not meet DOE's objectives, as set forth in the Solicitation.

DOE decided not to fund alternatives, or alternative components, that were analyzed in the 1996 FEIS but were not authorized under FERC's 2010 Order. Without a FERC license, Tacoma would not be able to implement such alternatives.

Issued in Washington, DC, on this 18th day of November 2010.

Cathy Zoi,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 2010-29936 Filed 11-26-10; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13848-000]

Qualified Hydro 27, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

November 19, 2010.

On September 30, 2010, Qualified Hydro 27, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Howard A. Hanson Dam Hydroelectric Project (Howard A. Hanson project) to be located in King County, Washington, near the town of Palmer. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project will consist of the following: (1) The existing 675-foot-long, 235-foot-high earth and rockfill Howard A. Hanson dam; (2) the existing Howard A. Hanson reservoir, which has a maximum usable storage of 106,000 acre-feet between elevation 1,206 feet above mean sea level (msl) and elevation 1,035 feet msl; (3) an 800-foot-long steel liner, placed within the existing outlet tunnel, bifurcated above the existing discharge outlet; (4) a 200-foot-long, 10-foot-diameter steel penstock leading from the right branch of the bifurcation to the powerhouse; (5) a 40-foot-long, 80-foot-wide reinforced concrete powerhouse containing one 2-megawatt (MW) and one 3-MW Francis-type turbine; (6) a substation adjacent to the powerhouse; (7) a 1,000-foot-long, 69-kilovolt (kV) transmission line that will interconnect with the local utility; and (8) appurtenant facilities. The estimated annual generation of the Howard A. Hanson project would be 14 gigawatt-hours.

Applicant Contact: Ramya Swaminathan, Qualified Hydro 27, LLC, 33 Commercial Street, Gloucester, MA 01930; phone: (978) 283-2822.

FFP Missouri 15, LLC Project No. 13762-000.
Morgantown Hydro, LLC Project No. 13773-000.
Three Rivers Hydro, LLC Project No. 13784-000.

On May 18, 2010, FFP Missouri 15, LLC, Morgantown Hydro, LLC, and Three Rivers Hydro LLC filed applications, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of hydropower at the U.S. Army Corps of Engineers Morgantown Lock & Dam located on the Monongahela River in Monongahela County, West Virginia. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

Descriptions of the Proposed Morgantown Lock & Dam Projects

FFP Missouri 15, LLC's project (Project No. 13762-000) would consist of: (1) An excavated intake channel slightly longer and wider than the powerhouse; (2) a 60-foot-long, 110-foot-wide, 40-foot-high proposed powerhouse containing two generating units having a total installed capacity of 9.0 megawatts (MW); (3) an excavated tailrace channel slightly longer and

FERC Contact: Kelly Wolcott, (202) 502-6480.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal

Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13848-000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29858 Filed 11-26-10; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13762-000; Project No. 13773-000; Project No. 13784-000]

Notice of Competing Preliminary Permit Applications Accepted for Filing and Soliciting Comments, and Motions To Intervene

November 19, 2010.

wider than the powerhouse; and (4) a proposed 13-mile-long, ranging from 34.0 to 230-kilovolt (kV) transmission line. The proposed project would have an average annual generation of 26.0 gigawatt-hours (GWh), which would be sold to a local utility.

Applicant Contact: Ms. Ramya Swaminathan, Free Flow Power Corporation, 33 Commercial Street, Gloucester, MA 01930; phone (978) 283-2822.

Morgantown Hydro LLC's project (Project No. 13773-000) would consist of: (1) A proposed 80-foot-long excavated power canal; (2) a proposed powerhouse containing two generating units having a total installed capacity of 7.2 MW; (3) a 120-foot-long excavated tailrace; and (4) a proposed 0.3-mile-long, 69.0-kV transmission line. The proposed project would have an average annual generation of 26.2 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Brent Smith, Symbiotics, LLC., P.O. Box 535, Rigby, ID 83442; phone (208) 745-0834.

Three Rivers Hydro, LLC's project (Project No. 13784-000) would consist of: (1) A proposed 85-foot-long excavated power canal; (2) a 45-foot-long, 110-foot-wide, 40-foot-high

proposed powerhouse containing two generating units having a total installed capacity of 3.7 MW; (3) a 95-foot-long excavated tailrace; and (4) a proposed 1,100-foot-long, ranging from 34 to 230-kV transmission line. The proposed project would have an average annual generation of 20.0 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Joseph Watt, Esq., Three Rivers Hydro, LLC, 316 South Clinton Street, Suite 4, Syracuse, NY 13202; phone (315) 477-9914.

FERC Contact: Tim Looney (202) 502-6096.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the

eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-free at (866) 208-3676; or, for TTY, contact (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13762-000, 13773-000, or 13784-000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29856 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13736-000; Project No. 13777-000]

Lock Hydro Friends Fund XLI; Allegheny 7 Hydro, LLC; Notice of Competing Preliminary Permit Applications Accepted for Filing and Soliciting Comments, and Motions To Intervene

November 19, 2010.

On May 18, 2010, Lock Hydro Friends Fund XLI, and Allegheny 7 Hydro, LLC filed applications, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of hydropower at the U.S. Army Corps of Engineers (Corps) Allegheny River Lock & Dam No. 7 located on the Allegheny River in Armstrong County, Pennsylvania. The sole purpose of a preliminary permit, if

issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

Descriptions of the Proposed Allegheny River Lock & Dam No. 7 Projects

Lock Hydro Friends Fund XLI's project (Project No. 13736-000) would consist of: (1) Two 24-foot-high, 75-foot-long prefabricated concrete walls attached to the downstream side of the Corps dam which would support one frame module; (2) the frame module would be 109 feet long and weigh 1.16 million pounds and contain 10 generating units with a total combined capacity of 12.5 megawatts (MW); (3) a new switchyard containing a transformer; (4) a proposed 6,000-foot-long, 36.7-kilovolt (kV) transmission line to an existing substation. The proposed project would have an average annual generation of 54,787 gigawatt-hours (GWh), which would be sold to a local utility.

Applicant Contact: Mr. Mark R. Stover, Hydro Green Energy LLC, 5090 Richmond Avenue #390, Houston, TX 77056; phone (877) 556-6566 x711.

Allegheny 7 Hydro, LLC's project (Project No. 13777-000) would consist of: (1) A proposed 100-foot-long excavated power canal; (2) a proposed powerhouse containing three generating units having a total installed capacity of 13.3 MW; (3) a 260-foot-long excavated tailrace; (4) a proposed 2.1-mile-long, 69.0-kV transmission line. The proposed project would have an average annual generation of 49.7 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Brent Smith, Symbiotics LLC, P.O. Box 535, Rigby, ID 83442; phone (208) 745-0834.

FERC Contact: Michael Spencer, (202) 502-6093.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18

CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-free at (866) 208-3676; or, for TTY, contact (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13736-000 or 13777-000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29852 Filed 11-26-10; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13740-000; Project No. 13749-000; Project No. 13775-000; Project No. 13781-000]

Notice of Competing Preliminary Permit Applications Accepted for Filing and Soliciting Comments, and Motions To Intervene

November 19, 2010.

Lock+ Hydro Friends Fund XXXIX	Project No. 13740-000
FFP Missouri 3, LLC	Project No. 13749-000
Allegheny 3 Hydro, LLC	Project No. 13775-000
Three Rivers Hydro, LLC	Project No. 13781-000

On May 18, 2010, Lock+ Hydro Friends Fund XXXIX, FFP Missouri 3, LLC, Allegheny 3 Hydro, LLC, and Three Rivers Hydro LLC filed applications, pursuant to section 4(f) of

the Federal Power Act, proposing to study the feasibility of hydropower at the U.S. Army Corps of Engineers (Corps) C.W. Bill Young Lock and Dam located on the Allegheny River in

Allegheny County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary

permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

Descriptions of the proposed C.W. Bill Young Lock and Dam Projects:

Lock+ Hydro Friends Fund XXXIX's project (Project No. 13740-000) would consist of: (1) Two 41-foot-high, 75-foot-long prefabricated concrete walls attached to the downstream side of the Corps dam which would support one frame module; (2) each frame module would be 109 feet long and weigh 1.16 million pounds and contain 10 generating units with a total combined capacity of 12.5 megawatts (MW); (3) a new switchyard containing a transformer; and (4) a proposed 6,000-foot-long, 69-kilovolt (kV) transmission line connecting to an existing substation. The proposed project would have an average annual generation of 54.787 gigawatt-hours (GWh), which would be sold to a local utility.

Applicant Contact: Mr. Mark R. Stover, Hydro Green Energy LLC, 5090 Richmond Avenue #390, Houston, TX 77056; phone (877) 556-6566 x711.

FFP Missouri 3, LLC's project (Project No. 13749-000) would consist of: (1) An excavated intake channel slightly longer and wider than the powerhouse; (2) a 125-foot-long, 160-foot-wide, 60-foot-high proposed powerhouse containing three generating units having a total installed capacity of 15.0 MW; (3) an excavated tailrace channel slightly longer and wider than the powerhouse; and (4) a proposed 6,500-foot-long, ranging from 34.0 to 230-kV transmission line. The proposed project would have an average annual generation of 93.0 GWh, which would be sold to a local utility.

Applicant Contact: Ms. Ramya Swaminathan, Free Flow Power Corporation, 33 Commercial Street, Gloucester, MA 01930; phone (978) 283-2822.

Allegheny 3 Hydro, LLC's project (Project No. 13775-000) would consist of: (1) A proposed 170-foot-long excavated power canal; (2) a proposed powerhouse containing three generating units having a total installed capacity of 21.0 MW; (3) a 160-foot-long excavated tailrace; and (4) a proposed 1.6-mile-long, 69.0-kV transmission line. The proposed project would have an average annual generation of 92.2 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Brent Smith, Symbiotics, LLC., P.O. Box 535, Rigby, ID 83442; phone (208) 745-0834.

Three Rivers Hydro, LLC's project (Project No. 13781-000) would consist of: (1) A proposed 85-foot-long

excavated power canal; (2) a 125-foot-long, 160-foot-wide, 60-foot-high proposed powerhouse containing three generating units having a total installed capacity of 15.0 MW; (3) a 95-foot-long excavated tailrace; and (4) a proposed 500-foot-long, 25-kV transmission line. The proposed project would have an average annual generation of 93.0 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Joseph Watt, Esq., Three Rivers Hydro, LLC, 316 South Clinton Street, Suite 4, Syracuse, NY 13202; phone (315) 477-9914.

FERC Contact: Tim Looney (202) 502-6096.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-free at (866) 208-3676; or, for TTY, contact (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13740-000, 13749-000, 13775-000, or 13781) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010-29853 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11-22-000]

Tennessee Gas Pipeline Company; Notice of Application

November 18, 2010.

Take notice that on November 5, 2010 Tennessee Gas Pipeline Company (Tennessee), 1001 Louisiana Street, Houston, Texas 77002, filed in Docket No. CP11-22-000, an application pursuant to section 3 of the Natural Gas Act (NGA), to amend its authorization under NGA section 3 and Presidential Permits to allow it to import and export natural gas from the United States to Canada utilizing Tennessee's existing cross-border facilities. Specifically, Tennessee proposes that its Presidential Permits be amended and reissued, and authorizations under Section 3 of the NGA be amended to authorize Tennessee to operate bi-directionally two existing international border crossings between Canada and the United States located near Niagara Falls, New York. Tennessee proposes no new facilities, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may also be viewed on the Commission's Web site at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, call (202) 502-8659 or TTY, (202) 208-3676.

Any questions regarding this application should be directed to Mr. Thomas Joyce, Manager, Certificates, Tennessee Gas Pipeline Company, 1001 Louisiana Street, Houston, Texas 77002, phone (713) 420-3299 or facsimile (713) 420-1605 or e-mail tom.joyce@elpaso.com.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the below listed comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and

by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Motions to intervene, protests and comments may be filed electronically via the Internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Comment Date: December 9, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29846 Filed 11-26-10; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13869-000]

Qualified Hydro 35, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

November 18, 2010.

On October 15, 2010, Qualified Hydro 35, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Tionesta Dam Hydroelectric Project to be located on Tionesta Creek near Tionesta, in Forest County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or

otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) Two vertical Kaplan turbine-generators with a combined capacity of 5 megawatts; (2) a 150-foot-long steel liner with a bifurcated 75-foot-long penstock leading to the powerhouse; (3) a 40-foot by 80-foot concrete powerhouse; (4) a new 5 MVA substation adjacent to the powerhouse; (5) a 9,800-foot-long transmission line; and (6) appurtenant facilities. The estimated annual generation of the Tionesta Dam Hydroelectric Project would be 22,000 megawatt-hours.

Applicant Contact: Ramya Swaminathan, Qualified Hydro 35, LLC, 33 Commercial Street, Gloucester, MA 01930; phone: (978) 283-2822.

FERC Contact: Allyson Conner (202) 502-6082.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-free at (866) 208-3676; or for TTY, contact (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13869-000) in the docket number field to access the document. For

assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29842 Filed 11-26-10; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13763-000; Project No. 13772-000]

FFP Missouri 13, LLC; Grays Hydro, LLC; Notice of Competing Preliminary Permit Applications Accepted for Filing and Soliciting Comments, and Motions To Intervene

November 19, 2010.

On May 18, 2010, FFP Missouri 13, LLC and Grays Hydro, LLC filed applications, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of hydropower at the U.S. Army Corps of Engineers (Corps) Grays Landing Lock & Dam located on the Monongahela River in Greene County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

Descriptions of the proposed Grays Landing Lock & Dam Projects:

FFP Missouri 13, LLC's project (Project No. 13763-000) would consist of: (1) An excavated intake channel slightly longer and wider than the powerhouse; (2) a 140-foot-long, 16-foot-wide, 40-foot-high proposed powerhouse containing two generating units having a total installed capacity of 15.0 megawatts (MW); (3) an excavated tailrace channel slightly longer and wider than the powerhouse; (4) a proposed 7,400-foot-long, 34.0 to 230-kilovolt (kV) transmission line. The proposed project would have an average annual generation of 47.0 gigawatt-hours (GWh), which would be sold to a local utility.

Applicant Contact: Ms. Ramya Swaminathan, Free Flow Power Corporation, 33 Commercial Street, Gloucester, MA 01930; phone (978) 283-2822.

Grays Hydro, LLC's project (Project No. 13772-000) would consist of: (1) A proposed 230-foot-long excavated power canal; (2) a proposed powerhouse

containing three generating units having a total installed capacity of 12.0 MW; (3) a 450-foot-long excavated tailrace; (4) a proposed 0.9-mile-long, 25.0-kV transmission line. The proposed project would have an average annual generation of 52.6 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Brent Smith, Symbiotics LLC, P.O. Box 535, Rigby, ID 83442; phone (208) 745-0834.

FERC Contact: Michael Spencer, (202) 502-6093.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 Days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the

instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-free at (866) 208-3676; or, for TTY, contact (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at

<http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13763-000, or 13772-000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29857 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13746-000; Project No. 13750-000; Project No. 13776-000; Project No. 13782-000]

Notice of Competing Preliminary Permit Applications Accepted for Filing and Soliciting Comments, and Motions To Intervene

Lock + Hydro Friends Fund XL	Project No. 13746-000.
FFP Missouri 4, LLC	Project No. 13750-000.
Allegheny 4 Hydro, LLC	Project No. 13776-000.
Three Rivers Hydro, LLC	Project No. 13782-000.

November 19, 2010.

On May 18, 2010, Lock+ Hydro Friends Fund XL, FFP Missouri 4, LLC, Allegheny 4 Hydro, LLC, and Three Rivers Hydro LLC filed applications, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of hydropower at the U.S. Army Corps of Engineers (Corps) Allegheny River Lock and Dam No. 4 located on the Allegheny River in Allegheny County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

Descriptions of the proposed Allegheny River Lock and Dam No. 4 Projects:

Lock+ Hydro Friends Fund XL project (Project No. 13746-000) would consist of: (1) Two 34-foot-high, 75-foot-long prefabricated concrete walls attached to the downstream side of the Corps dam which would support one frame modules; (2) each frame module would be 109 feet long and weigh 1.16 million pounds and contain 10 generating units with a total combined capacity of 10.0 megawatts (MW); (3) a new switchyard containing a transformer; and (4) a proposed 400-foot-long, 69-kilovolt (kV)

transmission line connecting to an existing substation. The proposed project would have an average annual generation of 43.83 gigawatt-hours (GWh), which would be sold to a local utility.

Applicant Contact: Mr. Mark R. Stover, Hydro Green Energy LLC, 5090 Richmond Avenue #390, Houston, TX 77056; phone (877) 556-6566 x711.

FFP Missouri 4, LLC's project (Project No. 13750-000) would consist of: (1) An excavated intake channel slightly longer and wider than the powerhouse; (2) a 125-foot-long, 160-foot-wide, 60-foot-high proposed powerhouse containing three generating units having a total installed capacity of 15.0 MW; (3) an excavated tailrace channel slightly longer and wider than the powerhouse; and (4) a proposed 500-foot-long, ranging from 34.0 to 230-kilovolt (kV) transmission line. The proposed project would have an average annual generation of 89.0 GWh, which would be sold to a local utility.

Applicant Contact: Ms. Ramya Swaminathan, Free Flow Power Corporation, 33 Commercial Street, Gloucester, MA 01930; phone (978) 283-2822.

Allegheny 4 Hydro, LLC's project (Project No. 13776-000) would consist of: (1) A proposed 165-foot-long excavated power canal; (2) a proposed powerhouse containing three generating units having a total installed capacity of

15.9 MW; (3) a 135-foot-long excavated tailrace; and (4) a proposed 0.3-mile-long, 69.0-kV transmission line. The proposed project would have an average annual generation of 62.6 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Brent Smith, Symbiotics, LLC., P.O. Box 535, Rigby, ID 83442; phone (208) 745-0834.

Three Rivers Hydro, LLC's project (Project No. 13782-000) would consist of: (1) A proposed 85-foot-long excavated power canal; (2) a 125-foot-long, 160-foot-wide, 60-foot-high proposed powerhouse containing three generating units having a total installed capacity of 15.0 MW; (3) a 95-foot-long excavated tailrace; and (4) a proposed 500-foot-long, 138-kV transmission line. The proposed project would have an average annual generation of 89.0 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Joseph Watt, Esq., Three Rivers Hydro, LLC, 316 South Clinton Street, Suite 4, Syracuse, NY 13202; phone (315) 477-9914.

FERC Contact: Tim Looney (202) 502-6096.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and

competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-free at (866) 208-3676; or, for TTY, contact (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be

paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13746-000, 13750-000, 13776-000, or 13782) in the docket number field to

access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29855 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Competing Preliminary Permit Applications Accepted for Filing and Soliciting Comments, and Motions To Intervene

November 19, 2010.

Lock Hydro Friends Fund XLIII	Project No. 13745-000
FFP Missouri 14, LLC	Project No. 13758-000
Solia 4 Hydroelectric LLC	Project No. 13767-000
Monongahela 4 Hydro, LLC	Project No. 13788-000

On May 18, 2010, Lock Hydro Friends Fund XLIII, FFP Missouri 14, LLC, Solia 4 Hydroelectric LLC, and on May 19, 2010, Monongahela 4 Hydro, LLC filed applications, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of hydropower at the U.S. Army Corps of Engineers (Corps) Monongahela River Lock & Dam No. 4 located on the Monongahela River in Washington County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

Descriptions of the proposed Monongahela River Lock & Dam No. 4 Projects:

Lock Hydro Friends Fund XLIII's project (Project No. 13745-000) would consist of: (1) Two 45-foot-high, 75-foot-long prefabricated concrete walls attached to the downstream side of the Corps dam which would support one frame module; (2) the frame module would be 109 feet long and weigh 1.16 million pounds and contain 10 generating units with a total combined capacity of 18.0 megawatts (MW); (3) a new switchyard containing a transformer; (4) a proposed 5,000-foot-long, 36.7-kilovolt (kV) transmission line to an existing substation. The proposed project would have an average annual generation of 78.894 gigawatt-hours (GWh), which would be sold to a local utility.

Applicant Contact: Mr. Mark R. Stover, Hydro Green Energy LLC, 5090 Richmond Avenue #390, Houston, TX 77056; phone (877) 556-6566 x711.

FFP Missouri 14, LLC's project (Project No. 13758-000) would consist of: (1) An excavated intake channel slightly longer and wider than the powerhouse; (2) a 200-foot-long, 25-foot-wide, 60-foot-high proposed powerhouse containing four generating units having a total installed capacity of 20.0 MW; (3) an excavated tailrace channel slightly longer and wider than the powerhouse; (4) a proposed 5,500-foot-long, 34.0 to 230-kV transmission line. The proposed project would have an average annual generation of 85.0 GWh, which would be sold to a local utility.

Applicant Contact: Ms. Ramya Swaminathan, Free Flow Power Corporation, 33 Commercial Street, Gloucester, MA 01930; phone (978) 283-2822.

Solia 4 Hydroelectric LLC's project (Project No. 13767-000) would consist of: (1) A proposed 300-foot-long, 80-foot-wide excavated intake channel on the left bank of the dam, requiring removal of part of the left dam abutment; (2) a proposed powerhouse containing four generating units having a total installed capacity of 18.7 MW; (3) a 200-foot-long, 80-foot-wide excavated tailrace; (4) a proposed 4,900-foot-long, 34.0 to 230-kV transmission line. The proposed project would have an average annual generation of 81.8 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Douglas Spaulding, Nelson Energy, 8441

Wayzata Blvd. Suite 101, Golden Valley, MN 55426; phone (952) 544-8133.

Monongahela 4 Hydro, LLC's project (Project No. 13788-000) would consist of: (1) A proposed 190-foot-long excavated power canal; (2) a proposed powerhouse containing two generating units having a total installed capacity of 8.2 MW; (3) a 145-foot-long excavated tailrace; (4) a proposed 0.8-mile-long, 69.0-kV transmission line. The proposed project would have an average annual generation of 28.1 GWh, which would be sold to a local utility.

Applicant Contact: Mr. Brent Smith, Symbiotics LLC., P.O. Box 535, Rigby, ID 83442; phone (208) 745-0834.

FERC Contact: Michael Spencer, (202) 502-6093.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-

free at (866) 208-3676; or, for TTY, contact (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13745-000, 13758-000, 13767-000, or 13788-000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29854 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13855-000]

NorthHydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

November 18, 2010.

On October 1, 2010, and supplemented on November 16, 2010, NorthHydro, LLC filed an application for a preliminary permit pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Boulder Creek Water Power Project (Boulder Creek project) to be located on Boulder Creek in the vicinity of Bonner's Ferry, Idaho and Troy,

Montana in Boundary County, Idaho and Lincoln County, Montana. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project will consist of the following: (1) A 6-foot-high, 75-foot-long reinforced concrete diversion and inlet structure on Boulder Creek; (2) an impoundment of less than 1 acre-foot; (3) an 8,500-foot-long, 4.5-foot-diameter pressurized HDPE penstock from the intake structure to the powerhouse; (4) a powerhouse containing one or more turbines with a total installed capacity of 4.3 megawatts; (5) a concrete or rip-rap-lined tailrace channel to return flows from the powerhouse to Boulder Creek; (6) an approximately 5-mile-long, 115 kV transmission line which will tie into an undetermined interconnection; and (7) appurtenant facilities. The estimated annual generation of the Boulder Creek project would be 15.75 gigawatt-hours.

Applicant Contact: Darius Ruen, NorthHydro, LLC, 3201 Huetter Rd Suite 102, Coeur d'Alene, ID 83814; phone: (208) 292-0820.

FERC Contact: Ryan Hansen (202) 502-8074.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the

instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>.

Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13855-000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29841 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR10-97-001; Docket No. PR10-101-001; Docket No. PR10-125-001; Docket No. PR10-83-001]

Enstor Grama Ridge Storage and Transportation, LLC, Enstor Katy Storage and Transportation, LP, et al.; Notice of Baseline Filings

November 18, 2010.

Enstor Grama Ridge Storage and Transportation, LLC	Docket No. PR10-97-001.
Enstor Katy Storage and Transportation, LP	Docket No. PR10-101-001.
NorthWestern Corporation	Docket No. PR10-125-001.
New York State Electric & Gas Corporation	Docket No. PR10-83-001.
	Not Consolidated.

Take notice that on November 10, 2010, November 12, 2010, and November 17, 2010, the applicants listed above submitted a revised baseline filing of their Statement of Operating Conditions for services provided under Section 311 of the Natural Gas Policy Act of 1978 ("NGPA").

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must

file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must

be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the

"eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on Monday, November 29, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29844 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2621-009]

Lockhart Power Company, South Carolina; Notice of Availability of Environmental Assessment

November 19, 2010.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC's) regulations, 18 Code of Federal Regulations (CFR) Part 380 (Order No. 486, 52 *Federal Register* [FR] 47897), the Office of Energy Projects has reviewed Lockhart Power Company's application for license for the Pacolet Hydroelectric Project (FERC Project No. 2621), located on the Pacolet River in Spartanburg County, South Carolina. The project does not occupy any Federal lands.

Staff prepared an environmental assessment (EA), which analyzes the potential environmental effects of relicensing the project, and concludes that licensing the project, with appropriate environmental protection measures, would not constitute a major Federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on

the Commission's Web site at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov; toll-free at 1-866-208-3676, or for TTY, 202-502-8659.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. Comments may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/doc-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission; 888 First Street, NE., Washington, DC 20426.

For further information, contact Lee Emery at (202) 502-8379, or by e-mail at lee.emery@ferc.gov.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29851 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10-493-000]

Empire Pipeline, Inc.; Notice of Availability of the Environmental Assessment for the Proposed Tioga County Extension Project

November 19, 2010.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Tioga County Extension Project proposed by Empire Pipeline, Inc. (Empire) in the above-referenced docket. Empire requests authorization to

construct and replace pipeline facilities to provide an additional 350,000 dekatherms per day of natural gas capacity from new producer interconnections in Pennsylvania to new interconnections on its pipeline system and on Tennessee Gas Pipeline Company's system in New York.

The EA assesses the potential environmental effects of the construction and operation of the Tioga County Extension Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The New York State Department of Environmental Conservation, New York State Department of Agriculture and Markets, and the U.S. Army Corps of Engineers participated as cooperating agencies in the preparation of the EA. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and generally participate in the NEPA analysis.

The proposed Tioga County Extension Project includes the following facilities:

- Construction of approximately 14.9 miles of new 24-inch-diameter pipeline in Tioga County, Pennsylvania and Steuben County, New York;
- Replacement of approximately 1.4 miles of existing 24-inch-diameter pipeline in Ontario County, New York;
- Construction of a new interconnect with Tennessee Gas Pipeline Company in Ontario County, New York; and
- Construction of miscellaneous pipeline modifications and appurtenant facilities at the existing Oakfield Compressor Station in Genesee County, New York.

The EA has been placed in the public files of the FERC and is available for public viewing on the FERC's Web site at <http://www.ferc.gov> using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426. (202) 502-8371.

Copies of the EA have been mailed to Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are properly recorded and considered prior to a Commission decision on the proposal, it is important that the FERC receives your comments in Washington, DC, on or before December 20, 2010.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the project docket number (CP10-493-000) with your submission. The Commission encourages electronic filing of comments and has dedicated eFiling expert staff available to assist you at (202) 502-8258 or efiling@ferc.gov.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's Web site at <http://www.ferc.gov> under the link to Documents and Filings. An eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's Web site at <http://www.ferc.gov> under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing"; or

(3) You may file a paper copy of your comments at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Although your comments will be considered by the Commission, simply filing comments will not serve to make the commenter a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).¹ Only intervenors have the

right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208-FERC or on the FERC Web site (<http://www.ferc.gov>) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number excluding the last three digits in the Docket Number field (i.e., CP10-493). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to <http://www.ferc.gov/esubscribenow.htm>.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29837 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10-82-000]

Northern Natural Gas Company, Southern Natural Gas Company, Florida Gas Transmission Company, LLC, Transcontinental Gas Pipe Line Company, LLC, Enterprise Field Services, LLC; Notice of Availability of the Environmental Assessment for the Proposed Matagorda Offshore Pipeline System Abandonment Project

November 19, 2010.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the

Matagorda Offshore Pipeline System Abandonment Project proposed by Northern Natural Gas Company, Southern Natural Gas Company, Florida Gas Transmission Company, LLC, Transcontinental Gas Pipe Line Company, LLC, and Enterprise Field Services, LLC (Applicants) in the above referenced docket. The Applicants request authorization to abandon in place about 86.9 miles of pipeline and related facilities onshore in Refugio and Calhoun Counties, Texas, and offshore in state and Federal waters. These facilities are referred to as the Matagorda Offshore Pipeline System (MOPS). The onshore facilities that would be abandoned in place include about 26.8 miles of pipeline, the Tivoli Dehydration Plant, and several interconnect. The offshore facilities, would be abandoned include about 60.1 miles of pipeline and several interconnects. Further, about 19.8 miles of the MOPS offshore pipeline is nonjurisdictional gathering pipeline and related facilities; abandonment of these facilities are also considered in this EA.

The EA assesses the potential environmental effects of the abandonment of the Matagorda Offshore Pipeline System Abandonment Project in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The EA has been placed in the public files of the FERC and is available for public viewing on the FERC's Web site at <http://www.ferc.gov> using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426, (202) 502-8371.

Copies of the EA have been mailed to Federal, State, and local government representatives and agencies; elected officials; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are properly recorded and

¹ Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

of its specific pre-existing generation development plans to support priority rights for itself and its affiliates to the existing and planned capacity of the Dixie Valley Line, in compliance with the Commission's October 8, 2010, *Notice of Extension of Time*, Docket Nos. EL10-29-000 and EL10-36-000 (Oct 8, 2010).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all the parties in this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on December 6, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29847 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11-74-000]

Washington Gas Light Company; Notice of Filing

November 18, 2010.

Take notice that on November 15, 2010, Washington Gas Light Company (Washington Gas) filed its annual actual lost and unaccounted for volumes (LAUF) adjustment to comply with Paragraph IV.F. of its Firm Interstate Transportation Service Operating Statement (FITSOS). Washington Gas states the actual LAUF applicable to the firm transportation service provided to Mountaineer Gas Company effective from November 1, 2010 will be 1.22 percent.

Any person desiring to participate in this rate filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on Monday, November 29, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29845 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-2063-000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

November 18, 2010.

Duke Energy Vermillion II, LLC.	Docket No. ER11- 2063-000.
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This is a supplemental notice in the above-referenced proceeding, of Duke Energy Vermillion II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is December 7, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29849 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-2079-000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

November 18, 2010.

Duke Energy Fayette II, LLC.	Docket No. ER11-2079-000.
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This is a supplemental notice in the above-referenced proceeding, of Duke Energy Fayette II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is December 7, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.
[FR Doc. 2010-29840 Filed 11-26-10; 8:45 am]

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29840 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-2064-000]

Duke Energy Hanging Rock II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

November 18, 2010.

This is a supplemental notice in the above-referenced proceeding, of Duke Energy Hanging Rock II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to

intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is December 7, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29838 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-2066-000]

Duke Energy Washington II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

November 18, 2010.

This is a supplemental notice in the above-referenced proceeding, of Duke Energy Washington II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that

such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is December 7, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29839 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR08-28-002]

Calpine Texas Pipeline, L.P.; Notice of Motion for Extension of Rate Case Filing Deadline

November 18, 2010.

Take notice that on November 10, 2010, Calpine Texas Pipeline, L.P. (Calpine Texas) filed a motion to extend the date for filing its next rate case to August 22, 2013. Calpine Texas states that in Order No. 735 the Commission modified its policy concerning periodic reviews of rates charges by section 311 and Hinshaw pipelines to extend the cycle for such reviews from three to five years.¹ Therefore, Calpine Texas requests that the date for Calpine Texas' next rate filing be extended to August 22, 2013, which is five years from the date of Calpine Texas' most recent rate filing with this Commission.

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public

Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on Tuesday, November 23, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29843 Filed 11-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL10-77-000]

Notice of Motion To Add Exhibit to Petition for Declaratory Order and Complaint

November 18, 2010.

City of Pella, Iowa	Docket No. EL10-77-000.
v. Midwest Independent Transmission System Operator, Inc., MidAmerican Energy Company, Inc.	

Take notice that on November 15, 2010, the City of Pella, Iowa (Complainant) filed a motion to add a document as Exhibit P-28 to its July 2, 2010 petition for declaratory order and formal complaint against Midwest Independent System Operator, Inc. and MidAmerican Energy Company, Inc. (Respondents).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the

¹ Contract Reporting Requirements of Intrastate Natural Gas Companies, Order No. 735, 131 FERC ¶ 61,150 (May 20, 2010).

"eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on December 15, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29848 Filed 11-26-10; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP11-1538-000]

National Gas Supply Association, American Forest and Paper Association, Inc., American Public Gas Association, Independent Petroleum Association of America, Process Gas Consumers Group; Notice of Petition

November 19, 2010.

Take notice that on November 17, 2010, the Natural Gas Supply Association, American Forest and Paper Association, Inc., American Public Gas Association, Independent Petroleum Association of America, and Process Gas Consumers Group (collectively, the Associations), filed in Docket No. RP11-1538-000, a petition pursuant to Rule 207(a)(5) of the Commission's Rules of Practice and Procedure, requesting that the Commission exercise its authority under section 5 of the Natural Gas Act to enforce its policy regarding pipeline reservation charge crediting during outages and order pipelines to amend their tariffs in accordance with Commission policy.

Specifically, the Associations ask the Commission to ensure that: (1) All pipelines incorporate into their tariffs an acceptable sharing mechanism that allows for partial reservation charge credits during outages that are due to unexpected and uncontrollable *force*

majeure events, and (2) all pipeline tariffs require full reservation charge credits to shippers during outages that are not due to unexpected and uncontrollable *force majeure* events.

Any person desiring to intervene or to protest in this proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 8, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-29859 Filed 11-26-10; 8:45 am]
BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-OAR-2007-0093, FRL-9232-8]

Agency Information Collection Activities; Proposed Collection; Comment Request; Clean Air Act Tribal Authority, EPA ICR No. 1676.05, OMB Control No. 2060-0306

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR is scheduled to expire on 05/31/2011. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before January 28, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-OAR-2007-0093 identified by the Docket ID numbers provided for each item in the text, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- *E-mail:* a-and-r-Docket@epa.gov.
- *Fax:* 202-566-9744.

- *Mail:* Clean Air Act Tribal Authority, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460

- *Hand Delivery:* EPA Docket Center, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-OAR-2007-0093. 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 e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov> your e-mail 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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 EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

FOR FURTHER INFORMATION CONTACT: Danielle Dixon, Office of Air and Radiation, Office of Air Quality Planning and Standards, Outreach & Information Division, (C304-01), Environmental Protection Agency, 109 TW Alexander Dr., Durham, NC 27707; telephone number: 919-541-0028; fax number: 919-541-0072; e-mail address: dixon.danielle@epa.gov.

SUPPLEMENTARY INFORMATION:

How can I access the docket and/or submit comments?

EPA has established a public docket for this ICR under Docket ID No. EPA-OAR-2007-0093, which is available for online viewing at <http://www.regulations.gov>, or in person viewing at the Clean Air Act Tribal Authority Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 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 Clean Air Act Tribal Authority Docket is 202-566-1742.

Use <http://www.regulations.gov> to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in

the docket ID number identified in this document.

What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits 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. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under **DATES**.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What information collection activity or ICR does this apply to?

Docket ID No. EPA-OAR-2007-0093; FRL 8336-3.

Affected entities: Entities potentially affected by this action are State, local or Tribal governments.

Title: Clean Air Act Tribal Authority.
ICR numbers: EPA ICR No. 1676.05, OMB Control No. 2060-0306.

ICR status: This ICR is currently scheduled to expire on 05/31/2011. 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 OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This Information Collection Request (ICR) seeks authorization for Tribes to demonstrate their eligibility to be treated in the same manner as States under the Clean Air Act (CAA) and to submit applications to implement a CAA program. This ICR extends the collection period of information for determining eligibility, which expires May 31, 2011. The ICR also is revising the estimates of burden costs for Tribes in completing a CAA application.

The program regulation provides for Indian Tribes, if they so choose, to assume responsibility for the development and implementation of CAA programs. The regulation, Indian Tribes: Air Quality Planning and Management (Tribal Authority Rule [TAR] 40 CFR parts 9, 35, 49, 50 and 81), sets forth how Tribes may seek authority to implement their own air quality planning and management programs. The rule establishes: (1) Which CAA provisions Indian Tribes may seek authority to implement, (2) what requirements the Tribes must meet when seeking such authorization, and (3) what Federal financial assistance may be available to help Tribes establish and manage their air quality programs. The TAR provides Tribes the authority to administer air quality programs over all air resources, including non-Indian owned fee lands, within the exterior boundaries of a reservation and other areas over which the Tribe can demonstrate jurisdiction. An Indian Tribe that takes responsibility for a CAA program would essentially be treated in the same way as a State would be treated for that program.

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 OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 40 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 27.

Frequency of response: One-time application.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 1080.

Estimated total annual costs: \$18,838.80. This includes an estimated burden cost of \$18,838.80 and an estimated cost of \$0 for capital investment or maintenance and operational costs.

Are there changes in the estimates from the last approval?

There is no decrease of hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB.

What is the next step in the process for this ICR?

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 pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you

have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: November 18, 2010.

Jan Cortelyou-Lee,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 2010-29942 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2010-0761; FRL-8854-7]

FIFRA Scientific Advisory Panel; Notice of Change of Meeting Location

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Agency is issuing this notice to change the meeting location of the December 7, 2010 Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) meeting. The FIFRA SAP is meeting to consider and review scientific issues associated with pesticide exposure models and climate change.

DATES: The meeting will be held on December 7, 2010, from 8:30 a.m. to approximately 5 p.m.

ADDRESSES: The meeting will be held at the Hyatt Regency, Tidewater Room Hyatt Regency Crystal City at Reagan National Airport, 2799 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Fred Jenkins, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3327; fax number: (202) 564-8382; e-mail address: jenkins.fred@epa.gov.

SUPPLEMENTARY INFORMATION: All other information provided in the September 29, 2010 (75 FR 60110) **Federal Register** notice remains unchanged.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: November 23, 2010.

Frank Sanders,

Director, Office of Science Coordination and Policy.

[FR Doc. 2010-29982 Filed 11-23-10; 4:15 pm]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2010-0919; FRL-9232-5]

Human Studies Review Board (HSRB); Notification of a Public Teleconference To Review Draft Report From the October 27-28, 2010 HSRB Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Human Studies Review Board (HSRB) announces a public teleconference meeting to discuss its draft report from the October 27-28, 2010 HSRB meeting.

DATES: The teleconference will be held on Monday, December 13, 2010 from 3-5 p.m. (Eastern Time).

Location: The meeting will take place via telephone only.

Meeting Access: For information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least ten business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT**, so that appropriate arrangements can be made.

Procedures for Providing Public Input:

Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in section I, under subsection D, of this notice.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to receive further information should contact Jim Downing at telephone number: (202) 564-2468; fax: (202) 564-2070; e-mail address: downing.jim@epa.gov, or Lu-Ann Kleibacker at telephone number: (202) 564-7189; fax: (202) 564-2070; e-mail address: kleibacker.lu-ann@epa.gov; mailing address: U.S. Environmental Protection Agency, Office of the Science Advisor, Mail Code 8105R, 1200 Pennsylvania Ave., NW., Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA Web site at <http://www.epa.gov/osa/hsrbl/>.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2010-0919, by one of the following methods: <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

E-mail: ORD.Docket@epa.gov.

Mail: ORD Docket, U.S. Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Hand Delivery: EPA Docket Center (EPA/DC), Public Reading Room, Infoterra Room (Room Number 3334), EPA West Building, 1301 Constitution Ave., NW., Washington, DC 20460, Attention Docket ID No. EPA-ORD-2010-0919. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2010-0919. 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 comments 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 e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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. If you send an e-mail comment directly to EPA, without going through <http://www.regulations.gov>, your e-mail 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.

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to persons who conduct or assess human studies on substances regulated by EPA or to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected

by this notice. If you have any questions regarding the applicability of this notice to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I access electronic copies of this document and other related information?

In addition to using www.regulations.gov, you may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

Docket: All documents in the docket are listed in the index under the docket number. Even though it will be listed by title in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Copyright material will be publicly available only in hard copy. Publicly available docket materials are electronically available either through <http://www.regulations.gov> or in hard copy at the ORD Docket, EPA/DC, Public Reading Room, Infoterra Room (Room Number 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, and the telephone number for the ORD Docket is (202) 566-1752.

C. What should I consider as I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you use that support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and **Federal Register** citation.

D. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-ORD-2010-0919 in the subject line on the first page of your request.

1. **Oral comments.** Requests to present oral comments will be accepted up to December 6, 2010. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments at the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via e-mail) to Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, December 6, 2010 in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, public comments may be possible.

2. **Written comments.** Although you may submit written comments at any time, for the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your comments at least five business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, December 6, 2010. You should submit your comments using the instructions in section I, under subsection C, of this notice. In addition, the Agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Lu-Ann Kleibacker or Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit

on the length of written comments for consideration by the HSRB.

E. Background

The EPA Human Studies Review Board will be reviewing its draft report from the October 27–28, 2010 HSRB meeting. The Board may also discuss planning for future HSRB meetings. Background on the October 27–28, 2010 HSRB meeting can be found at **Federal Register** 75 193, 61748 (October 6, 2010) and at the HSRB Web site <http://www.epa.gov/osa/hsrb/>. The October 27–28, 2010 meeting draft report is now available. You may obtain electronic copies of this document and certain other related documents that might be available electronically from the <http://www.regulations.gov> Web site and the HSRB Internet home page at <http://www.epa.gov/osa/hsrb/>. For questions on document availability or if you do not have access to the Internet, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: November 19, 2010.

Paul T. Anastas,
EPA Science Advisor.

[FR Doc. 2010-29814 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9233-2]

Notice of Public Hearing and Extension of Public Comment Period of Draft National Pollutant Discharge Elimination System (NPDES) General Permits for Small Municipal Separate Storm Sewer Systems (MS4)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Public Hearing and Extension of Public Comment Period of Draft NPDES General Permits.

SUMMARY: The Director of the Office of Ecosystem Protection, Environmental Protection Agency—Region 1 (EPA), issued a Notice of Availability of Draft NPDES general permits for discharges from small MS4s to certain waters of the Commonwealth of Massachusetts on November 4, 2010. The draft general permits are the Draft Small MS4 General Permits for Massachusetts Interstate, Merrimack, and South Coastal Watersheds. These three general permits are for the discharge of stormwater from Small MS4s to the waters in these watersheds. The November 4, 2010 notice included information on a public hearing. The notice did not meet the time frames required by 40 CFR 124.10.

Therefore, EPA has rescheduled the hearing and extended the comment permit of the draft permits. Throughout this documents the terms “this permit” and “the permit” will refer to all three general permits.

Information on the draft permits, appendices and fact sheet is available at: http://www.epa.gov/ne/npdes/stormwater/mimsc_sms4.html.

DATES: The public comment period is from the November 4, 2010 to January 21, 2011. Interested persons may submit comments on the draft general permit as part of the administrative record to the EPA—Region 1, at the address given below, no later than midnight January 21, 2011. The general permit shall be effective on the date specified in the **Federal Register** publication of the Notice of Availability of the final general permit. The final general permit will expire five years from the effective date.

ADDRESSES: Submit comments by one of the following methods:

- *E-mail:* Renahan.Kate@epa.gov.
- *Mail:* Kate Renahan, U.S. EPA—Region 1, Office of the Regional Administrator, 5 Post Office Square—Suite 100, Mail Code—ORA01-1, Boston, MA 02109-3912.

No facsimiles (faxes) will be accepted.

The draft permit is based on an administrative record available for public review at EPA—Region 1, Office of Ecosystem Protection, 5 Post Office Square—Suite 100, Boston, Massachusetts 02109-3912. A reasonable fee may be charged for copying requests. The November 4, 2010 Notice of Availability sets forth principal facts and the significant factual, legal, and policy questions considered in the development of the draft permit.

Public Meeting Information: EPA—Region 1 will hold two public meetings to provide information about the draft general permit and its requirements. Each public meeting will include a brief presentation on the draft general permit and a brief question and answer session. Written, but not oral, comments for the official draft permit record will be accepted at the public meetings. Public meetings will be held at the following times and locations:

Thursday—December 2, 2010

Lakeville Public Library (Large Meeting Room), 4 Precinct Street, Lakeville, MA 02347, 10 a.m.

Wednesday—January 12, 2011

Leominster Public Library Community Room, 30 West Street, Leominster, MA 01453, 10 a.m.—11 a.m.

The dates and times of any additional public meetings will be posted on EPA—Region 1's Web site at: http://www.epa.gov/ne/npdes/stormwater/mimsc_sms4.html.

Public Hearing Information: Following the January 12, 2011 public meeting, a public hearing will be conducted in accordance with 40 CFR 124.12 and will provide interested parties with the opportunity to provide written and/or oral comments for the official draft permit record. The public hearing will be held at the following time and location:

Wednesday—January 12, 2011

Leominster Public Library Community Room, 30 West Street, Leominster, MA 01453, 11:30 a.m.—2 p.m.

FOR FURTHER INFORMATION CONTACT:

Additional information concerning the draft permit may be obtained between the hours of 9 a.m. and 5 p.m. Monday through Friday excluding holidays from: Kate Renahan, Office of the Regional Administrator, Environmental Protection Agency, 5 Post Office Square—Suite 100, Mail Code: ORA01-1, Boston, MA 02109-3912; *telephone:* 617-918-1491; *e-mail:* Renahan.Kate@epa.gov.

SUPPLEMENTARY INFORMATION:

Information about the proposed permits including background of the permit and summary of permit conditions was previously published on the November 4, 2010 (75 FR 67960-67962).

Dated: November 19, 2010.

Ira W. Leighton,
Acting Regional Administrator, Region 1.
[FR Doc. 2010-29978 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9232-9]

Science Advisory Board Staff Office; Request for Nominations of Experts for the SAB Polychlorinated Biphenyls (PCBs) Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office is requesting public nominations of experts to form an SAB panel to review EPA's non-cancer health effects assessment for Polychlorinated Biphenyls (PCBs).

DATES: Nominations should be submitted by December 20, 2010 per instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and Request for Nominations may contact Dr. Diana Wong, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564-2049, by fax at (202) 565-2098, or via e-mail at wong.diana-M@epa.gov. General information concerning the EPA Science Advisory Board can be found at the EPA SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION:

Background: Polychlorinated biphenyls (PCBs) have been utilized for various commercial applications, such as insulating fluids, hydraulic and lubricating fluids, heat exchanger fluids, and additives in adhesives and paints. PCBs are widespread in the environment and represent a public health concern.

At present, there are IRIS reference doses (RfDs) for two commercial PCB mixtures: Aroclor 1016 and Aroclor 1254 that were last updated in 1993 and 1994, respectively. EPA's Office of Research and Development (ORD) is developing a draft assessment of the potential noncancer health hazards of complex PCB mixtures for inclusion on EPA's Integrated Risk Information System (IRIS). The new assessment will review current science with the goal of establishing an RfD for application to complex PCB mixtures.

The EPA's National Center for Environmental Assessment (NCEA) has requested the SAB to review ORD's draft assessment of the potential noncancer health hazards of PCBs. The SAB Staff Office will form an expert panel to review the PCBs assessment. The SAB (42 U.S.C. 4365) is a chartered Federal Advisory Committee that provides independent scientific and technical peer review, advice, consultation, and recommendations to the EPA Administrator on the technical basis for EPA actions. As a Federal Advisory Committee, the SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. The SAB Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Request for Nominations: The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise in one or more of the following areas, particularly with respect to PCBs: General toxicology, neurodevelopmental toxicology, immunotoxicology, endocrinology, reproductive toxicology, toxicokinetics, physiologically-based pharmacokinetic

modeling, epidemiology, statistics, dose-response assessment, and risk assessment.

Availability of the review materials: The Polychlorinated Biphenyls (PCBs) noncancer IRIS assessment to be reviewed by the PCBs Review Panel will be available by the Office of Research and Development at the following URL: http://cfpub.epa.gov/ncea/iris_drafts/, and at the SAB Web site <http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/BOARD>. For questions concerning the PCBs Assessment, please contact Dr. Geniece Lehmann of EPA's NCEA by phone (919) 541-2289, fax (919) 541-0245, or e-mail (lehmann.geniece@epa.gov).

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals in the areas of expertise described above for possible service on this expert Panel. Nominations should be submitted in electronic format (which is preferred over hard copy) following the instructions for "Nominating Experts to Advisory Panels and Ad Hoc Committees Being Formed" provided on the SAB Web site. The instructions can be accessed through the "Nomination of Experts" link on the blue navigational bar on the SAB Web site at <http://www.epa.gov/sab>. To receive full consideration, nominations should include all of the information requested below.

EPA's SAB Staff Office requests contact information about the person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's curriculum vita; sources of recent grant and/or contract support; and a biographical sketch of the nominee indicating current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations.

Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB Web site, should contact Dr. Diana Wong, DFO, as indicated above in this notice. Nominations should be submitted in time to arrive no later than December 20, 2010. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

The EPA SAB Staff Office will acknowledge receipt of nominations. The names and bio-sketches of qualified nominees identified by respondents to this **Federal Register** notice, and

additional experts identified by the SAB Staff, will be posted in a List of Candidates on the SAB Web site at <http://www.epa.gov/sab>. Public comments on this List of Candidates will be accepted for 21 calendar days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. In forming this expert panel, the SAB Staff Office will consider public comments on the List of Candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for Panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and, (f) for the Panel as a whole, diversity of expertise and viewpoints.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110-48). This confidential form allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities (which includes membership on an EPA Federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded from the following URL address <http://www.epa.gov/sab/pdf/epaform3110-48.pdf>.

The approved policy under which the EPA SAB Office selects subcommittees and review panels is described in the following document: *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* (EPA-SAB-EC-02-010), which is posted on the SAB

Web site at <http://www.epa.gov/sab/pdf/ec02010.pdf>.

Dated: November 18, 2010.

Anthony Maciorowski,
Deputy Director, EPA Science Advisory Board
Staff Office.

[FR Doc. 2010-29939 Filed 11-26-10; 8:45 am]

BILLING CODE 6560-50-P

EXPORT-IMPORT BANK OF THE U.S.

[Public Notice 2010-0058]

Agency Information Collection Activities: Final Collection; Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB Review
and Comments Request.

Form Title: Application for Approved
Finance Provider (EIB 10-06).

SUMMARY: The Export-Import Bank of
the United States (Ex-Im Bank), as a part
of its continuing effort to reduce
paperwork and respondent burden,
invites the general public and other
Federal Agencies to comment on the
proposed information collection, as
required by the Paperwork Reduction
Act of 1995.

The Application for Approved
Finance Provider will be used to
determine if the finance provider has
the financial strength and
administrative staff to originate,
administer, collect, and if needed,
restructure international loans. This
application will also improve Ex-Im
Bank's compliance with the Open
Government initiative by providing
transparency into specific information
used to determine if an applicant is
qualified to use our loan guarantee
programs. Export-Import Bank potential
finance providers will be able to submit
this form on paper. In the future, we
will consider allowing the submission
of this information electronically.

This application can be viewed at
[http://www.exim.gov/pub/pending/
EIB10_06.pfd](http://www.exim.gov/pub/pending/EIB10_06.pfd).

DATES: Comments should be received on
or before January 28, 2011 to be assured
of consideration.

ADDRESSES: Comments may be
submitted electronically on [http://
www.regulations.gov](http://www.regulations.gov) or by mail to
Jeffrey Abramson, Export-Import Bank
of the United States, 811 Vermont Ave.,
NW., Washington, DC 20571.

SUPPLEMENTARY INFORMATION: *Titles and
Form Number:* EIB 10-06 Application
for Approved Finance Provider.

OMB Number: 3048-xxxx.
Type of Review: New.

Need and Use: The Application for
Approved Finance Provider will be used
to determine the financial and
administrative capabilities of a financial
provider who will arrange, fund and
administer international loans.

Annual Number of Respondents: 50.
Estimated Time per Respondent: 3
hours.

Government Annual Burden Hours: 8
hours.

Frequency of Reporting or Use: As
needed.

Sharon A. Whitt,
Agency Clearance Officer.

[FR Doc. 2010-29909 Filed 11-26-10; 8:45 am]

BILLING CODE 6690-01-P

EXPORT-IMPORT BANK OF THE UNITED STATES

Notice of Open Meeting of the Advisory Committee of the Export- Import Bank of the United States (Ex- Im Bank)

SUMMARY: The Advisory Committee was
established by Public Law 98-181,
November 30, 1983, to advise the
Export-Import Bank on its programs and
to provide comments for inclusion in
the reports of the Export-Import Bank of
the United States to Congress.

TIME AND PLACE: Tuesday, December 14,
2010 from 11 a.m. to 3 p.m. A break for
lunch will be at the expense of the
attendee. Security processing will be
necessary for reentry into the building.
The meeting will be held at Ex-Im Bank
in the Main Conference Room 1143, 811
Vermont Avenue, NW., Washington, DC
20571.

AGENDA: Agenda items include a
briefing of the Advisory Committee
members on challenges for 2011, their
roles and responsibilities and an ethics
briefing.

PUBLIC PARTICIPATION: The meeting will
be open to public participation, and the
last 10 minutes will be set aside for oral
questions or comments. Members of the
public may also file written statement(s)
before or after the meeting. If you plan
to attend, a photo ID must be presented
at the guard's desk as part of the
clearance process into the building, and
you may contact Susan Houser to be
placed on an attendee list. If any person
wishes auxiliary aids (such as a sign
language interpreter) or other special
accommodations, please contact, prior
to December 6, 2010, Susan Houser,
Room 1273, 811 Vermont Avenue, NW.,
Washington, DC 20571. *Voice:* (202)
565-3232.

FURTHER INFORMATION: For further
information, contact Susan Houser.

Room 1273, 811 Vermont Ave., NW.,
Washington, DC 20571, (202) 565-3232.

Jonathan Cordone,
Senior Vice President and General Counsel.
[FR Doc. 2010-29919 Filed 11-26-10; 8:45 am]

BILLING CODE 6690-01-M

EXPORT-IMPORT BANK OF THE UNITED STATES

Sunshine Act Meeting

ACTION: Notice of a Partially Open
Meeting of the Board of Directors of the
Export-Import Bank of the United
States.

TIME AND PLACE: Thursday, December 2,
2010 at 9:30 a.m. The meeting will be
held at Ex-Im Bank in Room 1143, 811
Vermont Avenue, NW., Washington, DC
20571.

OPEN AGENDA ITEM: Item No. 1: Ex-Im
Bank Advisory Committee for 2011.

PUBLIC PARTICIPATION: The meeting will
be open to public observation for Item
No. 1 only.

FURTHER INFORMATION: For further
information, contact: Office of the
Secretary, 811 Vermont Avenue NW.,
Washington, DC 20571 (Tele. No. 202-
565-3957)

Jonathan J. Cordone,
Senior Vice President and General Counsel.
[FR Doc. 2010-29918 Filed 11-26-10; 8:45 am]

BILLING CODE 6690-01-M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

November 18, 2010.

SUMMARY: The Federal Communications
Commission, as part of its continuing
effort to reduce paperwork burden
invites the general public and other
Federal agencies to take this
opportunity to comment on the
following information collection(s), as
required by the Paperwork Reduction
Act (PRA) of 1995, 44 U.S.C. 3501-3520.
Comments are requested concerning: (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
burden estimate; (c) ways to enhance
the quality, utility, and clarity of the
information collected; (d) ways to
minimize the burden of the collection of
information on the respondents.

including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently 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 (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before January 28, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or via Internet at Nicholas_A_Fraser@omb.eop.gov and to the Federal Communications Commission. To submit your PRA comments by e-mail send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:
OMB Control Number: 3060-0056.
Title: Part 68, Connection of Terminal Equipment to the Telephone Network.
Form No.: N/A.
Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 58,310 respondents; 68,077 responses.

Estimated Time per Response: .05 hours to 24 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in the 47 U.S.C. sections 151-154, 201-205, and 303(r).

Total Annual Burden: 21,369 hours.

Total Annual Cost: \$935,000.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality:

The information respondents are requested to provide is not proprietary, trade secret or other confidential information. Applicants are advised not to submit proprietary signal processing or control circuitry not directly involved with Part 68 requirements.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this comment period to obtain the full, three year clearance from them. The Commission is not changing any of the reporting, recordkeeping and/or third party disclosure requirements. The Commission is reporting a 10,658 hourly decrease in burden and a \$225,000 decrease in annual costs. This adjustment is due to 12,140 fewer respondents.

The purpose of 47 CFR Part 68 is to protect the telephone network from certain types of harm and prevent interference to subscribers. To demonstrate that terminal equipment

comply with criteria for protecting the network; and to ensure that consumers, providers of telecommunications, the Commission and others are able to trace products to the party responsible for placing terminal equipment on the market, it is essential to require manufacturers or other responsible parties to provide the information required by Part 68. In addition, incumbent local exchange carriers (ILECS) must provide the information in Part 68 to warn their subscribers of impending disconnection of service when the subscriber terminal equipment is causing telephone network harm.

There are sixteen specific reporting, recordkeeping and/or third party disclosure requirements under this OMB control number. Part 68 also establishes the right of consumers to use competitively provided inside wiring.

Marlene H. Dortch,

Secretary, Federal Communications Commission.

[FR Doc. 2010-29816 Filed 11-26-10; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; Open Commission Meeting

November 30, 2010.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Tuesday, November 30, 2010, which is scheduled to commence at 10:30 a.m. in Room TW-C305, at 445 12th Street, SW., Washington, DC.

Item No.	Bureau	Subject
1	OFFICE OF ENGINEERING AND TECHNOLOGY.	TITLE: Innovation in the Broadcast Television Bands: Allocations, Channel Sharing and Improvements to VHF. SUMMARY: The Commission will consider a Notice of Proposed Rulemaking seeking comment on rules to facilitate the most efficient use of the UHF and VHF TV bands. These proposals, an important step toward the agency's spectrum goals as outlined in the National Broadband Plan, would take steps to enable mobile broadband use within spectrum currently reserved for use by TV broadcasters, including through innovations such as channel sharing and generating increased value within the VHF band.
2	OFFICE OF ENGINEERING AND TECHNOLOGY.	TITLE: Promoting Expanded Opportunities for Radio Experimentation and Market Studies under Part 5 of the Commission's Rules and Streamlining Other Related Rules; 2006 Biennial Review of Telecommunications Regulations—Part 2 Administered by the Office of Engineering and Technology (OET) (ET Docket No. 06-105). SUMMARY: The Commission will consider a Notice of Proposed Rulemaking seeking comment on steps to promote innovation and efficiency in spectrum use under Part 5 Experimental Radio Service (ERS).
3	OFFICE OF ENGINEERING AND TECHNOLOGY AND WIRELESS TELECOMMUNICATIONS.	TITLE: Promoting More Efficient Use of Spectrum Through Dynamic Spectrum Use Technologies. SUMMARY: The Commission will consider a Notice of Inquiry seeking comment on promoting more intensive and efficient use of the radio spectrum, thereby potentially enabling more effective spectrum management, through dynamic spectrum use technologies.

Item No.	Bureau	Subject
4	CONSUMER AND GOVERNMENTAL AFFAIRS.	The Bureau will present an overview of the Twenty First Century Communications and Video Accessibility Act, Public Law 111-260, the Commission's implementation plans, and demonstrate accessibility technologies.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an e-mail to: fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Additional information concerning this meeting may be obtained from Audrey Spivack or David Fiske, Office of Media Relations, (202) 418-0500; TTY 1-888-835-5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at <http://www.fcc.gov/live>.

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services call (703) 993-3100 or go to <http://www.capitolconnection.gmu.edu>.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, Best Copy and Printing, Inc. (202) 488-5300; Fax (202) 488-5563; TTY (202) 488-5562. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio and video tape. Best Copy and Printing, Inc. may be reached by e-mail at FCC@BCPIWEB.com.

Marlene H. Dortch,
Secretary, Federal Communications Commission.

[FR Doc. 2010-30169 Filed 11-24-10; 4:15 pm]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes

and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank 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 BHC Act (12 U.S.C. 1842(c)). 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 4 of the BHC Act (12 U.S.C. 1843). 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 December 9, 2010.

A. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105-1579:

1. *Franklin Resources, Inc.*, San Mateo, California; to acquire additional voting shares of First Chicago Bancorp, and thereby indirectly acquire voting shares of First Chicago Bank & Trust, both of Chicago, Illinois.

Board of Governors of the Federal Reserve System, November 24, 2010.

Robert deV. Frierson,
Deputy Secretary of the Board.

[FR Doc. 2010-30050 Filed 11-26-10; 8:45 am]
BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Misconduct in Science

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Bengu Sezen, Ph.D., Columbia University: Based on the findings of an investigation by Columbia University (CU) and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, ORI found that Bengu Sezen, former graduate student, Department of Chemistry, CU, engaged in misconduct in science in research funded by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM60326.

Specifically, ORI made twenty-one (21) findings of scientific misconduct against Dr. Sezen based on evidence that she knowingly and intentionally falsified and fabricated, and in one instance plagiarized, data reported in three (3) papers¹ and her doctoral thesis.

The following administrative actions have been implemented for a period of five (5) years, beginning on November 4, 2010:

(1) Dr. Sezen is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government, referred to as "covered transactions," pursuant to HHS' Implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR 376 *et seq.*); and

(2) Dr. Sezen is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

¹ Sezen, B., Franz, R., & Sames, D. "C-C bond formation via C-H bond activations: Catalytic arylation and alkenation of alkane segments." *J. Am. Chem. Soc.* 124:13372-13373, 2002. Retracted in *J. Am. Chem. Soc.* 128:8364, 2006.

Sezen, B. & Sames, D. "Oxidative C-arylation of free (NH)-heterocycles via direct (sp³) C-H bond functionalization." *J. Am. Chem. Soc.* 126:13244-13246, 2004. Retracted in *J. Am. Chem. Soc.* 128:3102, 2006.

Sezen, B. & Sames, D. "Selective and catalytic arylation of N-phenylpyrrolidine: sp³ C-H bond functionalization in the absence of a directing group." *J. Am. Chem. Soc.* 127:5284-5285, 2005. Retracted in *J. Am. Chem. Soc.* 128:3102, 2006.

FOR FURTHER INFORMATION CONTACT:
Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

John Dahlberg,
Director, Division of Investigative Oversight,
Office of Research Integrity.

[FR Doc. 2010-29867 Filed 11-26-10; 8:45 am]

BILLING CODE 4150-31-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP): Office of Liaison, Policy, and Review; Availability of Draft NTP Technical Reports; Request for Comments; Announcement of a Panel Meeting to Peer Review Draft NTP Technical Reports

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Availability of Draft Reports; Request for Comments; and Announcement of a Meeting.

SUMMARY: The NTP announces the availability of draft NTP Technical Reports (TRs; available at <http://ntp.niehs.nih.gov/go/36051>) that will be peer-reviewed by an NTP Technical Reports Peer Review Panel at a meeting on January 26, 2011. The meeting is open to the public with time scheduled for oral public comment. The NTP also invites written comments on the draft reports (see "Request for Comments" below). Summary minutes from the peer review will be posted on the NTP Web site following the meeting.

DATES: The meeting to review the draft NTP TRs will be held on January 26, 2011. The draft NTP TRs will be available for public comment by December 8, 2010. The deadline to submit written comments is January 12, 2011, and the deadline for pre-registration to attend the meeting and/or provide oral comments at the meeting is January 19, 2011.

ADDRESSES: The meeting will be held at the Rodbell Auditorium, Rall Building, NIEHS, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709. Public comments and any other correspondence on the draft TRs should be sent to Dr. Lori White, NIEHS, P.O. Box 12233, MD K2-03, Research Triangle Park, NC 27709, FAX: (919) 541-0295, or whiteltd@niehs.nih.gov. Courier address: 530 Davis Drive, Room 2136, Morrisville, NC 27560. Persons needing interpreting services in order to

attend should contact (301) 402-8180 (voice) or (301) 435-1908 (TTY). Requests should be made at least seven business days in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, NTP Designated Federal Officer, (919) 541-9834, whiteltd@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Preliminary Agenda Topics and Availability of Meeting Materials

The agenda topic is the peer review of the findings and conclusions of draft NTP TRs of toxicology and carcinogenicity studies. The preliminary agenda listing the draft reports and electronic files (PDF) of the draft reports should be posted on the NTP Web site by December 8, 2010. Any additional information, when available, will be posted on the NTP Web site (<http://ntp.niehs.nih.gov/go/36051>) or may be requested in hardcopy from the Designated Federal Officer (see **ADDRESSES** above). Following the meeting, summary minutes will be prepared and made available on the NTP Web site. Information about the NTP testing program is found at <http://ntp.niehs.nih.gov/go/test>.

Attendance and Registration

The meeting is scheduled for January 26, 2011, from 8:30 a.m. EST to adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the NTP Web site (<http://ntp.niehs.nih.gov/go/36051>) by January 19, 2011, to facilitate access to the NIEHS campus. A photo ID is required to access the NIEHS campus. The NTP is making plans to videocast the meeting through the Internet at <http://www.niehs.nih.gov/news/video/live>. Registered attendees are encouraged to access the meeting page to stay abreast of the most current information regarding the meeting.

Request for Comments

The NTP invites written comments on the draft reports, which should be received by January 12, 2011, to enable review by the panel and NTP staff prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, e-mail, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP Web site, and the submitter will be identified by name, affiliation, and/or sponsoring organization.

Public input at this meeting is also invited, and time is set aside for the presentation of oral comments on the draft reports. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The available lines will be open from 8:00 AM until adjournment on January 26, although public comments will be received only during the formal public comment periods indicated on the preliminary agenda. Each organization is allowed one time slot per draft report. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the chair. Persons wishing to make an oral presentation are asked to notify Dr. Lori White via online registration at <http://ntp.niehs.nih.gov/go/166>, phone, or e-mail (see **ADDRESSES** above) by January 19, 2011, and if possible, to send a copy of the statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register on-site.

Background Information on NTP Peer Review Panels

NTP panels are technical, scientific advisory bodies established on an "as needed" basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. Previously, a subcommittee of the NTP Board of Scientific Counselors provided peer review of draft NTP Technical Reports. The subcommittee has been discontinued and peer review of the draft reports will now be conducted by peer review panels. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide a current *curriculum vita* to Dr. Lori White (see **ADDRESSES**). The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended.

The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: November 18, 2010.

John R. Bucher,
Associate Director, National Toxicology Program.

[FR Doc. 2010-29945 Filed 11-26-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4154-PN]

Medicare and Medicaid Programs; Renewal of Deeming Authority of the National Committee for Quality Assurance for Medicare Advantage Health Maintenance Organizations and Local Preferred Provider Organizations

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application to renew the Medicare Advantage Deeming Authority of the National Committee for Quality Assurance (NCQA) for Health Maintenance Organizations and Preferred Provider Organizations for a term of 4 years. The new term of approval would begin October 19, 2010, and would end October 18, 2014. In addition, this proposed notice announces a 30-day public comment period on the renewal of the application.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 28, 2011.

ADDRESSES: In commenting, please refer to file code CMS-4154-PN. 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-4154-PN, P.O. Box 8010, Baltimore, MD 21244-1850.

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-4154-PN, 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) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments 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: Caroline L. Baker (410) 786-0116.

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.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a Medicare Advantage (MA) organization that contracts with the Centers for Medicare & Medicaid Services (CMS). The regulations specifying the Medicare requirements that must be met in order for an Medicare Advantage Organization (MAO) to enter into a contract with CMS are located at 42 CFR part 422. These regulations implement Part C of Title XVIII of the Social Security Act (the Act), which specifies the services that an MAO must provide and the requirements that the organization must meet to be an MA contractor. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI of the Act pertaining to the provision of services by Medicare certified providers and suppliers.

Generally, for an entity to be an MA organization, the organization must be licensed by the State as a risk bearing organization as set forth in Part 422 of our regulations.

To assure compliance with certain Medicare requirements, an MA organization may choose to become accredited by a CMS approved accrediting organization (AO). By doing so, the MA organization may be "deemed" compliant in one or more of 6 requirements set forth in section 1852(e)(4)(B) of the Act. In order for an AO to be able to "deem" an MA plan as compliant with these MA requirements, the AO must prove to CMS that its standards are at least as stringent as Medicare requirements. MA organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved accrediting organization may receive, at their request, deemed status for CMS requirements in the following six MA survey areas: (1) Quality Improvement, (2) Antidiscrimination, Access to Services, (3) Confidentiality and Accuracy of Enrollee Records, (4) Information on Advanced Directives, and Provider Participation Rules. (See 42 CFR 422.156(b).) We note that at this

time, deeming does not include the Part D areas of review listed in § 422.156(b).

Organizations that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As we specified in § 422.157(b)(2), the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO must renew their application with CMS.

The National Committee for Quality Assurance (NCQA) was approved as an accrediting organization for MA deeming of HMOs from January 19, 2002 through January 18, 2008. The NCQA was reappraised as an accrediting organization for MA deeming of HMOs on January 18, 2008, for a term of 6 years, which was set to expire on January 17, 2014.

The NCQA was approved for MA deeming of PPOs from October 20, 2004 through October 19, 2010. On July 20, 2010, the NCQA submitted an application to renew their deeming authority which, at the request of CMS for administrative simplification purposes, combined their HMO and PPO deeming authority. On July 20, 2010, the NCQA also submitted all of the prerequisite materials as specified in § 422.158(a) for receiving CMS deeming program approval. This information was previously submitted to CMS by NCQA as a part of their initial HMO and PPO applications.

II. Approval of Deeming Organizations

Section 1852(e)(4)(C) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. At the end of the 210 day period, we must publish an approval or denial of the application in the **Federal Register**.

III. Evaluation of Deeming Authority Request

As set forth in § 1852(e)(4) of the Act and our regulations at § 422.158, the review and evaluation of NCQA's accreditation program (including its standards and monitoring protocol) were compared to the requirements set forth in part 422 for the MA program.

A. Components of the Review Process

The review of NCQA's application for approval of MA deeming authority included the following components:

- The types of MA plans that it would review as part of its accreditation process.

- A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

- Detailed information about the organization's survey process, including—

- ++ Frequency of surveys and whether surveys are announced or unannounced.

- ++ Copies of survey forms, and guidelines and instructions to surveyors.

- ++ Description of the survey review process and the accreditation status decision making process;

- ++ The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

- ++ The procedures used to enforce compliance with accreditation requirements.

- Detailed information about the individuals who perform surveys for the accreditation organization, including—

- ++ The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process.

- ++ The education and experience requirements surveyors must meet.

- ++ The content and frequency of the in-service training provided to survey personnel.

- ++ The evaluation systems used to monitor the performance of individual surveyors and survey teams.

- The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

- A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

- A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

- A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

- A description of all types (for example, full and partial) and categories

(for example, provisional, conditional, and temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

- A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

- A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

- The name and address of each person with an ownership or control interest in the accreditation organization.

- The NCQA's past performance in the deeming program and results of recent deeming validation reviews, or look-behind audits conducted as part of continuing Federal oversight of the deeming program under § 422.157(d).

B. Results of the Review Process

Using the information listed in section III.A. of this proposed notice, we determined that NCQA's current accreditation program for HMO and PPO MA plans continues to be at least as stringent as the MA requirements contained in the six categories specified in section 1852(e)(4)(C) of the Act and our methods of evaluation for those areas.

IV. Response to Public Comments and Notice Upon Completion of Evaluation

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 notice, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. 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 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 18, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010-29959 Filed 11-26-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS-2332-PN]

Medicare Program; Application by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for Deeming Authority for Providers of Outpatient Physical Therapy and Speech-Language Pathology Services.

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of a deeming application from the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for recognition as a national accrediting organization for providers of outpatient physical therapy and speech-language pathology services that wish to participate in the Medicare or Medicaid programs. Section 1865(a)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, the Secretary of the Department of Health and Human Services publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m., on December 29, 2010.

ADDRESSES: In commenting, please refer to file code CMS-2332-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.regulations.gov>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2332-PN, P.O. Box 8010, Baltimore, MD 21244-8010.

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 (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2332-PN, 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 (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH 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.)

Comments 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: L. Alexis Prete, (410) 786-0375.

Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-2332-PN and the specific "issue identifier" that precedes the section on which you choose to comment.

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>. Click on the link "Electronic Comments on CMS Regulations" 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.

I. Background

Under the Medicare program, eligible beneficiaries may receive outpatient physical therapy services (OPT) from a provider of services, a clinic, a rehabilitation agency, 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 (collectively, "organizations"), provided certain requirements are met. Section 1861(p)(4) of the Social Security Act (the Act) establishes distinct criteria for organizations seeking approval to provide OPT services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. Our regulations at 42 CFR part 485, subpart H specify the conditions that an organization providing OPT services must meet in order to participate in the Medicare program.

Generally, in order to enter into a provider agreement with the Medicare program, an organization offering OPT services must first be certified by a State survey agency as complying with the applicable conditions or requirements set forth in part 42 CFR part 485.

Thereafter, the organization is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

There is an alternative, however, to State certification and surveys by State agencies, as a means to enter into a Medicare provider agreement. Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a national accrediting organization approved by the Secretary, that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions of participation. The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every six years or sooner, as determined by the Secretary.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's Requirements consider, among other factors, the applying accrediting organization's:

Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide the Secretary with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that the Secretary publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. The Secretary has 210 days from the receipt of a complete

application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AAAASF's request for deeming authority for organizations providing OPT services. This notice also solicits public comment on whether AAAASF's requirements meet or exceed the Medicare conditions for participation for such organizations.

III. Evaluation of Deeming Authority Request

AAAASF submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for organizations providing OPT services. This application was determined to be complete on October 15, 2010. Under Section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAASF's standards for an organization providing OPT services, as compared with CMS' OPT organizations' conditions of participation.

- AAAASF's survey process to determine the following:

- The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- The comparability of AAAASF's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- AAAASF's processes and procedures for monitoring OPTs found out of compliance with the AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency will monitor corrections as specified at § 488.7(d).

- AAAASF's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- AAAASF's capacity to provide the Secretary with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- The adequacy of AAAASF's staff and other resources, and its financial viability.

- AAAASF's capacity to adequately fund required surveys.

- AAAASF's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

- AAAASF's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

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.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. 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 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 17, 2010.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010-29966 Filed 11-26-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3235-N]

Medicare Program; Listening Session on Development of Additional Imaging Efficiency Measures for Use in the Hospital Outpatient Quality Data Reporting Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a listening session to receive comments regarding the development of additional imaging efficiency measures for use in the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), which is authorized under section 1833(t)(17) of the Social Security Act. The purpose of this listening session is to solicit input from stakeholders to identify additional potential imaging efficiency measures that CMS could consider. Measure developers, hospitals, medical specialty societies, medical professionals, and other interested stakeholders are invited to participate either in person or via teleconference. The meeting is open to the public, but attendance is limited to space and teleconference lines available.

DATES: *Meeting Date:* The Listening Session announced in this notice will be held on Monday, January 31, 2011 from 1 p.m. to 5 p.m. Eastern Standard Time (E.S.T.).

Deadline for Meeting Registration and Request for Special Accommodations: Registration opens on January 7, 2011. For security reasons, registration must be completed by 5 p.m. E.S.T. on January 25, 2011. Requests for special accommodations must be received by 5 p.m. E.S.T. on January 25, 2011.

Deadline for Submission of Written Comments or Statements: Written comments or statements on the issues that were discussed at the listening session may be sent via mail, fax, or electronically to the address specified in the **ADDRESSES** section of this notice and must be received by 5 p.m. E.S.T. on February 10, 2011.

ADDRESSES: *Meeting Location:* The Listening Session will be held in the main auditorium of the Central Building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Registration and Special Accommodations: Persons interested in attending the meeting or participating

by teleconference must register by completing the on-line registration. For in person attendance registration is available via the Web site at <http://www.cms.gov/apps/events/event.asp?id=622>. Individuals who require special accommodations should send a request via e-mail to imagingmeasures@cms.hhs.gov or by regular mail to Imaging Measures/OCSQ/QMHAG at Centers for Medicare & Medicaid Services, Mail Stop S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850. For individuals interested in participating via teleconference, registration is available via the Web site at <https://www.magnetmail.net/events?cf4db6967a514fb681832e700ee3e5b0a>. Individuals are encouraged to register early as there are a limited number of spaces available for in person attendance, as well as a limited number of conference call lines for the listening session.

Written Comments or Statements: Any interested party may send written comments or statements by mail to Imaging Measures/OCSQ/QMHAG, Centers for Medicare & Medicaid Services, Mail Stop S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850; by e-mail to imagingmeasures@cms.hhs.gov; or by fax to 410-786-8532.

We will accept written testimony, questions, or other statements, not to exceed 5 single-spaced, typed pages, before the meeting, and up until 5 p.m. E.S.T. on February 10, 2011. Submitters of suggestions for new measures are requested to provide references to the evidence base supporting the suggested measures.

FOR FURTHER INFORMATION CONTACT: Susan Arday, (410) 786-3141. Eva Fung, (410) 786-7539.

You may also send inquiries about this listening session via e-mail to susan.arday@cms.hhs.gov or eva.fung@cms.hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

Section 1833(t)(17) of the Social Security Act (Act) requires that hospitals submit outpatient quality measures data to CMS in order to receive the full annual payment update factor applicable to Outpatient Prospective Payment System (OPPS) services furnished by hospitals in outpatient settings. Section 1833(t)(17)(E) of the Act further mandates that CMS make this data available to the public. CMS, therefore, has established the Hospital Outpatient Quality Data Reporting Program (HOP

QDRP). Beginning with the CY 2010 OPPS payment update, CMS adopted the following four claims-based imaging measures—(1) OP-8: MRI Lumbar Spine for Low Back Pain; (2) OP-9: Mammography Follow-up Rates; (3) OP-10: Abdomen CT Use of Contrast Material; and (4) OP-11: Thorax CT Use of Contrast Material.

These measures are claims-based and are calculated using Medicare claims data without imposing upon hospitals the burden of having to abstract the data from charts.

In the CY 2011 OPPS/ASC final rule published on November 24, 2010 (75 FR 71800) for the CY 2012 payment determination and subsequent payment determinations, CMS adopted three additional imaging efficiency measures—(1) Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery; (2) Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT); and (3) Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

Public reporting of imaging efficiency measures are important because of the health risks and financial implications associated with the use of imaging procedures in the Medicare beneficiary population. Research shows that a significant portion of imaging services received by patients may be inappropriate; and immoderate use of diagnostic imaging also contributes to inflated medical technology costs. The imaging efficiency measures fill a significant gap in the availability of imaging efficiency measures at the hospital outpatient facility level and are a seminal step in the promotion of more efficient imaging services provided to Medicare beneficiaries.

This listening session will be hosted to solicit input from professionals and other interested parties on the development of additional imaging efficiency measures for the HOP QDRP program. Potential topics for consideration will include:

- Other imaging procedures that would be appropriate candidates for imaging efficiency measures;
- Data sources appropriate for imaging efficiency measures, e.g. claims data, chart abstracted data, EHRs, use of registries, etc.;
- Other settings appropriate for imaging efficiency measures, in addition to outpatient hospitals; and
- Development of imaging measures using a diagnosis or condition based approach versus measures developed using a procedure specific basis.

Relevant recommendations should include feedback on the integration of the imaging efficiency measures into the overall HOP QDRP program.

II. Listening Session Format

The listening session will be held on January 31, 2011. Measure developers, hospitals, medical specialty societies, medical professionals, and other interested stakeholders are invited to participate in person or by teleconference. The session will begin at 1 p.m. E.S.T. with an overview of objectives for the session. The remainder of the meeting will be devoted to receiving input on additional imaging efficiency measures and their integration into the overall HOP QDRP program. The meeting will conclude by 5 p.m. E.S.T.

Participants will be permitted to speak in the order in which they sign up. Participants are encouraged to provide references to the evidence base supporting their suggested measures. Comments from individuals not registered to speak will be heard after scheduled statements only if time permits.

III. Registration Instructions

For security reasons, any persons wishing to attend this meeting must register by the date listed in the **DATES** section of this notice. Persons interested in attending the meeting must register by completing the on-line registration via the designated Web site <http://www.cms.gov/apps/events/event.asp?id=622>.

The on-line registration system will generate a confirmation page to indicate the completion of your registration. Please print this page as your registration receipt.

Individuals may also participate in the listening session by teleconference. For individuals interested in participating via teleconference, registration is available via the Web site at <https://www.magnetmail.net/events?cf4db6967a514fb681832e700ee3e5b0a>. Registration is required as the number of call-in lines will be limited.

Background information on the listening session will be posted on the QualityNet Web site at <http://www.qualitynet.org> prior to the session. The information will be posted under the tab for "Hospitals Outpatient," then select "Inaging Efficiency Measures" from the drop-down menu. We anticipate posting an audio download and/or transcript of the listening session in the same location on <http://www.qualitynet.org> after completion of the listening session.

Individuals requiring sign language interpretation or other special accommodations must contact the staff via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. The on-site check-in for visitors will begin at 12 noon E.S.T. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, including items such as laptops, cell phones, and palm pilots, are subject to physical inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for a presentation.

We note that individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 60 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 18, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 2010-29995 Filed 11-26-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1342-N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2012 Applications for Add-on Payments for New Medical Services and Technologies Under the Hospital Inpatient Prospective Payment System and Informational Workshop on the Application Process and Criteria for Add-on Payments for New Medical Services and Technologies Under the Inpatient and Outpatient Prospective Payment Systems

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting in accordance with section 1886(d)(5)(K)(viii) of the Social Security Act (the Act) to discuss fiscal year (FY) 2012 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2012 new medical services and technologies applications meet the substantial clinical improvement criterion.

Additionally, we will hold an Informational Workshop for all interested parties on the application process and criteria for add-on payments for new medical services and technologies under the IPPS and the application processes for the outpatient prospective payment system (OPPS) transitional pass-through payment for drugs, biological, and devices and new technology ambulatory payment classification (APC) group assignments for new services.

DATES: Meeting Date: Both the Town Hall Meeting and Informational Workshop announced in this notice will be held on Wednesday, February 2, 2011. The Informational Workshop will begin at 9 a.m., and check-in will begin at 8:30 a.m. eastern standard time (e.s.t.). The Town Hall Meeting will begin at 1 p.m. e.s.t. and check-in will begin at 12:30 p.m. e.s.t. Only one check-in is required to enter the building. Participants attending the Informational Workshop will be able to attend the Town Hall meeting without an additional check-in unless they exit the building. In this case, a participant will need to repeat the security

procedures and check-in again for the Town Hall Meeting.

Deadline for Registration of Presenters of the Town Hall Meeting: All presenters for the Town Hall Meeting, whether attending in person or by phone, must register and submit their agenda item(s) by January 19, 2011.

Deadline for Registration of All Other Participants for the Town Hall Meeting and the Informational Workshop and Submitting Requests for Special Accommodations: All other participants must register by January 24, 2011. Requests for special accommodations must be received no later than 5 p.m., e.s.t. on January 24, 2011.

Deadline for Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Written comments and agenda items for discussion at the Town Hall Meeting must be received by January 19, 2011. In addition to materials submitted for discussion at the Town Hall Meeting, individuals may submit other written comments, as specified in the ADDRESSES section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by February 16, 2011, for consideration before publication of the FY 2012 IPPS proposed rule.

ADDRESSES: Meeting Location: The Town Hall Meeting and Informational Workshop will both be held in the main Auditorium in the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Registration and Special Accommodations: Individuals wishing to participate in the meeting must register by following the on-line registration instructions located in section III. of this notice or by contacting staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Registration information and special accommodation requests may also be mailed to the address listed in the **ADDRESSES** section of this notice.

Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2012 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via e-mail to newtech@cms.hhs.gov or sent via regular mail to:

Division of Acute Care, New Technology Team, Mailstop C4-08-06,

Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore Maryland 21244-1850, Attention: Michael Treitel or Celeste Beauregard.

FOR FURTHER INFORMATION CONTACT:

Michael Treitel, (410) 786-4552, michael.treitel@cms.hhs.gov, or Celeste Beauregard, (410) 786-8102, celeste.beauregard@cms.hhs.gov. Alternatively, you may forward your requests via e-mail to newtech@cms.hhs.gov or regular mail as specified in the **ADDRESSES** section of this notice.

SUPPLEMENTARY INFORMATION:

I. Background on the Add-On Payments for New Medical Services and Technologies Under the IPPS

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the inpatient hospital prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered "new" if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the FY 2002 proposed rule (66 FR 22693, May 4, 2001) and final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.)

In the September 7, 2001 final rule (66 FR 46914), we noted that we evaluate a request for special payment for a new medical service or technology against the following criteria in order to determine if the new technology meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a patient.

- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

- ++ Reduced mortality rate with use of the device.
- ++ Reduced rate of device-related complications.
- ++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- ++ Decreased number of future hospitalizations or physician visits.
- ++ More rapid beneficial resolution of the disease process treatment because of the use of the device.
- ++ Decreased pain, bleeding, or other quantifiable symptoms.
- ++ Reduced recovery time.

In addition, we indicated that the requester is required to submit evidence that the technology meets one or more of these criteria.

Section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1886(d)(5)(K)(viii) of the Act to revise the process for evaluating new medical services and technology applications by requiring the Secretary to do the following:

- Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.
- Make public and periodically update a list of all the services and technologies for which an application is pending.
- Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.
- Provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS as to whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and alternatives provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2012. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2012 IPPS proposed rule.

II. Town Hall Meeting and Informational Workshop Formats and Conference Calling Information

A. Format of the Town Hall Meeting

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial improvement. This meeting will allow for a discussion of the substantial clinical improvement criteria on each of the FY 2012 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register and grouped by new technology applicant. Therefore, individuals who would like to present must register and submit their agenda item(s) to the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. Comments from participants will be heard after scheduled statements if time permits. Once the agenda is completed, it will be posted on the CMS IPPS Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.

In addition, written comments will also be accepted and presented at the meeting if they are received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the proposed rule, the comments must be received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice.

B. Informational Workshop Format

In addition to the statutorily-required Town Hall Meeting on whether an IPPS new technology application meets the substantial clinical improvement criteria, we will be holding an

Informational Workshop on applying for special payment for new medical services and technologies under the IPPS and OPSS. Specifically, for new technology add-on payments under the IPPS, we will discuss each criterion in detail along with other information that will be helpful in guiding an applicant through the new technology add-on payment process. We will also discuss the processes of diagnosis-related group (DRG) assignment and requesting new ICD-9-CM codes under the IPPS. (Information on DRGs can be found on the IPPS Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp#TopOfPage and information on ICD-9-CM coding can be found on our Web site at <http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/>).

In addition, to facilitate the public's knowledge of the OPSS application processes for transitional pass-through status of drugs, biologicals, and devices and assignment of new services to new technology ambulatory payment classification (APC) groups, the Informational Workshop will also include information on several processes for applying for special payment under the OPSS. One topic concerns the process for applying for a new category of devices for pass-through payment and criteria for evaluation. Interested parties may apply for a new device category, in accordance with section 1833(t)(6) of the Act. As background information, we have posted application and process background information on our Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage.

Furthermore, under section 1833(t)(6) of the Act interested parties may also apply for transitional pass-through payment for certain new drugs and biologicals. As background information, we have posted application and process background information on our Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage.

Finally, we provide the opportunity for the public to apply for new services to be placed in new technology APC groups in the OPSS, in accordance with our criteria and discussion in our November 30, 2001 final rule (66 FR 9897 through 59903). As background information, we have posted application and process background information on our Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage. We plan to discuss all three of these OPSS application processes at the

Informational Workshop that will be held on February 2, 2011.

The Informational Workshop is open to all interested parties including organizations representing hospitals, physicians, and manufacturers. We encourage all interested parties to attend, especially those who are not familiar with these processes. Individuals who want to attend this Informational Workshop must register by the date specified in the **DATES** section of this notice. Registration information is available below.

C. Conference Call Information

For participants who cannot come to CMS for the Informational Workshop or the Town Hall Meeting, an open toll-free phone line, (877) 267-1577, has been made available. The conference code is "0400."

III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for both the Town Hall Meeting and the Informational Workshop. While there is no registration fee, individuals must register to attend the Town Hall Meeting on substantial clinical improvement and for the Informational Workshop (two separate registrations).

Registration may be completed on-line at the following Web address: http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage. Select the link at the bottom of the page "Register to Attend the New Technology Town Hall Meeting" or "Register to Attend the New Technology Informational Workshop". After completing the registration, on-line registrants should print the confirmation page(s) and bring it with them to the meeting(s).

If you are unable to register on-line, you may register by sending an e-mail to the contacts listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Please include your name, address, telephone number, e-mail address and fax number. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

IV. Security, Building, and Parking Guidelines

Because these meetings will be located on Federal property, for security reasons, any persons wishing to attend these meetings must register by close of business by the date listed in the **DATES** section of this notice. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 8:30 a.m. e.s.t. if you are

attending the Informational Workshop and no later than 12:30 p.m. e.s.t. if you are attending the Town Hall Meeting so that you will be able to arrive promptly at the appropriate meeting.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meetings. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting(s).

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.

Authority: Section 503 of Pub. L. 108-173. (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 18, 2010.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010-29989 Filed 11-26-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3237-N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—January 19, 2011

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) ("Committee") will be held on Wednesday, January 19, 2011. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the currently available evidence regarding the effects of Erythropoiesis Stimulating Agents (ESAs) on health outcomes in adult chronic kidney disease (CKD) patients (pre-dialysis and dialysis). This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: Meeting Date: The public meeting will be held on Wednesday, January 19, 2011 from 7:30 a.m. until 4:30 p.m., Eastern Standard Time (EST).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the ADDRESSES section of this notice by 5 p.m. EST, Monday, December 20, 2010. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., EST on Monday, December 20, 2010. Speakers may register by phone or via e-mail by contacting the person listed in the FOR FURTHER INFORMATION CONTACT section of this notice. Presentation materials must be received at the address specified in the ADDRESSES section of this notice.

Deadline for All Other Attendees Registration: Individuals may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3>, or by phone by contacting the person listed in the FOR FURTHER INFORMATION CONTACT section of

this notice by 5 p.m. EST, Wednesday, January 12, 2011.

We will be broadcasting the meeting via Webinar. You must register for the Webinar portion of the meeting at <https://webinar.cms.hhs.gov/esamedcac119/event/registration.html> by 5 p.m. EST, Thursday, January 13, 2011.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the FOR FURTHER INFORMATION CONTACT section of this notice no later than 5 p.m., EST Friday, January 7, 2011.

ADDRESSES: Meeting Location: The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to MedCACpresentations@cms.hhs.gov or by regular mail to the contact listed in the FOR FURTHER INFORMATION CONTACT section of this notice by the date specified in the DATES section of this notice.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via e-mail at Maria.Ellis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 *Federal Register* (63 FR 68780).) This notice announces the January 19, 2011, public meeting of the Committee. During this meeting, the Committee will discuss the evidence that is currently available regarding the effects of Erythropoiesis Stimulating Agents (ESAs) on health outcomes in adult chronic kidney disease (CKD) patients (pre-dialysis and dialysis). Background information about this topic, including panel materials, is available at <http://www.cms.hhs.gov/center/coverage.asp>.

We encourage the participation of appropriate organizations with expertise in the use of ESAs for treatment of anemia in adults with CKD including patients on dialysis and patients not on dialysis.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating the meetings registration process. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp> *strOrderBy=1&type=3* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your government-issued photographic identification), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

You must register for the Webinar portion of the meeting at <https://webinar.cms.hhs.gov/esamedcac119/event/registration.html> by the deadline listed in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 16, 2010.

Barry M. Straube,
CMS Chief Medical Officer and Director,
Office of Clinical Standards and Quality,
Centers for Medicare & Medicaid Services.
[FR Doc. 2010-29964 Filed 11-26-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of New System of Records

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
ACTION: Notice of a New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is establishing a new system of records (SOR) titled, "Medicare and Medicaid Electronic Health Record (EHR) Incentive Program National Level Repository" System No. 09-70-0587. The final rule for the Medicare and Medicaid EHR Incentive Program implements the provisions of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111-5). Specifically, Title IV of Division B of the Recovery Act amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs) and Medicare Advantage (MA) Organizations participating in Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health record (EHR) technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the "Health Information Technology for Economic and Clinical Health Act," or the "HITECH Act."

The final rule specified the initial criteria EPs, eligible hospitals and CAHs, and MA Organizations must meet in order to qualify for an incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs, eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology beginning in 2015; and other program participation requirements. Also, the Office of the National Coordinator for Health Information Technology (ONC) issued a closely related final rule that specified the initial set of standards, implementation specifications, and certification criteria for certified EHR technology. ONC has also issued a separate final rule on the establishment of certification programs for health information technology (HIT).

To register for the Medicare and Medicaid EHR Incentive Program, EPs,

eligible hospitals and CAHs, and MA Organizations will be required to provide the following information: Name, National Provider Identifier (NPI), business address and business phone for each EP, eligible hospital or CAH; Taxpayer Identification Number (TIN) to which the EP, eligible hospital or CAH wants the incentive payment to be made; For EPs, whether they choose to participate in the Medicare EHR Incentive Program or the Medicaid EHR Incentive Program; For eligible hospitals and CAHs, their CMS Certification Number (CCN); and other information as specified by CMS. EPs, eligible hospitals and CAHs will also have the option to provide their e-mail address at the time of registration. MA Organizations will be required to provide their contract number on behalf of their MA-affiliated EPs and hospitals. At this time, participation in the Medicare and Medicaid EHR Incentive Programs is voluntary for EPs, eligible hospitals and CAHs.

Per section 1886(n)(4)(B) of the Act, as added by section 4102(c) of the HITECH Act, the Secretary will post on the Internet Web site of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names, business addresses, and business phone numbers of the Medicare EPs, eligible hospitals and CAHs who are meaningful EHR users in the Medicare EHR Incentive Program. Sections 1853(m)(5) and 1853(l)(7) of the Act, as added by sections 4101(c) and 4102(c) of the HITECH Recovery Act, require the Secretary to post the same information for EPs and eligible hospitals participating in the MA program as would be required if they were in the Medicare FFS program. Additionally, the Secretary must post the names of the qualifying MA Organizations receiving the incentive payment or payments. The routine uses established with this system contain a proper explanation as to the need for the disclosure provisions and provide clarity to CMS' intention to disclose provider-specific information contained in this system.

The primary purpose of this system, called the National Level Repository or NLR, is to collect, maintain, and process information that is required for the Medicare and Medicaid EHR Incentive Program. Information in this system will also be disclosed to: (1) Support regulatory, incentive payments and policy functions such as evaluation and reporting, whether performed by the Agency or by an Agency contractor or consultant; (2) assist another Federal and/or state agency, agency of a state government, or an agency established by

state law; (3) assist in making the individual physician-level participation data available through an Agency website and by various other means of data dissemination; (4) assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology; (5) support litigation involving the Agency; (6) combat fraud, waste, and abuse in certain health benefits programs, and (7) assist in a response to a suspected or confirmed breach of the security or confidentiality of information. We have provided background information about this new system in the "Supplementary Information" section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See "Effective Dates" section for information about the comment period.

DATES: Effective Dates: CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on November 29, 2010. To ensure that all parties have adequate time in which to comment, the new system, including routine uses, will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless CMS receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Information Security and Privacy Management, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N1-24-08, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.—3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Rachel Maisler, Health Insurance Specialist, Office of E-Health Standards and Services, CMS, 7500 Security Boulevard, Mail-stop: S2-26-17, Baltimore, MD 21244-1850. Office: 410-786-5754. Facsimile: 410-786-1347, E-mail address: rachel.maisler@cms.gov.

SUPPLEMENTARY INFORMATION: Sections 4101(a), 4102(a) and 4102(a)(2) of the HITECH Act respectively add sections 1848(o), 1886(n) and 1814(l)(A)(3) to the Act to limit incentive payments in the Medicare Fee-for-service (FFS) EHR incentive program to an EP, eligible hospital or CAH that is a "meaningful EHR user." Sections 4101(c) and 4102(c) of the HITECH Act respectively add sections 1853(l) and 1853(m) which outline the application of incentive payments for certain MA-affiliated EPs and MA-affiliated hospitals. Section 4201(a)(2) of the HITECH Act added section 1903(t) to the Act to limit incentive payments in the Medicaid context to EPs, as defined at section 1903(t)(2)(A), who meet the requirements of 1903(t). As described in our final rule discussed below, these eligible professionals can receive an incentive payment for adoption or utilization of, or upgrade to, certified EHR technology in 2011, and can receive incentive payments in certain subsequent years if they demonstrate meaningful use of certified EHR technology.

In sections 1848(o)(2)(A) and 1886(n)(3) of the Act, the Congress specified three types of requirements for meaningful use in the Medicare context: (1) Use of certified EHR technology in a meaningful manner; (2) that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of care; and (3) that, in using certified EHR technology, the provider submits to the Secretary information on clinical quality measures and such other measures selected by the Secretary.

In our final rule on the EHR incentive program, we stated that we are not limited to collecting only information pertaining to Medicare and Medicaid beneficiaries. Therefore, in our final rule, we require that, in order to demonstrate meaningful use, an EP, eligible hospital or CAH, or MA Organization must report aggregate information on clinical quality measures for all patients to whom clinical quality measures apply. As explained in the final rule for EHR incentive payments, for the 2011 payment year, we use an attestation methodology for the submission of summary information on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology.

For the Medicaid incentive program, as stated in our final rule, for their first year of payment, providers are not required to demonstrate meaningful use, and may receive an incentive payment by demonstrating adoption,

implementation, or upgrade to certified EHR technology. We expect that, for 2011, the majority of Medicaid providers will receive an incentive payment through this pathway. In their second, third, fourth, fifth and sixth payment year, Medicaid EPs and hospitals will be required to demonstrate meaningful use of certified EHR technology to qualify for an incentive payment.

As stated in our final rule, we will use a phased approach for meaningful use criteria, based on currently available technology capabilities and provider practice experience. We refer to the initial meaningful use criteria as "Stage 1." In the final rule, we require that EPs, eligible hospitals and CAHs, including MA-affiliated EPs and hospitals, demonstrate that they satisfy all the required meaningful use objectives and associated measures of the Stage 1 criteria during the reporting period for 2011 through attestation in order to receive incentive payments. In addition, we require that EPs, eligible hospitals and CAHs, and MA Organizations attest to the accuracy and completeness of the numerators and denominators for each of the applicable measures, and that the information submitted includes information on all patients to whom the measure applies.

To qualify as a meaningful EHR user for 2011, we require that EPs, eligible hospitals, or CAHs demonstrate that they meet all of the required meaningful use objectives and the associated measures using certified EHR technology. In order to receive an incentive payment, all EPs, eligible hospitals and CAHs must register for the program in the NLR and then attest that they have successfully demonstrated meaningful use of certified EHR technology after the completion of their EHR reporting period, which is defined at 75 FR 44566.

Section 1848(o)(3)(D) of the Act requires the Secretary to list, in an easily understandable format, the names, business addresses, and business phone numbers of the Medicare EPs for being meaningful EHR users under the Medicare FFS program on the Internet web site of CMS. Section 1886(n)(4)(B) of the Act requires the Secretary to list, in an easily understandable format, the names and other relevant data as determined appropriate, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on the CMS Internet web site. Sections 1853(m)(5) and 1853(l)(7) of the Act require the Secretary to post the same information for EPs and eligible hospitals in the MA program as would be required if they were in the Medicare

FFS program. Therefore, we collect the information necessary to post the name, business address and business phone numbers of all EPs, eligible hospitals and CAHs participating in the Medicare FFS and MA EHR Incentive Program,, and post this information on our Internet web site. The routine uses established with this system contain a proper explanation as to the need for the disclosure provisions and provide clarity to CMS' intention to disclose provider-specific information contained in this system.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for System

Authority for the collection, maintenance, and disclosures from this system is provided under §§ 1848(o), 1886(m), 1848(l), and 1853(m) of the Social Security Act which were added by the HITECH Act, respectively authorize incentive payments for EPs, eligible hospitals, CAHs and MA Organizations that successfully demonstrate meaningful use of certified EHR technology. Sections 1903(a)(3) and 1903(t) of the Social Security Act provides authority for the Medicaid EHR Incentive Program. These provisions are implemented by 75 FR 44314 and 42 CFR parts 412, 413, 422, collectively known as the Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule.

B. Collection and Maintenance of Data in the System

The National Level Repository (NLR) contains information on eligible professionals who receive Medicare incentives as meaningful users of certified EHR technology. Information in the NLR will be populated from other CMS systems, including the Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan & Provider Enumeration System (NPPES). The NLR will contain provider name, National Provider Identifier (NPI), business address and phone number, Taxpayer Identification Number (TIN) to which the EP, eligible hospital or CAH, or MA Organization wants the incentive payment to be made, and, for EPs, whether they choose to participate in the Medicare EHR Incentive Program or the Medicaid EHR Incentive Program. For eligible hospitals and CAHs, their CCN will also be included. For MA Organizations, their CMS contract number will be included. For providers participating in the Medicaid EHR Incentive Program, it will include the State in which they choose

to participate. Additionally, EPs, eligible hospitals and CAHs will have the option to provide an e-mail address for inclusion in the system. At this time, participation in the Medicare and Medicaid EHR Incentive Program is voluntary for EPs, eligible hospitals and CAHs.

II. Agency Policies, Procedures, and Restrictions On Routine Uses

A. The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." The government will only release information collected in the NLR that can be associated with an individual EP as provided for under "Section III. Proposed Routine Use Disclosures of Data in the System." Identifiable data may be disclosed under a routine use.

We will only disclose the minimum provider-level data necessary to achieve the purpose of the Medicare and Medicaid EHR Incentive Program. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. These policies do not apply to Routine Use No. 3 for this system. In general, disclosure of information from the system will be approved only for the minimum information necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.*, to collect, maintain, and process information promoting the nationwide health information technology infrastructure that allows for the electronic use and exchange of information.
2. Determines that:
 - a. The purpose of the disclosure can only be accomplished if the record is provided in an individually identifiable form;
 - b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual provider that additional exposure of the record might bring; and
 - c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).
3. Requires the information recipient to:
 - a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy at the earliest time all individually-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data In the System

A. Entities Who May Receive Disclosures under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the Medicare and Medicaid EHR Incentive Program without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors or consultants who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing a CMS function relating to purposes for this SOR.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or consultant whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or consultant from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant to return or destroy all information at the completion of the contract.

2. To assist another Federal or state agency, agency of a state government, or an agency established by state law pursuant to agreements with CMS to:

a. Contribute to the accuracy of CMS's proper incentive payment to Medicare

and Medicaid EHR Incentive Program participants, and

b. Assist Federal/state Medicaid programs which may require Medicare and Medicaid EHR Incentive Program information for purposes related to this system.

c. Assist other Federal agencies that have the authority to perform collection of debts owed to the Federal government.

Other Federal or state agencies in their administration of a Federal health program may require EHR Incentive Program information in order to support evaluations and monitoring of various aspects of the Medicare and Medicaid EHR Incentive payments.

2. To assist in making the information for EPs, eligible hospitals and CAHs, and MA Organizations that receive Medicare EHR incentive payments through the new payment contractor, available through a public web site. If local websites are used by a local or regional collaborative, CMS would have links to these Web sites on its main Web site.

This information would be posted for the purpose of, and in a manner that would promote the use of EHRs by EPs, eligible hospitals and CAHs, and MA Organizations to Medicare and Medicaid beneficiaries.

3. To assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology.

We contemplate disclosing information under this routine use only in situations in which CMS may be asked to provide necessary information to ONC grantees, also referred to as Health Information Technology Regional Extension Centers (RECs) to assist in accomplishing an ONC function relating to support for "eligible professional" (EP) adoption of, meaningful use of certified EHR technology, and provider support.

4. To support the Department of Justice (DOJ), court, or adjudicatory body when:

a. The Agency or any component thereof, or

b. Any employee of the Agency in his or her official capacity, or

c. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government, is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the

litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court, or adjudicatory body involved.

5. To assist a CMS contractor (including, but not limited to Medicare Administrative Contractors, fiscal intermediaries, and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contract or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste or abuse.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract or grant and requiring the contractor or grantee to return or destroy all information.

6. To assist another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

Other agencies may require Medicare and Medicaid EHR Incentive Program information for the purpose of

combating fraud, waste or abuse in such Federally-funded programs.

7. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and unnecessary for the assistance.

Other Federal agencies and contractors may require EHR Incentive Program information for the purpose of assisting in a respond to a suspected or confirmed breach of the security or confidentiality of information.

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the New System On the Rights of Individuals

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate

information only as prescribed therein. We will only disclose the minimum personal data necessary to achieve the purpose of the data collection and the routine uses contained in this notice. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure. CMS has assigned a higher level of security clearance for the information maintained in this system in an effort to provide added security and protection of data in this system.

CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

Dated: November 16, 2010.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM No. 09-70-0587

SYSTEM NAME:

"Medicare and Medicaid Electronic Health Record (EHR) Incentive Program National Level Repository" HHS/CMS/OESS.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244-1850 and at various contractor sites.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The National Level Repository (NLR) contains information on eligible professionals who receive Medicare incentives as meaningful users of certified EHR technology.

CATEGORIES OF RECORDS IN THE SYSTEM:

The NLR will contain provider name, National Provider Identifier (NPI), business address and phone number, Taxpayer Identification Number (TIN) to which the EP, eligible hospital or CAH, or MA Organization wants the incentive payment to be made, and, for EPs,

whether they choose to participate in the Medicare EHR Incentive Program or the Medicaid EHR Incentive Program. For eligible hospitals and CAHs, their CCN will also be included. For MA Organizations, their CMS contract number will be included. For providers participating in the Medicaid EHR Incentive Program, it will include the State in which they choose to participate. Additionally, EPs, eligible hospitals and CAHs will have the option to provide an e-mail address for inclusion in the system. At this time, participation in the Medicare and Medicaid EHR Incentive Program is voluntary for EPs, eligible hospitals and CAHs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for the collection, maintenance, and disclosures from this system is provided under §§ 1848(o), 1886(m), 1848(l), and 1853(m) of the Social Security Act which were added by the HITECH Act, respectively authorize incentive payments for EPs, eligible hospitals, CAHs and MA Organizations that successfully demonstrate meaningful use of certified EHR technology. Sections 1903(a)(3) and 1903(t) of the Social Security Act provides authority for the Medicaid EHR Incentive Program. These provisions are implemented by 75 FR 44314 and 42 CFR parts 412, 413, 422, collectively known as the Medicare and Medicaid Programs: Electronic Health Record Incentive Program; Final Rule.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this system, called the National Level Repository or NLR, is to collect, maintain, and process information that is required for the Medicare and Medicaid EHR Incentive Program. Information in this system will also be disclosed to: (1) Support regulatory, incentive payments and policy functions such as evaluation and reporting, whether performed by the Agency or by an Agency contractor or consultant; (2) assist another Federal and/or state agency, agency of a state government, or an agency established by state law; (3) assist in making the individual physician-level participation data available through an Agency website and by various other means of data dissemination; (4) assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology; (5) support litigation involving the Agency; (6) combat fraud, waste, and abuse in certain health

benefits programs, and (7) assist in a response to a suspected or confirmed breach of the security or confidentiality of information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

A. ENTITIES WHO MAY RECEIVE DISCLOSURES UNDER ROUTINE USE

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the EHRI without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, or CMS grantees who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.
2. To assist another Federal or state agency, agency of a state government, or an agency established by state law pursuant to agreements with CMS to:
 - a. Contribute to the accuracy of CMS's proper incentive payment to Medicare and Medicaid EHR Incentive Program participants, and
 - b. Assist Federal/state Medicaid programs which may require Medicare and Medicaid EHR Incentive Program information for purposes related to this system.
 - c. Assist other Federal agencies that have the authority to perform collection of debts owed to the Federal government.
3. To assist in making the information for EPs, eligible hospitals and critical access hospitals (CAHs), who receive EHR incentive payments through the new payment contractor, available through a public website. If local Web sites are used by a local or regional collaborative, CMS would have links to these websites on its main website.
4. To assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology.

5. To support the Department of Justice (DOJ), court, or adjudicatory body when:

- a. The Agency or any component thereof, or
- b. Any employee of the Agency in his or her official capacity, or
- c. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or
- d. The United States Government, is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

6. To assist a CMS contractor (including, but not limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

7. To assist another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

8. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for the assistance.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on both tape cartridges (magnetic storage media) and

in a DB2 relational database management environment (DASD data storage media).

RETRIEVABILITY:

Information is most frequently retrieved by provider number (facility, physician, IDs), service dates, and prescriber identification number.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 10 years. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER AND ADDRESS:

Director, Office of E-Health Standards and Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Mail-stop: S2-26-17, Baltimore, MD 21244-1850.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name, and the retrieval selection criteria (e.g., Provider number, SSN, etc.).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Information in the National Level Repository will be populated from other CMS systems of records, including the

Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan & Provider Enumeration System (NPPES).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2010-29952 Filed 11-26-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Proposed Information Collection Activity; Comment Request**

Title: Evaluation of Pregnancy Prevention Approaches and Teen Pregnancy Prevention Evaluation.

OMB No.: 0970-0360.

Description: The Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and the Office of the Assistant Secretary for Health (ASH), 13.5, Department of Health and Human Services (HHS), are proposing a data collection activity to be undertaken by two related studies—the Evaluation

of Pregnancy Prevention Approaches study and the Teen Pregnancy Prevention Evaluation. Both studies are sponsored by ASH and will use the same data collection instruments; ACF is facilitating the Evaluation of Pregnancy Prevention Approaches, while ASPE is facilitating the Teen Pregnancy Prevention Evaluation.

These two studies will assess the effectiveness of a range of programs designed to prevent or reduce sexual risk behavior and pregnancy among older adolescents. Knowing what types of programs are effective will enhance programmatic decisions by policymakers and practitioners.

The proposed activity involves the collection of information from observations of program activities and interviews with a range of experts and persons involved with programs about various aspects of existing prevention programs and topics the experts view as important to address through evaluation. These data will be used to help enhance decisions about the types of programs to be evaluated in the studies.

Respondents: Researchers and policy experts, program directors, program staff, or school administrators.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Discussion Guide for Use with Researchers and Policy Experts	30	1	1	30
Discussion Guide for Use with Program Directors	30	2	2	120
Discussion Guide for Use with Program Staff	60	1	2	120
Focus Group Discussion Guide for Use with Program Participants	300	1	1.5	450
Discussion Guide for Use with School Administrators	200	1	1	200

Estimated Total Annual Burden Hours: 920.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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 collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 22, 2010.

Steven Hanmer,
OPRE Reports Clearance Officer.

[FR Doc. 2010-29917 Filed 11-26-10; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-N-0601]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

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 recordkeeping requirements for manufacturers of medicated animal feeds.

DATES: Submit either electronic or written comments on the collection of information by January 28, 2011.

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: John V. Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, juanmanuel.vilela@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:

Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR Part 225 (OMB Control Number 0910-0152)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C

Act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (*i.e.*, batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to assure that their feeds meet the requirements of the FD&C Act as to safety and also that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

A license is required when the manufacture of a medicated feed involves the use of a drug or drugs that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required and the recordkeeping requirements are less demanding for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixer-feeders.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED COMMERCIAL FEED MILLS) ¹

21 CFR Section	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.42(b)(5) through (b)(8)	1,004	260	261,040	1	261,040
225.58(c) and (d)	1,004	45	45,180	.5	22,590
225.80(b)(2)	1,004	1,600	1,606,400	.12	192,768
225.102(b)(1)	1,004	7,800	7,831,200	.08	626,496
225.110(b)(1) and (b)(2)	1,004	7,800	7,831,200	.015	117,468
225.115(b)(1) and (b)(2)	1,004	5	5,020	.12	602
Total					1,220,964

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED MIXER-FEEDERS) ¹

21 CFR Section	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.42(b)(5) through (b)(8)	100	260	26,000	.15	3,900
225.58(c) and (d)	100	36	3,600	.5	1,800
225.80(b)(2)	100	48	4,800	.12	576
225.102(b)(1)	100	260	26,000	.4	10,400
Total					16,676

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED UNLICENSED COMMERCIAL FEED MILLS) ¹

21 CFR Section	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.142	8,000	4	32,000	1	32,000
225.158	8,000	1	8,000	4	32,000
225.180	8,000	96	768,000	.12	92,160
225.202	8,000	260	2,080,000	.65	1,352,000
Total					1,508,160

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED UNLICENSED MIXER-FEEDERS) ¹

21 CFR Section	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.142	45,000	4	180,000	1	180,000
225.158	45,000	1	45,000	4	180,000
225.180	45,000	32	1,440,000	.12	172,800
225.202	45,000	260	11,700,000	.33	3,861,000
Total					4,393,800

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on Agency communications with industry. Other information needed to finally calculate the total burden hours (i.e., number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from Agency records and experience.

Dated: November 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-29928 Filed 11-26-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0600]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet, Form 3546

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 burden hours necessary to complete FDA Form 3546, Animal Drug User Fee Act (ADUFA) Cover Sheet.

DATES: Submit either electronic or written comments on the collection of information by January 28, 2011.

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: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, juanmanuel.vilela@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.

Animal Drug User Fee Cover Sheet; FDA Form 3546 (OMB Control Number 0910-0539)—Extension

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-12), as amended by ADUFA, FDA has the authority to assess and collect for certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is

required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet (FDA Form 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Section of the FD&C Act as amended by ADUFA	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
740(a)(1), FDA Form 3546 (Cover Sheet)	76	1	76	1	76
Total					76

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's database system, there are an estimated 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 2008. The estimated hours per response are based on past FDA experience with the various submissions. The hours per response are based on the average of these estimates.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

{FR Doc. 2010-29820 Filed 11-26-10; 8:45 am}

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0547]

Clinical Development Programs for Sedation Products; Request for Assistance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. FDA is inviting any interested party, or parties, to facilitate an evaluation of critical fundamentals of the science related to sedation products by conducting and managing a coordination of activities that will bring together experts in the field, including from academia, patient organizations, and industry. The first step in this process would be for the party or parties to plan and hold one or

more public meetings to discuss these issues. FDA intends to take into account the information provided from these activities as we develop FDA guidance on clinical development programs for sedation products. We intend to submit to the docket all the information received in response to this notice so that interested parties may be fully informed.

DATES: Submit electronic or written comments on this notice by January 28, 2011.

ADDRESSES: Submit electronic comments on this notice to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sara E. Stradley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3162, Silver Spring, MD 20993-0002, 301-796-1298, FAX:301-796-9713, e-mail: sara.stradley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Because of the need for more information on the development of products intended to be used in humans for sedation in hospital and outpatient settings, FDA is requesting assistance from the public in conducting scientific analyses for the purpose of further understanding the physiology of sedation and clinical trial design issues related to the development of sedation products.

II. Request for Assistance

FDA is inviting any interested group or consortium of interested groups from academia, industry, practitioners, as well as patients and their representatives to conduct and manage the coordination of a critical evaluation of certain fundamentals of the science related to sedation products. Initially, the party or parties would organize and hold one or more public meetings or workshops to discuss relevant questions associated with the spectrum of sedation, particularly as it relates to procedural and intensive care unit (ICU) sedation, as well as associated clinical trial design issues. FDA believes that a public meeting would help solicit feedback from all parties leading to conceptual advances and a discussion of such advances in a concept paper. This discussion would take into account challenges involved in assessment of sedation and emphasize the rationale for various approaches to key clinical trial design issues involving sedation products. The effort would ultimately lead to developing a draft guidance that would be issued by FDA for broad public comment before finalization, consistent with FDA's good guidance practices regulation (21 CFR 10.115).

III. Suggestions

FDA welcomes other suggestions of activities that could be undertaken as part of this guidance development effort.

IV. Possible Questions/Issues to Be Considered

To provide a starting point for discussion, FDA has developed a list of some key concepts that the interested parties may want to consider for discussion at the meeting as follows:

1. Currently, sedation is studied primarily in the procedural and ICU settings. Procedural sedation may involve an outpatient setting, and may require the institution of Monitored Anesthesia Care (MAC). There is great interest among health care providers with varied medical backgrounds in

sedation for surgical and diagnostic procedures in the outpatient setting. What generally constitutes MAC, and what qualifies a product for MAC? How should the need for MAC be assessed in clinical trials involving sedation products?

2. Assessment of procedural sedation involves conducting clinical trials in a wide range of diagnostic and surgical procedures. What surgical and diagnostic procedures are of particular value in assessing the procedural sedation indication? Are there certain procedures that should be evaluated for every product that seeks the procedural sedation indication, or can the range of trials be governed by the pharmacologic profile of the product? Should the scope of the sedation guidance apply to settings other than procedural or ICU sedation?

3. There are patient subgroups in which the use of sedation products should be particularly evaluated. For example, pediatric and geriatric age groups often require dose adjustment because of varying metabolic needs and other clinical parameters. In addition, dose adjustment may be required in patients with renal and hepatic impairment. Are there other patient subgroups that require specific evaluation in clinical trials involving sedation products?

4. Sedation products usually are used as infusions that are titrated to achieve the desired sedation effect. What are optimal trial designs for sedation products? Should clinical trials involving sedation products be placebo-controlled or active-controlled? Currently, Midazolam, Propofol, Ketamine, and Dexmedetomidine are commonly used sedation products. Of these, Midazolam is the most commonly used active comparator in sedation product trial designs. Is it possible to accurately predict the actual size of the treatment effect based on use of Midazolam or other commonly used sedation products? Although trial designs involving these products are believed to be predictive, it may not be possible to generalize from them. If active- and placebo-controlled product trial designs are not optimal, what alternative designs can be used to support sedation claims? Would dose-escalation comparative trial designs be useful in studying sedation products?

5. How is sedation defined and what are appropriate outcome measures to assess sedation? At present, there is diverse opinion among health care providers regarding the definition of sedation. For example, is the assessment of anxiolysis and agitation a separate entity or is it contained within the

spectrum of sedation itself? Should this depend upon the known pharmacologic profile of the product? Currently, the primary efficacy endpoint in sedation clinical trials is usually assessed using sedation scales. Commonly used sedation scales include the Ramsey Sedation Scale, Richmond Agitation and Sedation Scale, and Mean Observer's Assessment of Agitation/Sedation Scale. How appropriate is the use of such sedation scales in clinical trials involving sedation products? Should all sedation scales be standardized and validated?

6. Sedation scales are used for assessing the primary efficacy endpoint for sedation products. What are meaningful secondary efficacy endpoints in such trials? Are subjective and objective assessments of memory, recall, anxiety, agitation, delirium, among others, appropriate as efficacy endpoints? Which of these efficacy endpoints should be considered clinically significant? If so, what outcome measures and trial designs should be used? Specifically, how should anxiolysis and agitation be assessed within the realm of products primarily indicated for sedation purposes and not to treat an anxiety disorder or agitation? Should there be different scales for assessing each component, or can the assessment be contained within the spectrum of sedation using an appropriate scale? Further, is an accurate assessment of anxiolysis feasible given the multiple variables that can affect anxiety in a procedural sedation setting that would have to be standardized (e.g., physician and practice setting profile, pre-procedure anticipatory patient prepping, individual thresholds for anxiety)?

7. ICU sedation products are often used for periods longer than 24 hours. Should an ICU sedation indication include a short-term (less than 24 hours) and long-term (more than 24 hours) use assessment for purposes of efficacy and safety? Long-term use may be associated with tolerance/tachyphylaxis and a dose-related increase in adverse effects. What should the size and duration of exposure of the safety database be for sedation products?

V. Comments

Interested persons should submit comments and expressions of interest in conducting and managing a critical evaluation to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: November 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-29927 Filed 11-26-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0565]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Clostridium difficile*; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Clostridium difficile*." This draft guidance document describes FDA's recommendations concerning 510(k) submissions for various types of in vitro diagnostic devices (IVDs) intended to be used for detecting *Clostridium difficile* (*C. difficile*). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 28, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Clostridium difficile*" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY**

INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Stephen Lovell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4435, Silver Spring, MD 20993-0002, 301-796-6968.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance includes recommendations concerning 510(k) submissions for various types of (IVDs) intended to be used for detecting *C. difficile*. The document is a revision of "Review Criteria for Assessment of Laboratory Tests Directed at Assisting in the Diagnosis of *C. difficile* Associated Disease" issued on May 31, 1990. It is updated to include new issues and technologies identified since the 1990 guidance. Such methods include detection of *C. difficile* nucleic acids (e.g., *C. difficile* toxin B gene by nucleic acid amplification methods such as the Real-Time Polymerase Chain Reaction technique).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the Agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection of *C. difficile*. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Clostridium*

difficile," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1715 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 42 CFR section 493.15 have been approved under OMB control number 0910-0598; the collections of information in 21 CFR section 50.23 have been approved under OMB control number 0910-0586; and the collections of information in 21 CFR section 56.115 have been approved under OMB control number 0910-0130.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-29794 Filed 11-26-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-D-0589]

Draft Guidance for Industry on Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment; Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP). The science of clinical trial design and our understanding of these diseases have advanced in recent years, and this draft guidance, when finalized, will inform sponsors of the recommendations for clinical development.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 28, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of HABP and VABP. This guidance revises and replaces the draft guidance regarding nosocomial pneumonia published in 1998. The guidance also addresses the clinical development of new drugs to treat drug-resistant bacterial pathogens implicated in HABP/VABP.

The issues in HABP/VABP clinical trials were discussed at a 2009 workshop co-sponsored by FDA and professional societies. The science of clinical trial design and our understanding of these diseases have advanced in recent years, and this draft guidance informs sponsors of the changes in our recommendations. Specifically, the guidance defines a primary efficacy endpoint of all-cause mortality and provides a justification for a noninferiority margin for the design of active-controlled clinical trials that can be used to provide evidence of efficacy for the treatment of HABP/VABP.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under 0910-0014, the collections of information in 21 CFR part 314 have been approved under 0910-0001, and the collections of information referred to in the guidance "Establishment and Operation of Clinical Trial Data Monitoring

Committees" have been approved under 0910-0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-29799 Filed 11-26-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-D-0590]

Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling; Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling." FDA is issuing this guidance with labeling recommendations because of concerns that both healthcare providers and patients may be unaware of the serious adverse health risks associated with using the same blood lancet device for assisted withdrawal of blood from more than one patient, even when the lancet blade is changed for each blood draw. FDA recommends that all blood lancet devices be labeled for use only on a single patient. A statement limiting use to a single patient should also appear on the label attached to the device, if possible. The guidance document is immediately in effect, but it remains subject to comment in

accordance with the Agency's good guidance practices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Shelia Murphey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2510, Silver Spring, MD 20993-0002, 301-796-6302.

SUPPLEMENTARY INFORMATION:

I. Background

On August 26, 2010, the FDA and Centers for Disease Control and Prevention (CDC) issued a joint Initial Communications warning that the use of fingerstick devices (blood lancets) to obtain blood from more than one patient poses a risk of transmitting bloodborne pathogens. The Agencies recommended that blood lancet devices should never be used to obtain blood samples from more than one person.

CDC has noted a progressive increase in reports of bloodborne pathogen transmission (primarily hepatitis B) resulting from the use of a blood lancet in multiple patients in various healthcare provision settings. These settings include acute care hospitals, long term care facilities and assisted living facilities as well as non-residential care settings.

Blood lancet devices may be unsafe when used to draw blood from more than one patient for several reasons. Improper device design, device malfunction, or user error may leave the

blood from one patient on the reusable lancet device base and in a position to contaminate a new lancet blade. Healthcare users of blood lancets may have difficulty ensuring that all blood contamination has been successfully removed from a reusable lancet base device. The cleaning and disinfection instructions provided with reusable lancet devices may not be adequately validated for efficacy or followed in their entirety. FDA recommends that all blood lancet devices be labeled for use only on a single patient. A statement limiting use to a single patient should also appear on the label attached to the device, if possible.

FDA is making this guidance document immediately available because prior public participation is not appropriate. Due to the urgent public health need to support the joint Initial Communications issued by CDC and FDA concerning the risk of hepatitis transmission caused by the use of blood lancets on more than one patient, FDA believes that current lancet labeling which does not restrict the use of lancets to a single patient must be corrected as quickly as possible. FDA believes that this guidance will provide significant assistance to lancet manufacturers as they work to improve their labeling as recommended.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on blood lancet labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1732 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-29795 Filed 11-26-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0584]

Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "ANDAs: Impurities in Drug Products." This guidance updates recommendations regarding degradation products and updates the draft guidance "ANDAs: Impurities in Drug Products" announced in December 1998 in conformance with the revision of the International Conference on Harmonisation (ICH) guidance for industry "Q3B(R) Impurities in New Drug Products," which was announced in August 2006.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Devinder Gill, Center for Drug Evaluation and Research (HFD-630), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8483.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "ANDAs: Impurities in Drug Products." In December 1998, FDA issued the draft guidance "ANDAs: Impurities in Drug Products," and in August 2005, FDA revised it in conformance with the "Q3B(R) Impurities in New Drug Products" guidance for industry that was announced in August 2006.

We are issuing the final guidance to: (1) Update information on listing of degradation products, setting acceptance criteria, and qualifying degradation products (thresholds and procedures) in abbreviated new drug applications (ANDAs) in conformance with the revision of the guidance for industry on Q3B(R) and (2) remove those sections of the 1998 draft guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3B(R). The Q3B(R) was developed by the ICH to provide guidance on impurities in drug products for new drug applications (NDAs). However, the Agency believes that many of the recommendations provided on impurities in NDAs also apply to ANDAs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on impurities in drug products submitted as ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-29896 Filed 11-26-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0150; Formerly Docket No. 2007D-0367]

Guidance for Industry on Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval." The purpose of this guidance is to provide information on FDA's current thinking regarding appropriate use of noninferiority (NI) clinical trial designs to evaluate antibacterial drug products. The Agency's thinking in this area has evolved in recent years in response to a number of public discussions on the use of active-controlled trials designed to show NI as the basis for approval of antibacterial drug products. This guidance finalizes the draft guidance published in the **Federal Register** of October 15, 2007.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the

Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002. 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval." The purpose of this guidance is to inform industry, sponsors, applicants, researchers, and the public on the appropriate uses of NI clinical trial designs to evaluate antibacterial drug products and to amend ongoing or completed trials accordingly. In the **Federal Register** of October 15, 2007 (72 FR 58312), FDA announced a notice of availability of the draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval" in response to numerous public discussions that focused primarily on the following indications: Acute bacterial sinusitis; acute bacterial exacerbation of chronic bronchitis, and acute bacterial otitis media. Since FDA issued the draft guidance, there have been public discussions on consistent and reliable estimates of the efficacy of active treatment to placebo for other infectious disease indications for the NI trial design. The public comments received on the draft guidance have been considered and the guidance has been revised as appropriate. The guidance emphasizes that adequate scientific evidence should be provided to support the proposed NI margin for any indication being studied in any proposed, ongoing, or completed active-controlled trial designed to show NI.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively, and the collection of information under the guidance for industry "Special Protocol Assessment" has been approved under OMB control number 0910-0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-29796 Filed 11-26-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Replacement Awards to Upper Room AIDS Ministry, Inc.

SUMMARY: The Health Resources and Services Administration (HRSA) will transfer Health Center Program (section 330 of the Public Health Service Act) Increased Demand for Services (IDS) and Capital Improvement Project (CIP) funds, awarded under the American Recovery and Reinvestment Act (ARRA), originally awarded to Harlem United Community AIDS Center, Inc. (HUCAC) to Upper Room AIDS Ministry, Inc. to ensure the provision of critical primary health care services and continuity of services to low-income, underserved homeless patients in New York City.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Harlem United Community AIDS Center, Inc.

Original Period of Grant Support: March 27, 2009, to March 26, 2011 (IDS) and June 29, 2009, to June 28, 2011 (CIP).

Replacement Awardee: Upper Room AIDS Ministry, Inc.

Amount of Replacement Award: \$103,317 (IDS) and \$262,740 (CIP).

Period of Replacement Award: The period of support for the replacement awards is March 27, 2009 to March 26, 2011 (IDS) and June 29, 2009 to June 28, 2011 (CIP).

Authority: Section 330(h) of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.703

Justification for Exception to Competition: Under the original grant applications approved by HRSA, Harlem United Community AIDS Center, Inc. (HUCAC) was identified as the grantee of record. HUCAC had a subrecipient agreement in place with Upper Room AIDS Ministry, Inc., a HUCAC-subsidary organization. Through this arrangement, Upper Room AIDS Ministry, Inc. provided all services and carried out the full scope of project for the homeless program. Instead of continuing this agreement, both organizations decided that Upper Room AIDS Ministry, Inc. should become the direct grantee recipient for the ARRA IDS and CIP grants. Upper Room AIDS Ministry, Inc. competed successfully for fiscal year 2010 Service Areas Competition funding and has become the direct grant recipient of the health center homeless grant. HUCAC and the Upper Room AIDS Ministry, Inc. requested that full responsibility for the grants be transferred from HUCAC to Upper Room AIDS Ministry, Inc. Upper Room AIDS Ministry has provided documentation to HRSA that it meets Section 330 statutory and regulatory requirements as well as applicable grant management requirements.

The transfer of these grants will ensure critical primary health care services continue and remain available to low income, underserved homeless populations with no interruption in services to the target population. Transferring the funds to Upper Room AIDS Ministry, Inc. does not materially change the projects as originally proposed and funded. Upper Room AIDS Ministry, Inc. will fulfill the expectations of the former grantee's originally funded IDS and CIP grant applications. In order to ensure that critical primary health care services continue to be available to the original target population in a timely manner, these ARRA CIP and IDS awards will not be competed.

FOR FURTHER INFORMATION, CONTACT: Marquita Cullom-Stott via e-mail at MCullom-Stott@hrsa.gov or 301-594-4300.

Dated: November 19, 2010.

Mary K. Wakefield,
Administrator.

[FR Doc. 2010-29866 Filed 11-26-10; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Part C Early Intervention Services Grant under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of a non-competitive one-time replacement award from Ryan White HIV/AIDS Program, Part C funds for the Louisiana State University, Health Sciences Center, Viral Disease Clinic in Shreveport, Department of Medicine, Shreveport, Louisiana.

SUMMARY: HRSA will be giving a non-competitive one-time replacement award to support comprehensive primary care services for persons living with HIV/AIDS, including primary medical care, laboratory testing, oral health care, outpatient mental health and substance abuse treatment, specialty and subspecialty care, referrals for health and support services and adherence monitoring/education services to the Louisiana State University, Health Sciences Center, Viral Disease Clinic to ensure continuity of critical HIV medical care and treatment services, to clients in Shreveport, Louisiana.

SUPPLEMENTARY INFORMATION:

Grantee of record: Premier Care and Learning Center, Shreveport, Louisiana.

Intended recipient of the award: Louisiana State University, Health Sciences Center, Shreveport, Louisiana.

Amount of the award: \$268,377 to ensure ongoing clinical services to the target population.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff-51.

CFDA Number: 93.918.

Project period: July 1, 2010, to June 30, 2011. The period of support for this non-competitive one-time replacement award is from July 1, 2010, to June 30, 2011.

Justification for the Exception to Competition

Critical funding for HIV medical care and treatment services to clients in Shreveport, Louisiana, will be continued through a non-competitive replacement award to an existing grant award to the Louisiana State University, Health Sciences Center, Viral Disease Clinic. This is a non-competitive one-time replacement award because the previous grant recipient serving this population notified HRSA that it would not continue in the program after the fiscal year (FY) 2010 award was made. Louisiana State University, Health Sciences Center, Viral Disease Clinic is the best qualified grantee for this supplement, since it serves many of the former grantee's patients and is the closest Part C Program to the former grantee. Further funding beyond

June 30, 2011, for this service area will be competitively awarded during the Part C HIV Early Intervention Service competing application process for FY 2011.

FOR FURTHER INFORMATION CONTACT:

Kathleen Treat, by e-mail ktreat@hrsa.gov, or by phone, 301-443-7602.

Dated: November 19, 2010.

Mary K. Wakefield,
Administrator.

[FR Doc. 2010-29865 Filed 11-26-10; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Customer and Other Partners Satisfaction Surveys

SUMMARY: In compliance with the requirement of Section 3507(A)(1)(D) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Clinical Center (CC) of the National Institutes of Health, (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 21, 2010, pages 57470-57472 and allowed 60 days for public comments. One comment regarding the use of government resources to conduct surveys was received during the 60-day comment period. The purpose of this notice is to provide an additional 30 days for public comment.

5 CFR 1320.5 Respondents to this request for information collection should not respond unless the request displays a currently valid OMB control number.

Proposed Collection: Title: Generic Clearance for Satisfaction Surveys of Customer and Other Partners. *Type of Information Collection Request:* Extension (OMB Control Number: 0925-0458). *Need and Use of Information Collection:* The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the satisfaction of various Clinical Center

customers and other partners with Clinical Center services; (2) to assist with the design of modifications of these services, based on customer input; (3) to develop new services, based on customer need; and (4) to evaluate the satisfaction of various Clinical Center customers and other partners with implemented service modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization. *Frequency of Response:* The participants will respond yearly. *Affected Public:* Individuals and households, businesses and other for profit, small businesses and organizations. *Types of Respondents:* These surveys are designed to assess the satisfaction of the Clinical Center's major internal and external customers with the services provided. These customers include, but are not limited to, the following groups of individuals: Clinical Center patients, family members of Clinical Center patients, visitors to the Clinical Center, NIH intramural collaborators, private physicians or organizations who refer patients to the Clinical Center, volunteers, vendors and collaborating commercial enterprises, small businesses, regulators, and other organizations. The annual reporting burden is as follows:

Customer	Number of respondents	Frequency of response	Average time per response	Annual hour burden
FY 2010				
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	2000	1	.5	1000
Visitors to the Clinical Center	1000	1	.17	170
NIH Intramural Collaborators	2000	1	.17	340
Vendors and Collaborating Commercial Enterprises	2500	1	.33	833
Professionals and Organizations Referring Patients	2000	1	.33	833
Regulators	30	1	.33	10
Volunteers	275	1	.5	138
Total	14,805	5,824

Customer	Number of respondents	Frequency of response	Average time per response	Annual hour burden
FY 2011				
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	3000	1	.5	1500
Visitors to the Clinical Center	1500	1	.17	255
NIH Intramural Collaborators	1500	1	.25	375
Vendors and Collaborating Commercial Enterprises	1000	1	.25	250
Professionals and Organizations Referring Patients	3000	1	.33	1000
Regulators	30	1	.33	10
Volunteers	275	1	.33	92
Total	15,305			5,982
FY 2012				
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	2000	1	.5	1000
Visitors to the Clinical Center	1000	1	.17	170
NIH Intramural Collaborators	1000	1	.17	170
Vendors and Collaborating Commercial Enterprises	2500	1	.25	625
Professionals and Organizations Referring Patients	3000	1	.33	1000
Regulators	25	1	.25	6
Volunteers	300	1	.25	75
Total	14,825			5,546

Estimated costs to the respondents consists of their time; time is estimated using a rate of \$10.00 per hour for patients and the public; \$30.00 for vendors, regulators, organizations and \$55.00 for health care professionals. The estimated annual costs to respondents for each year for which the generic clearance is requested is \$127,885 for 2010, \$126,895 for 2011, and \$120,730 for 2012. Estimated Capital Costs are \$7,000. Estimated Operating and Maintenance costs are \$75,000.

Requests for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Clinical Center and the agency, including whether the information shall have practical utility; (2) 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; (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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response

time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. David K. Henderson, Deputy Director for Clinical Care, National Institutes of Health Clinical Center, Building 10, Room 6-1480, 10 Center Drive, Bethesda, Maryland 20892, or call non-toll free: 301-496-3515, or e-mail your request or comments, including your address to: dkh@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: November 22, 2010.

David K. Henderson,
Deputy Director for Clinical Care, CC,
National Institutes of Health.

[FR Doc. 2010-29953 Filed 11-26-10; 8:45 am]

BILLING CODE 4140-01-P

HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notification of Request for Emergency Clearance; GuLF Study: Gulf Long-term Follow-up Study for Oil Spill Clean-Up Workers and Volunteers

In accordance with Section 3507(j) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) hereby publishes notification of request for Emergency Clearance for the information collection related to the GuLF Study: Gulf Long-term Follow-up Study for Oil Spill Clean-Up Workers and Volunteers.

This information collection is essential to the mission of NIEHS (42 U.S.C. 285l), which is to conduct and support research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly. Through this mission, the NIEHS has a mandate to study the environmental impact on individuals of natural and man-made catastrophes and the long term health effects of these incidents. The Deepwater Horizon disaster, with its release of approximately 5 million barrels (~ 680,000 tons) of crude oil into the Gulf of Mexico, represents the largest oil spill in U.S. history. Given the magnitude of this spill and the scope of the potential exposures—over 100,000 persons have completed safety training in preparation for participation

in clean-up activities related to the spill—study of the human health effects of this spill is urgently needed to monitor gulf clean-up workers and to understand the adverse consequences of oil spills in general.

Close ongoing community engagement will enhance scientific validity of the study, make it more broadly relevant from a public health perspective, and expand its benefits to the affected communities. We have established contacts with community organizations, representative worker organizations, advocacy groups, and State and local governments to identify the primary health issues of concern locally and to discuss study implementation issues across the five State area. Further, we will identify Community Outreach Coordinators to organize and implement outreach activities in each of the Gulf States. In addition to the continuing efforts with public health and community group representatives, we have been conducting and will continue webinars, dockside chats, and phone and in-person briefings with key stakeholder groups and health departments.

NIEHS cannot reasonably comply with the normal clearance procedures to initiate this information collection, because the use of normal procedures will delay the collection and hinder the agency in accomplishing its mission, to the detriment of the public good. Compelling reason exists to collect the required information at the earliest opportunity in order to capture information that may be lost with passage of time and to initiate contact with the workers and populations exposed to the effects of the spill.

The information to be obtained by this survey will provide the NIEHS, the U.S. government and the private sector with information on potential short- and long-term human health effects associated with clean-up and disposal activities surrounding the Deepwater Horizon oil spill in the Gulf of Mexico. Health areas of interest include, but are not limited to, respiratory,

cardiovascular, hematologic, dermatologic, neurologic, cancer, reproductive, mental health, substance abuse, immunologic, hepatic, and renal effects. The study will investigate biomarkers of potentially adverse biological effect, including DNA damage, aberrant epigenetic profiles, and alterations in gene expression, some of which have been observed in previous studies of oil spill clean-up workers. The study will create a resource for additional collaborative research on specific scientific hypotheses or on subgroups of interest, and work with external scientists to facilitate nested sub-studies within the existing cohort to examine outcomes and exposure subgroups of interest; and create a resource to better understand the short and long-term human health effects of oil and oil dispersants in the environment.

Proposed Collection: Title: GuLF Study: Gulf Long-term Follow-up Study for Oil Spill Clean-Up Workers and Volunteers. *Type of Information Collection Request:* Emergency. *Need and Use of Information Collection:* The purpose of the GuLF Study is to investigate potential short- and long-term health effects associated with oil spill clean-up activities and exposures surrounding the Deepwater Horizon disaster; and to create a resource for additional collaborative research on focused hypotheses or subgroups. Over 55,000 persons participating in oil-spill clean-up activities have been exposed to a range of known and suspected toxins in crude oil, burning oil, and dispersants, to excessive heat, and possibly to stress due to widespread economic and lifestyle disruption. Exposures range from negligible to potentially significant, however, potential long-term human health consequences are largely unknown due to insufficient research in this area. Participants will be recruited from across job/exposure groups of primarily English, Spanish, or Vietnamese speaking adults (accommodations for other languages developed as

appropriate) who performed oil-spill clean-up-related work (“exposed”) and similar persons who did not (“unexposed”) controls), and followed in either an *Active Follow-up Cohort* (N=27,000) or a *Passive Follow-up Cohort* (N=28,000). Exposures will be estimated using detailed job-exposure matrices developed from data from monitoring performed by different agencies and organizations during the crisis, information obtained by interview, and the available scientific literature. We will investigate acute health effects among all cohort members via self-report from the enrollment interview, and via clinical measures and biological samples from Active Follow-up Cohort members only. All cohort members will be followed for development of a range of health outcomes through record linkage (e.g., cancer, mortality) and possibly through linkage with routinely collected health surveillance data (collected by health departments and the CDC) or with electronic medical records. Recruitment of subjects should begin in late 2010, with telephone interviews and the baseline home visits conducted within 18 months.

Frequency of Response: Participation will include one enrollment telephone interview (0.5 hr); collection of biological and environmental samples, basic clinical measurements, and GPS coordinates (2.75 hr) from the Active Follow-up Cohort only; annual contact information update (0.25; Active and Passive) or biennial follow-up telephone or Web interviews (0.5 hr; Active only) for 10 years or more. We also anticipate screening 25,000 ineligible respondents. *Affected Public:* Individuals or households. *Type of Respondents:* Workers involved in Deepwater Horizon disaster clean-up, and similar individuals not involved in clean-up effort. The annual reporting burden is as follows: *Estimated Number of Respondents:* Active Follow-up Cohort (N=27,000) and Passive Follow-up Cohort (N=28,000). *Estimated Number of Responses per Respondent:* See table.

Activity (3-yrs)	Estimated number of respondents	Estimated responses per respondent	Burden hours per response	Total burden hours per respondent	Estimated total burden hours
Ineligible respondents	25,000	1	0.25	0.25	6,250
Enrollment interview (All)	55,000	1	0.50	0.50	27,500
Home Visit (Active)	27,000	1	2.75	2.75	74,250
Annual Contact Info Update (Passive)	28,000	3	0.25	0.75	21,000
Annual Contact Info Update (Active)	27,000	2	0.25	0.50	13,500
Biennial interview (Active)	27,000	1	0.50	0.50	13,500
Passive Cohort Total responses & hrs		4		1.25	
Active Cohort Total responses & hrs		5		4.25	
Total responses & avg hrs per response		9		0.58	156,000
Average per year					52,000

Average Burden Hours per Response: 0.58 hour; and *Estimated Total Burden Hours Requested:* 156,000 (over 3 years). The average annual burden hours requested is 52,000. The annualized cost to respondents is estimated at \$11.60 (assuming \$20 hourly wage × 0.58 hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3-05, PO Box 12233, Research Triangle Park, NC 27709; non-toll-free number 919-541-4668 or E-mail sandler@niehs.nih.gov. Include your address.

By publication of this request of this request for emergency review, the NIEHS is requesting the approval for this collection. In view of the urgent public priority to initiate the study at the earliest opportunity in the wake of a public emergency, NIEHS requests that the collection of information be approved within 14 days of the publication of the **Federal Register** notice. This will allow sufficient time for public comment.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 10 days of the date of this publication.

Dated: November 18, 2010.

W. Christopher Long,
NIEHS, Acting Associate Director for
Management, National Institutes of Health.
[FR Doc. 2010-29944 Filed 11-26-10; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, December 7, 2010, 9 a.m. to December 7, 2010, 5:30 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on November 8, 2010, 75 FR 68611.

This notice is amending the start and end times of the closed session from 4:30 p.m.-5:30 p.m. to 4:15 p.m. to 5 p.m. The adjournment time of this meeting has also been changed from 5:30 p.m. to 5 p.m.

Dated: November 22, 2010.

Jennifer S. Spaeth,
Director, Office of Federal Advisory
Committee Policy.
[FR Doc. 2010-29950 Filed 11-26-10; 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: BMIT/CMIP/MEDI Imaging Applications.

Date: December 17, 2010.

Time: 1 p.m. to 5 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: Dharam S. Dhindsa, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892. (301) 435-1174. dhindsad@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Topics in Microbiology.

Date: December 28-29, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Fouad A. El-Zaatar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814-9692. (301) 435-1149. elzaataf@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group, Psychosocial Risk and Disease Prevention Study Section.

Date: January 27-28, 2011.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Serrano Hotel, 405 Taylor Street, San Francisco, CA 94102.

Contact Person: Stacey FitzSimmons, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892. 301-451-9956. fitzsimmons@csr.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group, Developmental Therapeutics Study Section.

Date: January 27-28, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Sharon K. Gubanich, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892. (301) 408-9512. gubanics@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Acute Neural Injury and Epilepsy Study Section.

Date: January 27-28, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Fairmont San Francisco, 950 Mason Street, San Francisco, CA 94108.

Contact Person: Seetha Bhagavan, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892. (301) 237-9838. bhagavas@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: November 22, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-29949 Filed 11-26-10; 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, Program Project: Grant in Cell Biology.

Date: December 16-17, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: David Balasundaram, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892. 301-435-1022. balasundaramd@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: November 19, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-29947 Filed 11-26-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 an Interagency Autism Coordinating Committee (IACC) meeting.

The purpose of the IACC meeting is to discuss plans for the annual update of the IACC Strategic Plan for Autism Spectrum Disorder Research. The meeting will be open to the public and will be accessible by webcast and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open Meeting.

Date: December 14, 2010.

Time: 10 a.m. to 5 p.m. *Eastern Time*—Approximate end time.

Agenda: The IACC will discuss plans for the annual update of the IACC Strategic Plan for Autism Spectrum Disorder Research.

Place: The Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Conference Call: Dial: 888-577-8995.

Access code: 1991506.

Cost: The meeting is free and open to the public.

Webcast Live: <http://videocast.nih.gov/>.

Registration: <http://www.acclaroresearch.com/oarc/12-14-10>.

Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis.

Deadlines: Notification of intent to present oral comments: December 6th by 5 p.m. ET. Submission of written/electronic statement for oral comments: December 7th by 5:00 p.m. ET.

Submission of written comments: December 10th by 5 p.m. ET.

Access: Medical Center Metro (Red Line)—1½ miles from the hotel On-site parking with parking validation available.

Contact Person: Ms. Liná Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 8185a, Rockville, MD 20852. Phone: (301) 443-6040. E-mail: IACCPublicInquiries@mail.nih.gov.

Please Note: Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5 p.m. ET on Monday, December 6, 2010 with their request to present oral comments at the meeting. Interested individuals and representatives of organizations must submit a written/electronic copy of the oral statement/comments including a brief description of the organization represented by 5 p.m. ET on Tuesday, December 7, 2010. Statements submitted will become a part of the public record. Only one representative of an organization will be allowed to present oral

comments, and presentations will be limited to three to five minutes per speaker, depending on number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received, along with the required submission of the written/electronic statement by the specified deadline.

In addition, any interested person may submit written comments to the IACC prior to the meeting by sending the comments to the Contact Person listed on this notice by 5 p.m. ET, Friday, December 10, 2010. The comments should include the name and, when applicable, the business or professional affiliation of the interested person. All written comments received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record.

The meeting will be open to the public through a conference call phone number and webcast live on the Internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please e-mail IACCTechSupport@acclaroresearch.com.

To access the webcast live on the Internet the following computer capabilities are required: (A) Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later; (B) Windows® 2000, XP Home, XP Pro, 2003 Server or Vista; (C) Stable 56k, cable modem, ISDN, DSL or better Internet connection; (D) Minimum of Pentium 400 with 256 MB of RAM (Recommended); (E) Java Virtual Machine enabled (Recommended).

Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 7 days prior to the meeting.

As a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered. Please note: Online pre-registration will close by 5 p.m. Eastern Time the day before the meeting. After that time, registration will have to be done onsite the day of the meeting.

Schedule is subject to change.

Information about the IACC is available on the Web site: <http://www.iacc.hhs.gov>.

Dated: November 19, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-29923 Filed 11-26-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2008-0333]

Delaware River and Bay Oil Spill Advisory Committee; Meetings

AGENCY: Coast Guard, DHS.

ACTION: Notice of advisory committee meetings.

SUMMARY: The Delaware River and Bay Oil Spill Advisory Committee (DRBOSAC) will meet in Philadelphia, Pennsylvania, to discuss and approve DRBOSAC's report on oil spill prevention and response strategies for the Delaware River and Bay. These meetings will be open to the public.

DATES: The Committee will meet on Thursday December 16, 2010 and possibly Friday December 17th, 2010 from 10 a.m. to 4 p.m. These meetings may close early if all business is finished. Written material, requests to make oral presentations, and requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before Friday December 10, 2010.

ADDRESSES: The Committee will meet at Coast Guard Sector Delaware Bay, 1 Washington Ave., Philadelphia, Pennsylvania 19147. Send written material and requests to make oral presentations to Gerald Conrad, Liaison to the Designated Federal Officer (DFO) of the DRBOSAC, at the address above. This notice and any documents identified in the **SUPPLEMENTARY INFORMATION** section as being available in the docket may be viewed online, at <http://www.regulations.gov>, using docket number USCG-2008-0333.

FOR FURTHER INFORMATION CONTACT: Gerald Conrad, Liaison to the DFO of the DRBOSAC, telephone 215-271-4824.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2 (Pub. L. 92-463). The Coast Guard Authorization Act of 2010 (Pub. L. 111-281) extended the statutory authorization for the Committee until Dec 31, 2010.

Agenda of the Meetings

The agenda for the December 16 & 17, 2010 Committee meetings are as follows:

- (1) Opening comments.
- (2) Administrative announcements.
- (3) Introductions and roll call.
- (4) Presentations from the public.

(5) Debriefs from: Response, Prevention, Recovery/Mitigation subcommittees.

(6) Public comments.

(7) Committee's report recommendation(s), discussion and votes.

(8) Closing.

More information and details on the meetings will be available at the committee Web site, located at <https://home&port.uscg.niil/drbosac>, or on the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>. To locate documents related to this Committee on FDMS, search <http://www.Regulations.gov> for the docket number USCG-2008-0333. Additional details may be added to the agenda up to December 10, 2010.

Procedural

These meetings are open to the public. All persons entering the building will have to present identification and may be subject to screening. Please note that the meetings may close early if all business is finished.

The public will be able to make oral presentations, for a length of time as decided by the Chair, when given the opportunity, as noted in the agenda. Members of the public wishing to make an oral presentation to the committee are encouraged to contact the Coast Guard at the contacts listed above no later than December 10, 2010. The public may file written statements with the committee; written material should reach the Coast Guard no later than December 10, 2010. If you would like a copy of your material distributed to each member of the committee, please submit 35 copies to the Liaison to the DFO no later than December 10, 2010, and indicate that the material is to be distributed to committee members at the December 16 and 17, 2010 meetings.

Please register your attendance with the Liaison to the DFO no later than December 10, 2010.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meetings, contact the Liaison to the DFO as soon as possible.

Dated: November 23, 2010.

Joseph M. Re,

Captain, U.S. Coast Guard, Office of Performance Management (CG-0954).

[FR Doc. 2010-29938 Filed 11-26-10; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2007-0008]

National Advisory Council Teleconference Meeting

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of teleconference meeting.

SUMMARY: The National Advisory Council (NAC) will be holding a teleconference meeting for the purpose of discussing and gathering feedback on the National Disaster Housing Task Force's Practitioners' Guide to Disaster Housing.

DATES: Meeting Date: Thursday, December 16, 2010 from approximately 2 p.m. EST to 4 p.m. EST.

Comment Date: Written comments must be received by Thursday, December 9, 2010.

ADDRESSES: The meeting will be held via teleconference only. Members of the public who wish to obtain the listen-only call-in number, access code, and other information for the public teleconference may contact Alyson Price as listed in the **FOR FURTHER INFORMATION CONTACT** section by Thursday, December 9, 2010. All written comments must be received by Thursday, December 9, 2010. All submissions received must include the Docket ID FEMA-2007-0008 and may be submitted by any one of the following methods:

Federal Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments on the Web site.

E-mail: FEMA-RULES@dhs.gov. Include Docket ID FEMA-2007-0008 in the subject line of the message.

Facsimile: (703) 483-2999.

Mail: FEMA, Office of Chief Counsel, 500 C Street, SW., Room 840, Washington, DC 20472-3100.

Hand Delivery/Courier: FEMA, Office of Chief Counsel, 500 C Street, SW., Room 840, Washington, DC 20472-3100.

Instructions: All submissions received must include the Docket ID: FEMA-2007-0008. Comments received will also be posted without alteration at <http://www.regulations.gov>, including any personal information provided. You may want to read the Privacy Act Notice, which is found via the Privacy Notice link in the footer of <http://www.regulations.gov>.

Docket: For access to the docket to read documents or comments received by the National Advisory Council, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Alyson Price, Designated Federal Officer, FEMA, 500 C Street, SW., Room 832, Washington, DC 20472-3100, telephone 202-646-3746, fax 202-646-3930, and e-mail FEMA-NAC@dhs.gov. The NAC Web site is located at: <http://www.fema.gov/about/nac/>.

SUPPLEMENTARY INFORMATION: Notice of this meeting is required under the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App. 1, *et seq.*).

The National Disaster Housing Task Force (NDHTF) provides a full-time, multi-agency focus on disaster housing related issues and seeks to elevate the significance of disaster housing preparedness in all jurisdictions. FEMA will conduct a public teleconference with the National Advisory Council (NAC) to brief them and gather feedback on the NDHTF Practitioners' Guide to Disaster Housing (Practitioners' Guide) document currently under development by the NDHTF.

The Practitioners' Guide will provide guidance for State, Tribal, territory, and local disaster housing assistance practitioners to develop disaster housing strategies that improve responsiveness. It emphasizes the cooperative efforts required to provide disaster housing assistance by encouraging the involvement of private sector and non-governmental agencies.

The meeting is open to the public. Persons with disabilities who require special assistance should advise the Designated Federal Officer of their anticipated special needs as early as possible. Although members of the public will not be allowed to comment orally during the meeting, they may file a written statement with the NAC before the date of the meeting. For those wishing to submit written comments, please follow the procedure described in the **ADDRESSES** section.

Dated: November 22, 2010.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-29908 Filed 11-26-10; 8:45 am]

BILLING CODE 9111-48-P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

New Agency Information Collection Activity Under OMB Review: Pipeline Corporate Security Review

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the new Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on August 20, 2009, 74 FR 42086. The collection encompasses interviews and site visits with pipeline operators regarding company security planning and implementation.

DATES: Send your comments by December 29, 2010. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to oira_submission@omb.eop.gov or faxed to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT:

Joanna Johnson, TSA Paperwork Reduction Act (PRA) Officer, Office of Information Technology (OIT), TSA-40, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6040; telephone (571) 227-3651; e-mail TSAPRA@dhs.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Pipeline Corporate Security Review (PCSR).

Type of Request: New collection.

OMB Control Number: Not yet assigned.

Form(s): Pipeline Corporate Security Review (PCSR) Protocol Form.

Affected Public: Hazardous Liquids and Natural Gas Pipeline Industry.

Abstract: Under the Aviation and Transportation Security Act (ATSA) and delegated authority from the Secretary of Homeland Security, TSA is tasked with developing policies, strategies and plans for dealing with transportation security. TSA carries out this responsibility in the pipeline mode by assessing current industry security practices by way of its Pipeline Corporate Security Review (PCSR) program. The information will be collected during a voluntary, face-to-face visit with the pipeline operator, during which TSA will discuss the operator's security plan and also complete the PCSR Form. The PCSR Form asks approximately 218 questions concerning the operator's security planning and program, covering security topics such as threat assessments, criticality, vulnerability, credentialing, training, physical security countermeasures, and exercises and drills. TSA will use the information collected during the PCSR process to determine baseline security standards and areas of security weakness in the pipeline mode.

Number of Respondents: 2,200 potential respondents; likely 12 annual respondents.

Estimated Annual Burden Hours: An estimated 100 hours annually, based on TSA conducting 12 PCSR visits a year, each lasting 8 hours.

Issued in Arlington, Virginia, on November 23, 2010.

Joanna Johnson,

Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2010-29988 Filed 11-26-10; 8:45 am]

BILLING CODE 9110-05-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Andean Trade Preferences

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; Extension of an existing information collection: 1651-0091.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Andean Trade Preferences. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before January 28, 2011, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th Floor, Washington, DC. 20229-1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th Floor, Washington, DC. 20229-1177, at 202-325-0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (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 estimates 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 including

the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document the CBP is soliciting comments concerning the following information collection:

Title: Andean Trade Preferences.

OMB Number: 1651-0091.

Form Number: CBP Form 449.

Abstract: The information is to be used by CBP officers to document preferential tariff treatment under the provisions of the Andean Trade Preferences Act (ATPA) and the Andean Trade Promotion and Drug Eradication Act (ATPDEA), as codified in 19 U.S.C. 3201 through 3206. The ATPA Certificate of Origin format is found under the CBP Regulations, 19 CFR 10.201-10.207. The type of information collected includes the processing operations performed on articles, the material produced in a beneficiary country or in the U.S., and a description of those processing operations. The ATPDEA regulations are found in 19 CFR 10.251-10.257. Claims under ATPDEA are submitted using CBP Form 449. This form can be used only when claiming ATPDEA preferential treatment on the goods listed on the back of the form. CBP Form 449 can be found at: http://forms.cbp.gov/pdf/CBP_Form_449.pdf.

Current Actions: This submission is being made to extend the expiration date with no change to information collected or to CBP Form 449.

Type of Review: Extension (without change).

Affected Public: Businesses.

ATPA Certificate of Origin:

Estimated Number of Respondents: 2,133.

Estimated Number of Annual Responses per Respondent: 2.

Estimated Number of Total Annual Responses: 4,266.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 712.

ATPDEA Certificate of Origin:

Estimated Number of Respondents: 233.

Estimated Number of Annual Responses per Respondent: 7.

Estimated Number of Total Annual Responses: 1,631.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 815.

Dated: November 23, 2010.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2010-29981 Filed 11-26-10; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R9-IA-2010-N263; 96300-1671-0000-P5]

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1018-0093; Federal Fish and Wildlife Permit Applications and Reports—Management Authority

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This ICR is scheduled to expire on November 30, 2010. We 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. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before December 29, 2010.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB-OIRA at (202) 395-5806 (fax) or OIRA_DOCKET@OMB.eop.gov (e-mail). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 222-ARLSQ, 4401 North Fairfax Drive, Arlington, VA 22203 (mail), or infocol@fws.gov (e-mail).

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at the addresses above or by telephone at (703) 358-2482. You may review the ICR online at <http://www.reginfo.gov>. Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: OMB Control Number: 1018-0093.

Title: Federal Fish and Wildlife Permit Applications and Reports—Management Authority, 50 CFR 13, 15, 16, 17, 18, 21, and 23.

Service Form Number(s): 3-200-19 through 3-200-37, 3-200-39 through 3-200-44, 3-200-46 through 3-200-53, 3-200-58, 3-200-61, 3-200-64 through 3-200-66, 3-200-69 to 3-200-70, 3-200-73 through 3-200-76, 3-200-80, and 3-200-85 through 3-200-87.

Type of Request: Revision of currently approved collection.

Description of Respondents: Individuals; biomedical companies; circuses; zoological parks; botanical gardens; nurseries; museums; universities; antique dealers; exotic pet industry; hunters; taxidermists; commercial importers/exporters of wildlife and plants; freight forwarders/brokers; and State, Tribal, local, and Federal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Estimated Annual Number of Respondents: 10,314.

Estimated Annual Number of Responses: 13,055.

Estimated Completion Time per Response: Varies from 6 minutes to 85 hours depending on activity.

Estimated Annual Number of Burden Hours: 9,525.

Estimated Nonhour Cost Burden: \$982,751 associated with application fees.

Abstract: This information collection covers permit applications and reports that our Division of Management Authority uses to determine the eligibility of applicants for permits requested in accordance with the criteria in various Federal wildlife conservation laws and international treaties, including:

- Endangered Species Act (16 U.S.C. 1531 *et seq.*).
- Migratory Bird Treaty Act (16 U.S.C. 703 *et seq.*).
- Lacey Act (16 U.S.C. 3371 *et seq.*).
- Bald and Golden Eagle Protection Act (16 U.S.C. 668).
- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (27 U.S.T. 1087).
- Marine Mammal Protection Act (16 U.S.C. 1361-1407 *et seq.*).
- Wild Bird Conservation Act (16 U.S.C. 4901-4916 *et seq.*).

Service regulations implementing these statutes and treaties are in Chapter I, Subchapter B of Title 50, Code of Federal Regulations (CFR). These regulations stipulate general and specific requirements that when met

allow us to issue permits to authorize activities that are otherwise prohibited.

In addition to the forms and reports currently approved under OMB Control No. 1018-0093, this revised ICR includes:

- FWS Forms 3-200-74 (Single-Use Export Permits Under a Master File or Annual Program File) and 3-200-75 (Registration of a Production Facility for Export of Certain Native Species). These forms are currently approved under OMB Control Number 1018-0137. If OMB approves this ICR, we will discontinue 1018-0137.

- Four new forms that we believe will reduce burden on applicants, improve customer service, and allow us to process applications and issue CITES documents quickly:

(1) FWS Form 3-200-80 (Export of Fertilized Live Eggs, Caviar, or Meat from Aquacultured Paddlefish or Sturgeon (CITES)). Applicants currently use FWS Form 3-200-24 or 3-200-76 for this activity.

(2) FWS Form 3-200-85 (Master File for the Export of Live Captive-bred Animals (CITES)). Applicants currently use FWS Form 3-200-24 for this activity.

(3) FWS Form 3-200-86 (Photography of Marine Mammals for Educational or Commercial Purposes (MMPA)). Applicants currently use FWS Form 3-200-43 for this activity.

(4) FWS Form 3-200-87 (Transfer of Live Captive-held Marine Mammals (MMPA)). Applicants currently submit letters for notification or authorization.

Comments: On August 31, 2010, we published in the *Federal Register* (75 FR 53328) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on November 1, 2010. We received one comment. The comment did not address issues surrounding the proposed collection of information or the cost and hour burden estimates, but did object to other aspects of our permitting program and the killing of wildlife. We have not made any changes to this collection as a result of the comment. The commenter did question the groups that we included under the heading "Affected Public" in our previous *Federal Register* notice and stated that the entire U.S. public and animal protection groups are affected by this information collection. The groups listed under this heading were potential respondents. To ensure clarity, we have changed the heading title to "Description of Respondents."

We again invite comments concerning this information collection on.

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;

- The accuracy of our estimate of the burden for this collection of information;

- 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.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, e-mail 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: November 22, 2010.

Hope Grey,

Information Collection Clearance Officer, Fish and Wildlife Service.

[FR Doc. 2010-29980 Filed 11-26-10; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R9-R-2010-N265; 93261-1263-0000-4A]

Proposed Information Collection; OMB Control Number 1018-0102; Applications for Special Use Permits on National Wildlife Refuges

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on April 30, 2011. We 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: To ensure that we are able to consider your comments on this IC, we must receive them by January 28, 2011.

ADDRESSES: Send your comments on the IC to the Service Information Collection Clearance Officer, Fish and Wildlife Service, MS 222-ARLSQ, 4401 North Fairfax Drive, Arlington, VA 22203 (mail); or infocol@fws.gov (e-mail).

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Kevin Kilcullen by e-mail at Kevin.Kilcullen@fws.gov or by telephone at (703) 358-2382.

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd-668ee) (Administration Act) and the Refuge Recreation Act of 1962 (16 U.S.C. 460k-460k-4) (Recreation Act) govern the administration and uses of national wildlife refuges and wetland management districts. The Administration Act consolidated all of the different refuge areas into a single National Wildlife Refuge System (System). It also authorizes us to permit public accommodations, including commercial visitor services, on lands of the System when we find that the activity is compatible and appropriate with the purpose for which the refuge was established. The Recreation Act allows the use of refuges for public recreation when it is not inconsistent or does not interfere with the primary purpose(s) of the refuge.

In our general refuge regulations, we provide for public entry for specialized purposes, including economic activities such as the operation of guiding and other visitor services on refuges by concessionaires or cooperators under the appropriate legal instrument or special use permits (50 CFR 25.41, 25.61, 26.36, 27.71, 27.91, 27.97, 29.1, 29.2, 30.11, 31.2, 31.13, 31.14, 31.16, 32.2(1), 36.31, 36.32, 36.33, 36.37, 36.39, and 36.41, and 43 CFR 5). These regulations provide the authorities and procedures for allowing permits on refuges.

Previously, we used FWS Form 3-1383 (Special Use Application and Permit) for all activities. However, experience has indicated that some types of activities, such as commercial use or research, require that we collect detailed information on the specific activity so that we can more effectively

manage the numerous uses being conducted on System lands.

We are proposing to use three forms as applications for Special Use Permits:

(1) FWS Form 3-1383. We will use this form for the majority of activities including, but not limited to:

- Special events, such as fishing tournaments.
- Personal events, such as weddings.
- Beneficial management activities, such as wood cutting or rotational grazing, that we use to provide the best habitat possible on some refuges.
- Group visits and other one-time events.

(2) FWS Form 3-XXXX (Commercial Special Use Application and Permit). We will use this form for commercial activities including, but not limited to:

- Recreational visitor service operations.
- Commercial filming.
- Agricultural activities.
- Guiding for fishing, hunting, wildlife education, and interpretation.
- Building and using cabins to support subsistence or commercial activities (in Alaska).

(3) FWS Form 3-YYYY (Research Special Use Application and Permit). We will use this form to authorize research and monitoring activities on a refuge.

We plan to collect the following information. However, not all information will have to be provided, depending on the permit and specific activity:

- Type of activity/project.
- Identifying data (such as, name, business, or principal investigator, title, organization or affiliation, address, telephone number, and e-mail address).
- Whether the request is for a new permit or renewal or modification of an existing permit.
- Description, frequency and time line of the activity/project.
- Location/map.
- Assistants/subpermittees.
- Description of how the activity/project will help the refuge fulfill its purpose (FWS Form 3-YYYY).
- Insurance coverage.
- Licenses/permits required.
- Support/subcontractors used to support the activity.
- Equipment/gear and materials.
- Whether or not the activity requires overnight stay.
- Transportation logistics and requirements.

• Descriptions of work and living accommodations.

- Number of clients and/or participants.
- Certifications.
- Tax ID number or Social Security Number (FWS Form 3-XXXX).
- Whether or not an applicant or subpermittee has been convicted of a felony, or issued a national wildlife refuge notice of violation. If yes, applicant must provide details and court action taken (FWS Form 3-XXXX).
- Trip schedule(s).
- Curriculum Vitae or resume of principal researcher (FWS Form 3-YYYY).
- Relationship of principal researcher to affiliation/organization (such as professor, staff, student, etc) (FWS Form 3-YYYY).
- Full proposal of the planned research (FWS Form 3-YYYY).
- Description of how project will benefit the management of the refuge including how the project may benefit the management of threatened or endangered species (FWS Form 3-YYYY).

Some permits may require submission of:

- Interim and final reports.
- Safety plans.
- Operational plans.
- Minimum Requirements Decision Assessment for activities/projects requested in wilderness areas.
- Assurance of Animal Care Form (or equivalent) for research involving animals.
- Before and after photograph of site.

II. Data

OMB Control Number: 1018-0102.

Title: Applications for Special Use Permits on National Wildlife Refuges, 50 CFR 25.41, 25.61, 26.36, 27.71, 27.91, 27.97, 29.1, 29.2, 30.11, 31.2, 31.13, 31.14, 31.16, 32.2(1), 36.31, 36.32, 36.33, 36.37, 36.39, and 36.41.

Service Form Number(s): 3-1383, 3-XXXX, and 3-YYYY.

Type of Request: Revision of a currently approved collection.

Description of Respondents: Individuals and households; business and other for-profit organizations; nonprofit institutions; farms; and State, local, or Tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Activity	Number of respondents	Number of responses	Completion time per response	Total annual burden hours
FWS Form 3-1383	13,500	13,500	1 hour	13,500

Activity	Number of respondents	Number of responses	Completion time per response	Total annual burden hours
FWS Form 3-XXXX	1,200	1,200	4 hours	4,800
FWS Form 3-YYYY	300	300	4 hours	1,200
Totals	15,000	15,000	19,500

III. Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- 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.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, e-mail 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.

Dated: November 23, 2010.

Hope Grey,

Information Collection Clearance Officer,
Fish and Wildlife Service.

[FR Doc. 2010-29977 Filed 11-26-10; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R1-R-2010-N230; 10137-1265-0000 S3]

Bandon Marsh, Nestucca Bay, and Siletz Bay National Wildlife Refuges, Coos, Tillamook, and Lincoln Counties, OR; Comprehensive Conservation Plan and Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Intent; announcement of three public open house meetings; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), intend to prepare a comprehensive conservation plan (CCP) for the Bandon Marsh, Nestucca Bay, and Siletz Bay National Wildlife Refuges (NWRs), in or near the towns of Bandon, Pacific City, Neskowin, and Lincoln City, Oregon. We will also prepare an environmental assessment (EA) to evaluate the potential effects of various CCP alternatives. We provide this notice in compliance with our CCP policy to advise other Federal and State agencies, Tribes, and the public of our intentions and to obtain suggestions and information on the scope of issues to consider during the planning process. We are also announcing public meetings and requesting public comments.

DATES: To ensure consideration, please send your written comments by December 31, 2010. We will hold public meetings to begin the CCP planning process; see *Public Meetings* under **SUPPLEMENTARY INFORMATION** for dates, times, and locations.

ADDRESSES: Send your comments or requests for more information by any of the following methods:

E-mail: oregoncoastCCP@fws.gov. Include "Bandon Marsh, Nestucca Bay, and Siletz Bay CCP" in the subject line of the message.

Fax: Attn: Project Leader, 541-867-4551.

U.S. Mail: Oregon Coast National Wildlife Refuge Complex, 2127 SE Marine Science Drive, Newport, OR 97365.

In-Person Drop-off: You may drop off comments during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Roy W. Lowe, Project Leader, Oregon Coast National Wildlife Refuge Complex, 2127 SE Marine Science Drive, Newport, OR 97365; phone (541) 867-4550, and fax (541) 867-4551.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we initiate our process for developing a CCP for Bandon Marsh, Nestucca Bay, and Siletz Bay National Wildlife Refuges in Coos, Tillamook, and Lincoln Counties, Oregon. This notice complies with our CCP policy to (1) advise other Federal

and State agencies, Tribes, and the public of our intention to conduct detailed planning on these refuges, and (2) obtain suggestions and information on the scope of issues to consider in the environmental document and during development of the CCP.

Background

The CCP Process

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd-668ee) (Refuge Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. We will review and update the CCP at least every 15 years in accordance with the Refuge Administration Act.

Each unit of the National Wildlife Refuge System was established for specific purposes. These purposes are the foundation for developing and prioritizing the conservation and management goals and objectives for each refuge within the National Wildlife Refuge System, and determining compatible public uses for each refuge. The planning process is a way for us and the public to evaluate management goals and objectives for refuge wildlife, plant, and habitat conservation, while providing for wildlife-dependent recreation opportunities that are compatible with the refuge's establishing purposes and the mission of the National Wildlife Refuge System.

Our CCP process provides participation opportunities for Tribal, State, and local governments; agencies; organizations; and the public. At this time we encourage input in the form of issues, concerns, ideas, and suggestions for the future management of Bandon Marsh, Nestucca Bay, and Siletz Bay Refuges.

We will conduct an environmental review of this project and prepare an EA in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C.

4321 *et seq.*); NEPA regulations (40 CFR parts 1500–1508); other appropriate Federal laws and regulations; and our policies and procedures for compliance with those laws and regulations.

Bandon Marsh, Nestucca Bay, and Siletz Bay National Wildlife Refuges

Bandon Marsh NWR was established in 1983, with the acquisition of 289 acres of salt marsh, mudflats, and tidal sloughs. The Bandon Marsh Unit is located near the mouth of the Coquille River, with approximately 75 percent of the Unit within the city limits of Bandon, Oregon. The 582-acre Ni-les'tun Unit, established in 2000, includes 400 acres of historic salt marsh that is currently being restored to tidal action. The Ni-les'tun Unit is located on the east side of Highway 101 on the north bank of the Coquille River. The total land base of Bandon Marsh NWR is 889 acres.

The purpose for establishing Bandon Marsh NWR was "for the preservation and enhancement of the highly significant wildlife habitat of the area known as Bandon Marsh, in the estuary of the Coquille River * * * for the protection of migratory waterfowl, numerous species of shorebirds, and fish, including Chinook and silver salmon, and to provide opportunity for wildlife-oriented recreation and nature study on the marsh * * * (95 Stat. 1709, dated Dec 29, 1981). The Ni-les'tun Unit was added to Bandon Marsh NWR in order to (1) protect and restore intertidal marsh, freshwater marsh, and riparian areas to provide a diversity of habitats for migratory birds, including waterfowl, shorebirds, wading birds, and songbirds; (2) restore intertidal marsh habitat for anadromous fish such as the threatened coho salmon, chinook, chum salmon, steelhead, and cutthroat trout; (3) protect and restore habitat for species listed under the Endangered Species Act as threatened or endangered; and (4) provide wildlife-dependent public use opportunities compatible with refuge purposes.

Nestucca Bay NWR is located near Pacific City and Neskowin in Tillamook County, Oregon. The refuge was established in 1991 with the acquisition of a 384-acre dairy farm, and has since expanded to 818.5 acres. The primary need for establishing Nestucca Bay NWR was to protect high-quality coastal habitats for dusky Canada geese and threatened Aleutian Canada geese (delisted in 2001); other endangered and threatened species; and a variety of other migratory waterfowl, shorebirds, raptors, songbirds, anadromous fish, and other wildlife while preserving part of Oregon's biodiversity. In 2002, the

refuge was expanded to include the Neskowin Marsh Unit (222.6 acres acquired), located about 2.5 miles south of the Nestucca Bay Refuge Unit near the community of Neskowin, Oregon. Neskowin Marsh incorporates unique freshwater wetland and bog habitats and wildlife resources not found within the initial refuge boundary.

Siletz Bay NWR is located near Lincoln City on the central coast of Oregon. The refuge was established in 1991 with a donation of 46 acres of tidally muted salt marsh. The approved acquisition refuge boundary totals 1,936 acres and encompasses the northern tip of the Siletz spit, vegetated and unvegetated tidelands of the bay, and a portion of the diked former tidelands of the Siletz River floodplain. Approximately 1,060 acres within the authorized boundary are State-owned tidelands. Currently, refuge lands total 568 acres. The primary need for establishing this refuge was to protect coastal wetland habitats and upland buffers for a variety of waterfowl, shorebirds, marine mammals, endangered species, raptors, songbirds, fish, and other wildlife. The refuge serves to protect the remaining coastal wetlands and uplands adjacent to Siletz Bay from rapidly encroaching development, and management emphasis has been to enhance and restore wetland and upland habitats for a variety of estuarine-dependent fish and wildlife species.

Scoping: Preliminary Issues, Concerns, and Opportunities

We have identified preliminary issues, concerns, and opportunities that we may address in the CCP. We have briefly summarized these issues below. During public scoping, we may identify additional issues.

Bandon Marsh NWR Preliminary Issues: What actions should the Service take to sustain and restore priority species and habitats on this refuge over the next 15 years? Based upon the refuge's priority fish and wildlife species, which habitats would be monitored and managed to control invasive species? What management options should the refuge consider for restoration of the degraded upland forest and grassland? What possibilities exist for enhancing existing or adding additional wildlife-dependent recreational opportunities, including wildlife observation trails and/or photography points? Which areas/habitats of the refuge should be managed as undisturbed wildlife sanctuary areas (closed to the public) and which areas should be open to public use? Should the refuge consider

changes to the Bandon Marsh NWR waterfowl hunting program? Would allowing hunting and other wildlife-dependent recreational uses in new areas (e.g., Ni-les'tun Unit) have detrimental effects on the refuge's ability to provide adequate undisturbed quality wintering habitat for waterfowl and other wildlife? Is there enough use of the refuge by migrating waterfowl to provide a quality hunting program?

Nestucca Bay NWR Preliminary Issues: What actions should the Service take to sustain and restore priority species and habitats on this refuge over the next 15 years? Based upon the refuge's priority fish and wildlife species, which are the priority habitats to monitor for invasive species, and what is the range of Integrated Pest Management strategies that should be considered to reduce the incidence and spread of invasive species? Should the Service consider restoring some pastures at Nestucca Bay NWR to tidal marsh, and what effect would this have on the refuge's ability to provide wintering habitat for geese and reduce goose depredation on neighboring private lands? Should the Cannery Hill Unit at Nestucca Bay NWR be managed specifically to restore former coastal prairie, and if so, how much emphasis should be placed on specific needs of the threatened Oregon silverspot butterfly within a larger coastal prairie restoration plan? What options should be considered for the old roadbed through Neskowin Marsh (tsunami escape route) if it is found to be impacting water flows through Neskowin Marsh? Should the Service consider designating Neskowin Marsh as a Research Natural Area? What possibilities exist for adding or enhancing existing wildlife-dependent recreational opportunities on Nestucca Bay NWR? Are existing refuge access points and uses adequate and do they provide a quality experience? Should the refuge consider establishing waterfowl hunting programs at Nestucca Bay NWR? Can the level of migrating waterfowl use on Nestucca Bay NWR support a quality hunting program?

Siletz Bay NWR Preliminary Issues: What actions should the Service take to sustain and restore priority species and habitats on this refuge over the next 15 years? Based upon the refuge's priority fish and wildlife species, which habitats are most important to monitor for invasive species? What partnering possibilities exist for treatment of aquatic invasive species such as smooth cordgrass and New Zealand mud snail? Can wetlands currently hampered by fish passage barriers and other issues be restored, and if so, how should the

Service prioritize them? What opportunities exist for adding or enhancing existing wildlife-dependent recreational opportunities and access points? Which areas of the refuge should be managed as undisturbed sanctuary areas and which areas should be considered for public access? Should the refuge consider establishing a waterfowl hunting program at Siletz Bay

NWR? Would waterfowl hunting and other wildlife-dependent recreational activities have detrimental effects on the refuge's ability to provide adequate undisturbed quality wintering habitat for waterfowl? Is there enough use of the refuge by migrating waterfowl to support a quality hunting program? Should the refuge consider enhancing the currently offered seasonal

opportunities to observe wildlife via guided canoe/kayak excursion through the refuge?

Public Meetings

We will hold the following public meetings. For more information, contact the person under **FOR FURTHER INFORMATION CONTACT**.

Date	Time	Location
November 29, 2010	6-9 p.m. ..	Lincoln City Community Center, 2150 NE. Oar Place, Lincoln City, OR 97367.
November 30, 2010	6-9 p.m. ..	Kiawanda Community Center, 34600 Cape Kiawanda Drive, Pacific City, OR 97135.
December 2, 2010	6-9 p.m. ..	Bandon Community Center, 1200 11th Street SW., Bandon, OR 97411.

Public Availability of Comments

Before including your address, phone number, e-mail 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.

Dated: October 28, 2010.

Theresa E. Rabot,

Acting Regional Director, Region 1, Portland, Oregon.

[FR Doc. 2010-30063 Filed 11-26-10; 8:45 am]

BILLING CODE 4310-55-P

available for release. The BLM subsequently determined that additional information should have been included in the cumulative impact section of the EA. The BLM will be issuing a revised EA, which will be available for a 30-day comment period upon completion. After the end of the comment period, the BLM will hold a public hearing on the EA, the fair market value and the maximum economic recovery of the proposed leased tract.

FOR FURTHER INFORMATION CONTACT: Kurt M. Barton, Land Law Examiner, 2850 Youngfield Street, Lakewood, CO 80215 at (303) 239-3714, Kurt_Barton@blm.gov, or Jennifer Maiolo, Mining Engineer, 455 Emerson Street, Craig, CO 81625 at 970-826-5077, Jennifer_Maiolo@blm.gov.

Helen M. Hankins,
State Director.

[FR Doc. 2010-29864 Filed 11-26-10; 8:45 am]

BILLING CODE 4310-JB-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO-921000-L1320000-EL0000-LVELC10CC770; COC-74219]

Notice of Correction to Notice of Availability of the Environmental Assessment and Notice of Public Hearing for the Sage Creek Holdings, LLC, Federal Coal Lease Application, COC-74219

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Correction.

SUMMARY: The Bureau of Land Management (BLM) is correcting the Notice of Availability of the Environmental Assessment (EA) and Notice of Public Hearing for the Sage Creek Holdings, LLC, Federal Coal Lease Application, COC-74219 published in the **Federal Register** on August 13, 2010 [75 FR 49512]. The BLM incorrectly stated that the EA was complete and

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. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before December 29, 2010.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior, Office of Information and Regulatory Affairs, OMB, at (202) 395-5806 (fax) or OIRA_DOCKET@OMB.eop.gov (e-mail). Please provide a copy of your comments to Garry Oye, Chief of Wilderness Stewardship Division, National Park Service, 1201 Eye Street NW., (Room 1004), Washington DC 20005; via fax at (202) 371-6623; or via e-mail at Garry_Oye@nps.gov.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Garry Oye by mail, fax, or e-mail (see **ADDRESSES**) or by phone at (202) 513-7090.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1024-0022.

Title: Backcountry Use Permit (36 CFR 1.5, 1.6, and 2.10).

Form Number: 10-404A.

Type of Request: Extension of a currently approved collection.

Description of Respondents:

Individuals wishing to use backcountry areas within national parks.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Estimated Number of Respondents:

285,000.

Estimated Number of Responses:

285,000.

Completion Time per Response: 0.083 hours.

DEPARTMENT OF THE INTERIOR

National Park Service

[2462-PYB]

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1024-0022; Backcountry Use Permit

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This ICR is scheduled to expire on November 30, 2010. We may not

Estimated Annual Burden Hours: 23,750.

Estimated Annual Nonhour Burden Cost: None.

Abstract: The Backcountry Use Permit (Form 10-404A) is used to implement a backcountry reservation system and provide access into backcountry zones where registration is required or limits are imposed in accordance with regulations. Such permitting enhances the ability of the NPS to issue hazard warnings, to conduct search and rescue efforts, and to provide resource protection.

The objectives of the permit system are to ensure: (1) Requests by backcountry users are evaluated by park managers in accordance with applicable statutes and NPS regulations; (2) use of consistent standards and permitting criteria throughout the agency; and (3) to the extent possible, use of a single permitting document.

Comments: On July 19, 2010, we published in the **Federal Register** (75 FR 41879) a notice of our intent to request that OMB renew this information collection. In that notice, we solicited comments for 60 days, ending on September 17, 2010. We did not receive any comments in response to that notice.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- 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.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, e-mail 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: November 22, 2010.

Robert Gordon,

NPS, Information Collection Clearance Officer.

[FR Doc. 2010-29971 Filed 11-26-10; 8:45 am]

BILLING CODE 4310-70-P

DEPARTMENT OF THE INTERIOR

National Park Service

[2301-RYY]

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1024-0236; National Park Service Research Permit and Reporting System Applications and Reports

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost, and request public comment on this collection request. This information collection is scheduled to expire on November 30, 2010. We 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. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before December 29, 2010.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior, Office of Information and Regulatory Affairs, OMB, at (202) 395-5806 (fax) or OIRA_DOCKET@OMB.eop.gov (e-mail). Please provide a copy of your comments to Dr. John G. Dennis, Natural Resources (MIB 3130), National Park Service, 1849 C Street, NW., Washington, DC 20240; Voice: 202-513-7174; or via Fax at: 202-371-2131; or by E-mail: WASO_NRSS_researchcoll@nps.gov.

FOR FURTHER INFORMATION CONTACT: Dr. John G. Dennis, Natural Resources (MIB 3130), National Park Service, 1849 C Street, NW., Washington, DC 20240; Voice: 202-513-7174; Fax: 202-371-2131; E-mail: WASO_NRSS_researchcoll@nps.gov. If you comment to NPS via electronic mail, please submit your comments as an attached ASCII or MSWord file and avoid the use of special characters and any form of encryption. Please also include "Attn: NPS Research Permit and Reporting System" and your name and return address in your e-mail message. If you would like, but do not receive, a confirmation from the system that we have received your e-mail message,

contact us directly at the NPS phone number given here.

SUPPLEMENTARY INFORMATION: OMB Control Number: 1024-0236.

Title: National Park Service Research Permit and Reporting Systems Applications and Reports.

Form Number: 10-741A & B, 10-226.

Type of Request: Extension of a currently approved collection.

Description of Respondents: Individual scientific investigators, science educators, research organizations, and science education organizations who apply for a permit.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Estimated Number of Responses: 10-741A—4,980; 10-741B—415; 10-226—5,395.

Completion Time Per Response: 10-741A—1.375; 10-741B—1.00; 10-226—0.25.

Estimated Annual Burden Hours: 10-741A—6,872; 10-741B—415; 10-226—1,349.

Estimated Annual Nonhour Burden Cost: None.

Abstract: The NPS regulates scientific research, studies and science education activities inside park boundaries under regulations codified at 36 CFR Part 2, Section 2.5. The NPS administers these regulations to provide for scientific research while also protecting park resources and other park uses from adverse impacts that could occur if inappropriate scientific research and collecting studies or science education activities were to be conducted within park boundaries.

NPS uses the collected information for managing the use and preservation of park resources and for reporting to the public the status of permitted research and collecting activities. NPS is requesting that OMB renew its approval of the current Application for a Scientific Research and Collecting Permit, Application for a Science Education Permit, and Investigator's Annual Report collection of information forms.

Comments: On July 21, 2010, we published in the **Federal Register** (75 FR 42459) a notice of our intent to request that OMB renew this information collection. In that notice, we solicited comments for 60 days, ending on September 20, 2010. NPS received one comment on this notice. The one comment stated that the commenter has "no problems with the current permitting system for full-scale research projects in the National Parks. However, I would like to recommend a simplified and rapid permitting process

for limited and targeted collecting of arthropods." NPS found that this comment did not indicate any clear reasons for changing any of the three forms.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- 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.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, e-mail 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: November 23, 2010.

Robert Gordon,

NPS, Information Collection Clearance Officer.

[FR Doc. 2010-29975 Filed 11-26-10; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

[2410-OYC]

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1024-0233; National Park Service Leasing Program

AGENCY: National Park Service, Interior.
ACTION: Notice; request for comments.

SUMMARY: We (National Park Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This ICR is scheduled to expire on November 30, 2010. We 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. However, under OMB regulations, we may continue to

conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before December 29, 2010.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior, Office of Information and Regulatory Affairs, OMB, at (202) 395-5806 (fax) or *OIRA_DOCKET@OMB.eop.gov* (e-mail). Please provide a copy of your comments to Jo A. Pendry, Chief, Commercial Services Program, National Park Service, 1201 Eye Street, NW, 11th Floor, Washington, DC 20005, via fax at (202) 371-2090; at via e-mail at *jo_pendry@nps.gov*.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR contact Erica Chavis, Concessions Assistant, National Park Service, by mail at 1201 Eye Street, NW, 11th Floor, Washington, DC 20005, via fax at (202) 371-2090, via e-mail at *Erica_chavis@nps.gov*, or by telephone at (202) 513-7144.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1024-0233.

Title: National Park Service Leasing Program.

Form Number: None.

Type of Request: Revision of a currently approved collection.

Description of Respondents: Individuals seeking to lease or in current lease agreements for National Park Service-controlled public property and facilities.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Estimated Number of Respondents: 327.

Estimated Number of Responses: 327.

Completion Time per Response: 4.62 hours.

Estimated Annual Burden Hours: 1,512.

Estimated Annual Nonhour Burden Cost: None.

Abstract: The National Park Service leasing program allows the public to lease property located within the boundaries of the park system. Information is collected from anyone who wishes to submit a bid or proposal in response to a Request for Bids or a Request for Proposals; or from current lease holders who wish to sublet a leased property or assign the lease to a new lessee, construct or demolish portions of a leased property, amend a lease to change the type of activities permitted under the lease, or encumber (mortgage) the leased premises. The information collected will be used to evaluate offers, proposed subleases or

assignments, proposed construction or demolition, the merits of proposed lease amendments, and proposed encumbrances.

Comments: On July 24, 2010, we published in the **Federal Register** (75 FR 40849) a notice of our intent to request that OMB renew this information collection. In that notice, we solicited comments for 60 days, ending on June 4, 2010. We did not receive any comments in response to that notice.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- 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.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, e-mail 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: November 22, 2010.

Robert Gordon,

NPS, Information Collection Clearance Officer.

[FR Doc. 2010-29973 Filed 11-26-10; 8:45 am]

BILLING CODE 4312-53-P

DEPARTMENT OF THE INTERIOR

National Park Service

[2330-RYY]

Proposed Information Collection; National Park Service Visitor Survey Card

AGENCY: National Park Service, Interior.
ACTION: Notice; request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on renewal of an information

collection approved under OMB Control Number 1024-0216.

DATES: Public comments on this Information Collection Request (ICR) will be accepted on or before December 29, 2010.

ADDRESSES: Please send your comments and suggestions on this ICR to the Desk Officer for the Department of the Interior at OMB-OIRA at (202) 395-5806 (fax) or OIRA_DOCKET@OMB.eop.gov (e-mail). Please also send a copy of your comments on the ICR to Dr. Bruce Peacock, NPS Social Science Division, 1201 Oakridge Drive, Fort Collins, CO 80525; or at Bruce_Peacock@nps.gov (e-mail).

FOR FURTHER INFORMATION CONTACT: Jennifer Hoger-Russell, Park Studies Unit, College of Natural Resources, University of Idaho, P.O. Box 441139, Moscow, ID 83844-1139; *Phone:* (208) 885-4806; *Fax:* (208) 885-4216; jhoger@uidaho.edu (e-mail).

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Park Service Act of 1916, 38 Stat 535, 16 U.S.C. 1, *et seq.*, requires that the NPS preserve national parks for the use and enjoyment of present and future generations. At the field level, this means resource preservation, public education, facility maintenance and operation, and physical developments as are necessary for public use, health, and safety. Other Federal mandates (National Environmental Policy Act and NPS Management Policies) require visitor use data in the impact assessment of development on users and resources as part of each park's general management plan. The Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103-62) requires that the NPS develop goals to improve program effectiveness and public accountability and to measure performance related to these goals. The Visitor Survey Card (VSC) project measures performance toward those goals through a short visitor survey card. The project is an element of the NPS Strategic Plan and the Department of the Interior (DOI) Strategic Plan.

The NPS has used the VSC to conduct surveys at approximately 330 National Park Service units annually since 1998. The purpose of the VSC is to measure visitors' opinions about park facilities, services, and recreational opportunities in each park unit and System-wide. This effort is required by GPRA and other NPS and DOI strategic planning efforts. Data from the proposed survey is

needed to assess performance regarding NPS GPRA goals IIa1A and IIb1.

In addition, the survey collects data to support the DOI Strategic Plan goal on visitor satisfaction with the value for entrance fees paid to access public lands managed by the DOI. NPS performance on all goals measured in this study will contribute to DOI Department-wide performance reports. Results of the VSC will also be used by park managers to improve visitor services at the approximately 330 units of the National Park System where the survey is administered.

The VSC is a component of the Visitor Services Project, which is funded by the NPS through a cooperative agreement with the Park Studies Unit at the University of Idaho, and has been in use since 1998.

II. Data

OMB Number: 1024-0216.

Title: National Park Service Visitor Survey Card.

Type of Request: This is a renewal of a currently approved collection.

Respondent Obligation: Voluntary.

Frequency of Collection: One-time per respondent.

Description of respondents: Visitors to approximately 330 NPS units.

Estimated average number of respondents: 132,000 visitors who accept the survey card (92,400 non-respondents and 39,600 respondents) and 1,188 visitors who refuse to take the survey card but are willing to answer the two demographic questions and the overall satisfaction question.

Estimated average burden hours per response: 1 minute for non-respondents, 3 minutes for respondents, and 2 minutes for visitors who refuse to take the survey card but are willing to answer the two demographic questions and the overall satisfaction question.

Estimated annual reporting burden: 3,540 hours.

III. Request for Comments

We are inviting comments concerning this ICR on: (a) Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, usefulness, and clarity of the information to be collected; and (d) ways to minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of

public record. Before including your address, phone number, e-mail 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.

Dated: November 23, 2010.

Robert Gordon,

*Information Collection Clearance Officer,
National Park Service.*

[FR Doc. 2010-29974 Filed 11-26-10; 8:45 am]

BILLING CODE 4312-52-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-687]

Certain Video Displays, Components Thereof, and Products Containing Same; Notice of Commission Determination to Review a Final Initial Determination in Part and Set a Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on September 17, 2010, in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205-3116. 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: This investigation was instituted on September 16, 2009, based on a complaint filed by LG Electronics, Inc. ("LG"), alleging a violation of section 337 in the importation, sale for importation, and sale within the United States after importation of certain video displays, components thereof, or products containing same that infringe one or more of claims 24 and 25 of U.S. Patent No. 5,790,096; claims 1-9 of U.S. Patent No. 5,537,612; claim 1 of U.S. Patent No. 5,459,522; claims 1-5 and 7-16 of U.S. Patent No. 7,154,564. 74 FR 47616 (2009) Complainant named Funai Electric Company, Ltd. of Osaka, Japan, Funai Corporation, Inc. of Rutherford, New Jersey, P&F USA, Inc. of Alpharetta, Georgia (collectively, "Funai"), and Vizio, Inc. of Irvine, California ("Vizio") as respondents. On January 8, 2010, the presiding ALJ issued an ID granting Complainant's motion for leave to file a second amended complaint and amend the Notice of Investigation to, *inter alia*, add AmTran Technology Co. Ltd. and AmTran Logistics, Inc. as respondents to the investigation. Order No. 12 (unreviewed by the Commission). Subsequently, respondents Funai Electric Company, Ltd., Funai Corporation, Inc., and P&F USA, Inc. were terminated from the investigation based on a settlement agreement.

The evidentiary hearing on violation of Section 337 was held from June 9, 2010 through June 21, 2010. On September 17, 2010, the ALJ issued his final ID finding a violation of section 337. All the parties to the investigation, including the Commission investigative attorney (IA), filed timely petitions for review of various portions of the final ID, as well as timely responses to the petitions.

Having examined the record in this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part. In particular, the Commission has determined to review: (1) The ID's finding that dependent claims 4, 6, and 7 of the '612 patent are not invalid as anticipated or obvious; (2) the ID's findings and conclusions with respect to independent claim 5 of the '564 patent. The Commission has determined not to review the remainder of the final ID.

On review, the Commission requests briefing on the above-listed issues based on the evidentiary record. The

Commission is particularly interested in responses to the following questions:

(1) With respect to the '612 patent:
(a) Does the record evidence show, clearly and convincingly, that claim 4 is anticipated by: (i) The CableData HTU device (RPX-4); (ii) U.S. Patent No. 4,896,354 ("the '354 patent"); and (iii) U.S. Patent No. 4,930,160 ("the '160 patent")?

(b) Does the record evidence show, clearly and convincingly, that claim 4 is obvious in view of any of the above prior art references alleged to anticipate claim 4?

(c) Does the record evidence show, clearly and convincingly, that claim 6 is anticipated by: (i) the '160 patent; (ii) U.S. Patent No. 4,510,623 ("the '623 patent"); (iii) U.S. Patent No. 5,033,085 ("the '085 patent"); and (iv) the '354 patent?

(d) Does the record evidence show, clearly and convincingly, that claim 6 is obvious in view of any of the above prior art references alleged to anticipate claim 6?

(e) Does the record evidence show, clearly and convincingly, that claim 7 is anticipated by: (i) The '160 patent; (ii) the '623 patent; (iii) the '085 patent; and (iv) the '354 patent?

(f) Does the record evidence show, clearly and convincingly, that claim 7 is obvious in view of any of the above prior art references alleged to anticipate claim 7?

(2) With respect to the '564 patent:
(a) Does the record evidence show that claim 5 is infringed?

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or are likely to do so. For background, see *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (Dec. 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the

effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. See Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues under review. The submissions should be concise and thoroughly referenced to the record in this investigation. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the expiration date of the involved patents and state the HTSUS numbers under which the accused articles are imported. The written submissions and proposed remedial orders must be filed no later than the close of business on December 3, 2010. Reply submissions must be filed no later than the close of business on December 10, 2010. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must

request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See section 201.6 of the Commission's Rules of Practice and Procedure, 19 CFR 201.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

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 sections 210.42-.46 of the Commission's Rules of Practice and Procedure (19 CFR 210.42-.46).

Issued: November 19, 2010.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2010-29911 Filed 11-26-10; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-690]

Certain Printing and Imaging Devices and Components Thereof; Notice of Commission Determination To Review-in-Part a Final Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review a portion of the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on September 23, 2010 finding a violation of section 337 and to request briefing on the issues under review and on remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Daniel E. Valencia, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205-1999. 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 October 26, 2009, based on a complaint filed by Ricoh Company, Ltd. of Tokyo, Japan; Ricoh Americas Corporation of West Caldwell, New Jersey; and Ricoh Electronics, Inc. of Tustin, California (collectively "Ricoh"). 74 FR 55065 (Oct. 26, 2009). The complaint alleged, *inter alia*, violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain printing and imaging devices and components thereof by reason of infringement of U.S. Patent Nos. 6,209,048 ("the '048 patent"); 6,212,343 ("the '343 patent"); 6,388,771 ("the '771 patent"); 5,764,866 ("the '866 patent"); and 5,863,690 ("the '690 patent"). The complaint named Oki Data Corporation of Tokyo, Japan and Oki Data Americas, Inc. of Mount Laurel, New Jersey (collectively "Oki") as respondents.

On September 23, 2010, the ALJ issued his final ID finding that Oki violated section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain printing and imaging devices and components thereof by reason of infringement of several claims in the '690 patent. The ALJ found that Oki has not violated section 337 with respect to the '048, '343, '771, and '866 patents. Along with the ID, the ALJ issued a recommended determination on remedy and bonding ("RD"). Complainant Ricoh, respondent Oki, and the Commission investigative attorney ("IA") filed petitions for review of the ID on October 6, 2010. Ricoh, Oki, and the IA each filed responses to the petitions for review on October 14, 2010.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. In particular, the Commission has determined to review all findings and

conclusions relating to whether a violation of section 337 has occurred with respect to the '343 and '690 patents.

The parties are requested to brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following questions:

The '343 Patent

(1) The Commission has determined to review all findings relating to the limitation "a direction orthogonal to a longitudinal direction of the developing roller," as recited in the asserted claims of the '343 patent.

(a) Please state your position on the meaning of "a longitudinal direction of the developing roller," as recited in the asserted claims. How does your position differ from the ALJ's construction?

(b) Specifically, does "a longitudinal direction" include any line extending parallel to the central axis of the roller? Or, does this refer to the central axis itself?

(c) Please state your position on the meaning of "a direction orthogonal to a longitudinal direction of the developing roller." Please take into account that the planar blade is bent along its entire width, and do not confine your analysis to two-dimensional cross-sections.

(d) Assuming "a longitudinal direction" can include any line extending parallel to the central axis of the roller, can "a direction orthogonal" refer to a direction that is not perpendicular to the surface of the roller, *i.e.*, a tangent extending through the surface of the roller?

(e) Given the planar shape of the blade contacts the roller in three dimensions along the entire width of the blade, and is bent along the entire width of the blade, is there any bend that would not meet the "direction orthogonal" limitation?

(f) How does your answer to (d) comport with the preferred embodiment of the '343 patent shown in Figures 8A and 8B? Is the blade 17 shown in Figures 8A and 8B bent in "a direction orthogonal to a longitudinal direction of the developing roller?"

(g) How do your answers to (a) through (e) affect the ALJ's findings regarding infringement, validity, and domestic industry?

(2) The Commission has determined to review the ALJ's construction of "a lower edge," as recited in the asserted claims of the '343 patent. The asserted claims of the '343 patent recite, among other things:

wherein the blade includes a wide-width part * * * and a narrow-width part * * * configured * * * to be [sic] bend in a direction orthogonal to a longitudinal direction of the developing roller * * * and the narrow-width part is disposed downstream of the contact point of the blade and the roller part * * * in the rotation direction.

JX-4 ('343 patent), col. 25, ll. 16-30 (emphasis added).

(a) Please explain whether the language emphasized above informs the meaning of "a lower edge."

(b) Can the claimed "a lower edge" refer to an edge of the "narrow-width part," an edge of the "wide-width part," or both?

(c) If the narrow-width part of the blade is bent away from the roller such that the edge opposite the boundary between the wide-width part and the narrow-width part does not contact the roller, as shown in Figures 8A, 8B, and 12, how should "a lower edge" be construed?

(d) Can "a lower edge thereof contacts the roller part of the developing roller" refer to contact between the roller and an area extending from the lower edge of the blade to a point on the blade slightly above the lower edge?

(e) How do your answers to (a) through (d) affect the ALJ's findings regarding infringement, validity, and domestic industry?

The '690 Patent

(1) The Commission has determined to review the ALJ's determination of the level of ordinary skill in the art of the '690 patent. See ID at 99. Please comment on what the level of ordinary skill in the art is with respect to the '690 patent. Please provide specific citations to the record and testimony. Although the parties are invited to brief their respective positions generally on this issue, the Commission is specifically interested in answers to the following questions:

(a) Would it be appropriate for the Commission to modify the ALJ's determination to add the fields of applied rheology and/or applied material science to the types of experience that would satisfy the three-year minimum requirement in the ALJ's determination?

(b) Would it be appropriate for the Commission to modify or remove the ALJ's determination to remove the three-year minimum experience requirement altogether?

(c) Would it be appropriate for the Commission to modify the ALJ's familiarity requirement by, for example, requiring familiarity with at least one (as opposed to all) of the following

technological areas: heat transfer, fuser roller design and technology, toner rheology, toner adhesion, release agent management, nip geometry, image fixing, paper path geometry, contact angle and surface roughness characteristics and testing of xerographic user rollers?

(d) Would it be appropriate for the Commission to modify the ALJ's familiarity requirement to remove any technological areas not directly related to the interaction between a toner and a fuser roller?

(2) The Commission has determined to review the ALJ's determination that the asserted claims of the '690 patent are not anticipated.

(a) What are the "above-mentioned surface physical properties" mentioned in column 6, lines 4-5 of the '690 patent?

(b) Please comment on whether examples 1 and 2 of the '690 patent inform the patent's statement in column 6 that PTFE (polytetrafluoroethylene) and polytetrafluoroethylene/perfluoralkylvinylether (PFA) are "[s]pecific examples of materials for the fixing member which easily satisfy the above-mentioned surface physical properties."

(c) Under what circumstances (if any) would a PTFE fuser roller not have an adhesion constant ratio of less than about 8.0 when measuring receding and static contact angles using 2-nitropropane and n-heptane, respectively, as set forth in the '690 patent?

(d) To what extent is the adhesion constant ratio dependent on the surface roughness of the fuser roller and composition of the toner? How does the subject matter of dependent claims 9-16 inform your response, if at all?

(e) Is it appropriate under current legal precedent to consider the asserted patent's disclosure in determining what would be inherent in the prior art?

(f) Please comment on whether the dependent claims of the '690 patent are anticipated or obvious, assuming claim 1 of the '690 patent is found to be anticipated.

(g) What materials are the OL 400 rollers and OL 1200 rollers coated with? Has this material changed since the critical date of the '690 patent?

(3) Please state your position with respect to contributory infringement by Oki of the asserted claims of the '690 patent.

(4) Please provide a summary of Ricoh's annual labor costs associated with the C200 domestic product. Please isolate costs by year and indicate any possible trends.

(5) Are the C200 MFP's "articles protected by the ['690] patent" under section 337(a)(2)?

As to the '048, '771, and '866 patents, the Commission has determined that Oki did not violate section 337. The Commission has determined to review and take no position on the following findings and conclusions in the ID, however:

(1) The finding that the Taylor reference ("A Telerobot on the World Wide Web") (RX-281) does not anticipate or render obvious claims 19-21 and 23 of the '048 patent;

(2) The finding that U.S. Patent Nos. 5,657,448 and 5,784,622 do not anticipate or render obvious the asserted claims of the '048 patent;

(3) The ALJ's determination not to construe the following claim terms in the '048 patent: "descriptor," "resource identifier defining a resource and its location," "command," and "interconnected, on-line documents";

(4) The construction of "communications mechanism" in claim 19 of the '048 patent and associated findings on the issues of infringement, domestic industry, and validity;

(5) The finding that Japanese Published Application No. JP H07-306934 does not anticipate or render obvious the asserted claims of the '771 patent; and

(6) The finding that claim 13 of the '771 patent is infringed.

The Commission has determined to review the ALJ's findings that the claim terms "scan means," "print means," "copy means," and "test means" of the '866 patent, and the claim terms "scanning means," "means for setting an operation code," and "a code unit for setting an operation code" of the '771 patent do not render the asserted claims indefinite. Upon review, the Commission has determined that the terms at issue are not indefinite under the relevant standard set forth in *Aristocrat Technologies. v. International Game Technology*, 521 F.3d 1328, 1337 (Fed. Cir. 2008). The Commission adopts the ALJ's substantive analysis of these issues set forth in his Order No. 29 (May 4, 2010).

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent(s) being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is

interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. See Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the ALJ's recommendation on remedy and bonding set forth in the RD. Complainants and the IA are also requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the date that the '690 and '343 patents expire and the HTSUS numbers under which the accused

products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on Thursday December 9, 2010. Reply submissions must be filed no later than the close of business on Friday December 17, 2010. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

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 sections 210.42-46 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42-46 and 210.50).

Issued: November 22, 2010.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2010-29910 Filed 11-26-10; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree and Environmental Settlement under the Comprehensive Environmental Response, Compensation and Liability Act, and the Resource Conservation and Recovery Act

Notice is hereby given that on November 23, 2010, a proposed Consent Decree and Environmental Settlement Agreement ("Settlement Agreement") in the matter of *In re: Tronox Incorporated, et al.*, Case No.09-10156 (ALG) (Jointly Administered), was lodged with the United States Bankruptcy Court for the Southern District of New York.

The parties to the proposed Settlement Agreement are Tronox Incorporated, and fourteen of its affiliates (collectively, "Tronox" or "Debtors"), the United States, the Navajo

Nation, twenty-two states, and several municipalities (collectively, the "Governmental Environmental Claimants"). The proposed Settlement Agreement creates five environmental response trusts and provides for Tronox to pay \$270 million and certain other consideration to the environmental response trusts and Governmental Environmental Claimants. Additionally, Tronox is to assign its rights in a pending fraudulent conveyance lawsuit against its former parent, Kerr-McGee Corporation, and Anadarko Petroleum Corporation, which purchased Kerr-McGee, to a litigation trust that will pay 88% of its net recoveries to the environmental response trusts and Governmental Environmental Claimants. The fraudulent conveyance lawsuit alleges that Kerr-McGee and Anadarko defrauded Tronox and its creditors, including the United States, by imposing on Tronox all of Kerr-McGee's environmental liabilities without sufficient means to satisfy those liabilities.

The Settlement Agreement resolves certain environmental liabilities of the Debtors to the Governmental Environmental Claimants at more than 2000 sites and indicates the amount of cash and percentage of net recoveries from the fraudulent conveyance action that will be provided by site. Among the sites included in the settlement are:

The Mobile Pigment Complex, Mobile, AL
 The former Petroleum Terminal Site, Birmingham, AL
 The Jacksonville AgChem Site, Jacksonville, FL
 The former titanium dioxide Plant, Savannah, GA
 The Rare Earths Facility, W. Chicago, IL
 The Kress Creek and Residential Areas Sites, W. Chicago, IL
 The Lindsay Light Thorium Sites, Chicago, IL
 The former wood treating facility, Madison, IL
 The Soda Springs Vanadium Plant, Soda Springs, ID
 The former wood treating facility, Columbus, MS
 The former wood treating facility, Hattiesburg, MS
 The Navassa wood treating Site, Wilmington, NC
 The Henderson Facility, Henderson, NV
 The former wood treating facility, Bossier City, LA
 The Calhoun Gas Plant Site, Calhoun, LA
 The Fireworks Site, Hanover, MA
 The former nuclear fuels facility, Cimarron, OK
 The Cleveland Refinery Site, Cleveland, OK

The Cushing Refinery Sites, Cushing, OK
 The Corpus Christi Petrol Terminal Site, CC, TX
 The former wood treating facility, Texarkana, TX
 The former wood treating facility, Kansas City, MO
 The former wood treating facility, Springfield, MO
 The former wood treating facility, Rome, NY
 The former wood treating facility, Avoca, PA
 The Riley Pass Mine Site, Harding County, SD
 The former wood treating facility, Indianapolis, IN more than 50 former uranium mines and mills, including Shiprock, Churchrock, and Ambrosia Lake on and in the vicinity of Navajo Nation, NM, AZ
 The White King/Lucky Lass mine site, Lakeview, OR
 The Toledo Tie Site, Toledo, OH
 The Welsbach Gas and Mantle Site, Camden, NJ
 The former Federal Creosote facility, Mapville, NJ
 The former Moss American Site, Milwaukee, WI more than 1800 current and former service stations in twenty-four states

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree and Settlement Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to pubcomment-ees.enrd@usdoj.gov or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to In re Tronox, Incorporated *et al.*, D.J. Ref. 90-11-3-09688. Commenters may request an opportunity for a public meeting in the affected area, in accordance with section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The Consent Decree and Settlement Agreement may be examined at the Office of the United States Attorney, 86 Chambers Street—3rd Floor, New York, New York 10007. During the public comment period, the Consent Decree and Settlement Agreement may also be examined on the following Department of Justice Web site: http://www.usdoj.gov/enrd/Consent_Decrees.html. A copy of the Consent Decree and Settlement Agreement may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood (tonia.fleetwood@usdoj.gov),

fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$53.25 (213 pages, exclusive of signature pages and attachments; 25 cents per page reproduction cost) or \$123.75 (495 pages, including signatures and attachments) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen M. Katz,
Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2010-30027 Filed 11-26-10; 8:45 am]

BILLING CODE 4410-CW-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-70,599]

Innovion Corporation, Gresham, OR; Notice of Negative Determination on Reconsideration

On March 31, 2010, the Department of Labor issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of Innovion Corporation, Gresham, Oregon (subject firm). The notice was published in the **Federal Register** on April 19, 2010 (75 FR 20382). The workers supply ion implantation services for firms in the semiconductor industry.

The initial investigation resulted in a negative determination based on the finding that there was no shift to/acquisition from a foreign country by the workers' firm of services like or directly competitive with the ion implantation services supplied by the subject firm and no increased import by either the subject firm or its major declining customers of services like or directly competitive with the ion implantation services supplied by the subject firm [Section 222(a)]. Further, the workers are not eligible to apply for Trade Adjustment Assistance (TAA) as adversely affected secondary workers [Section 222(c)] or workers of a firm identified by the International Trade Commission as a member of a domestic industry injured under a provision of the Tariff Act of 1930 [Section 222(f)].

The initial investigation concluded that worker separations were attributable to a customer's decision to perform ion implantation services in-house instead of using the subject firm.

During the reconsideration investigation, the Department sought clarification from the subject firm's headquarters and conducted an expanded customer survey of the subject firm's major declining customers, including those identified in the request for reconsideration.

Information provided during the reconsideration investigation confirmed no shift to/acquisition from another country by the subject firm in the supply of ion implantation services, and no increased imports of ion implantation services, or like or directly competitive services, by the subject firm during the relevant period.

The customer survey conducted during the reconsideration investigation showed that, during the relevant time period, the three largest declining customers of the subject firm did not import services like or directly competitive with the ion implantation services provided by the subject workers.

Together, the surveyed customers accounted for 92 percent of subject firm sales in 2007, 89 percent of subject firm sales in 2008, and 84 percent of subject firm sales during the first four months of 2009. Those customers also accounted for 109 percent of the sales decline of the subject firm from 2007 to 2008 and 97 percent of the subject firm's sales decline during the first four months of 2009 as compared with the same period of 2009.

The assertion that the subject firm should be certified as a result of the certification of customer LSI Logic (TA-W-55,958; certified on November 3, 2003) was not investigated on reconsideration because a shift to a foreign country by a customer cannot be a basis of certification absent under Section 222(a), which requires that there has been a shift to a foreign country by the subject firm. Further, the certification of the Chandler, Arizona facility (TA-W-71,648) cannot be the basis of certification of workers of the Gresham, Oregon facility as adversely affected secondary workers because the certification of the Chandler, Arizona facility was based on the satisfaction of Section 222(c) and Section 222(c) requires that the primary firm be certified under Section 222(a).

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Innovion Corporation, Gresham, Oregon.

Signed in Washington, DC, this 15th day of November 2010.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2010-29822 Filed 11-26-10; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-70,910]

Sypris Technologies, Sypris Solutions Division, Kenton, OH; Notice of Revised Determination on Reconsideration

On October 7, 2010, the Department of Labor issued a Notice of Affirmative Determination Regarding Application for Reconsideration applicable to the request for administrative reconsideration filed by the United Steel Workers, Local 1-109, on behalf of workers and former workers of Sypris Technologies, Sypris Solutions Division, Kenton, Ohio (subject firm). The Department's Notice was published in the **Federal Register** on October 25, 2010 (75 FR 65514).

The initial investigation resulted in a negative determination that was based on the findings that increased imports did not contribute importantly to worker separations at the subject firm and no shift in production to a foreign country occurred.

During the reconsideration investigation, the Department conducted an expanded survey of the subject firm's major declining customers to supplement the information gathered during the initial investigation. The survey revealed increased customer reliance on imported trailer axle beams and that the increased imports had contributed importantly to worker separations at the subject firm.

Conclusion

After careful review of the additional facts obtained during the reconsideration investigation, I determine that workers of Sypris Technologies, Sypris Solutions Division, Kenton, Ohio, who are engaged in employment related to the production of trailer axle beams, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

"All workers of Sypris Technologies, Sypris Solutions Division, Kenton, Ohio, who became totally or partially separated

from employment on or after May 18, 2008, through two years from the date of this certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended."

Signed in Washington, DC, this 16th day of November, 2010.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2010-29823 Filed 11-26-10; 8:45 am]

BILLING CODE 4510-FN-P

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Notice of Proposed Information Collection Requests: Public Demand for Museum and Library Services (PDMLS) Survey

AGENCY: Institute of Museum and Library Services, The National Foundation for the Arts and the Humanities.

ACTION: Notice, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Services (IMLS), 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 (44 U.S.C. Chapter 35). This pre-clearance consultation 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 requirements on respondents can be properly assessed. By this notice, IMLS is soliciting comments concerning a proposed survey to collect information to monitor the use, expectations of and satisfaction with cultural programs and services, most especially library and museum services.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before January 22, 2011.

IMLS is particularly interested in comments that help the agency to:

- 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;

- 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 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 submissions of responses.

ADDRESSES: Send comments to: Carlos Manjarrez, Associate Deputy for Research and Statistics, Institute of Museum and Library Services, 1800 M St., NW., 9th Floor, Washington, DC 20036. Mr. Manjarrez can be reached by Telephone: 202-653-4671, Fax: 202-653-4600, or by e-mail at cmanjarrez@imls.gov, or by teletype (TTY/TDD) for persons with hearing difficulty at 202-653-4614.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Museum and Library Services is the primary source of Federal support for the Nation's 123,000 libraries and 17,500 museums. The Institute's mission is to create strong libraries and museums that connect people to information and ideas. The Institute works at the national level and in coordination with State and local organizations to sustain heritage, culture, and knowledge; enhance learning and innovation; and support professional development. IMLS is responsible for identifying national needs for, and trends of, museum and library services funded by IMLS; reporting on the impact and effectiveness of programs conducted with funds made available by IMLS in addressing such needs; and identifying, and disseminating information on, the best practices of such programs. (20 U.S.C. Chapter 72, 20 U.S.C. 9108).

II. Current Actions

Libraries and museums help create vibrant, energized learning communities. Our achievement as individuals and our success as a democratic society depend on learning continually, adapting to change readily, and evaluating information critically.

As stewards of cultural heritage, information and ideas, museums and libraries have traditionally played a vital role in helping us experience, explore, discover and make sense of the world. That role is now more essential than ever. Through building technological infrastructure and strengthening community relationships, libraries and museums can offer the public unprecedented access to and expertise in transforming information overload into knowledge. IMLS provides leadership and funding for the nation's museums and libraries, to help them fulfill their mission of becoming centers of life-long learning crucial to achieving personal fulfillment, a productive workforce and an engaged citizenry.

Consistent with this (20 U.S.C. Chapter 72, 20 U.S.C. 9108), the intention of the PDMLS is to monitor expectations of and satisfaction with library and museum services. A wide range of topics will be covered, with a small number of questions about each topic included on the survey.

The purpose of this survey is to determine attitudes, assess awareness of issues related to library and museum services, and tracking trends. The survey will be used to gather information on a wide range of library and museum services. The design of the PDMLS will be a random digital dial ("RDD") telephone survey of the adult, non-institutionalized U.S. population which will yield a minimum of 3,000 cases.

The PDMLS will include a core set of demographic questions (e.g., age, gender, race, geographic area) as well as a core set of questions that are based on critical information needs within IMLS (e.g., satisfaction with the library and museum services as a whole; frequency of utilization of various services; physical and virtual access to services). In addition to these core questions, supplemental questions may also be included. The telephone survey is projected to average 18 to 20 minutes to complete.

Agency: Institute of Museum and Library Services.

Title: Public Demand for Museum and Library Services Survey.

OMB Number: To Be Determined.
Frequency: Anticipated for Every Three Years.

Affected Public: The target population for the Public Demand for Museum and Library Services Survey is the noninstitutionalized population, aged 18 and older, who live in the United States. A national probability sample of households generated using list-assisted random digit dialing (RDD)

methodology will be employed by the survey. Individual survey respondents within selected households will be chosen at random.

Number of Respondents: 3,000.

Estimated Average Burden per Response: The burden per respondent is estimated to be an average of 18 minutes based on the size of the questionnaire.

Estimated Total Annual Burden: 900 hours (that is 18 minutes times 3,000 respondents equals 54,000 minutes or 900 hours).

Total Annualized Capital/Startup Costs: n/a.

Total Annual Costs: To be determined.

Public Comments Invited: Interested parties are invited to send comments regarding any aspect of this information collection, including, but not limited to: (1) The necessity and utility of the information collection for the proper performance of the functions of IMLS; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Carlos Manjarrez, Associate Deputy for Research and Statistics, Institute of Museum and Library Services, 1800 M St., NW., 9th Floor, Washington, DC 20036. Mr. Manjarrez can be reached by Telephone: 202-653-4671, Fax: 202-653-4600, or by e-mail at cmanjarrez@imls.gov, or by teletype (TTY/TDD) for persons with hearing difficulty at 202/653-4614. Office hours are from 8:30 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays.

Dated: November 22, 2010.

Kim Miller,
Management Analyst.

[FR Doc. 2010-29876 Filed 11-26-10; 8:45 am]

BILLING CODE 7036-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC-2010-0338]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

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 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 Associated Instructions (NUREG/BR-0006)"

2. *Current OMB approval number:* 3150-0003.

3. *How often the collection is required:* Form 741 is submitted when specified events occur (nuclear material 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:* For DOE/NRC Form 741, there are approximately 400 respondents annually.

6. *The number of hours needed annually to complete the requirement or request:* 20,616 hours.

7. *Abstract:* NRC is required to collect nuclear material transaction information for domestic safeguards use and to 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 source material. This form enables NRC to collect, retrieve, analyze, and submit the data to IAEA to fulfill its reporting responsibilities.

Submit, by January 28, 2011, 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?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: <http://www.nrc.gov/public-involve/doc-comment/omb/index.html>. 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-2010-0338. 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-2010-0338. Mail comments to 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 e-mail to INFOCOLLECTS.Resource@NRC.GOV.

Dated at Rockville, Maryland this 19th day of November 2010.

For the Nuclear Regulatory Commission.

Tremaine Donnell,
NRC Clearance Officer, Office of Information Services.

[FR Doc. 2010-29932 Filed 11-26-10; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-335 and 50-389; NRC-2010-0363]

Florida Power and Light Company, St. Lucie Plant, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering issuance of an exemption from Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, Section 26.9, for Facility Operating License Nos. DPR-67 and NPF-16, issued to Florida Power and Light Company, *et al.* (the licensee), for operation of St. Lucie

Plant, Units 1 and 2, located on Hutchinson Island in St. Lucie County, Florida. Therefore, as required by 10 CFR 51.21, the NRC performed an environmental assessment. Based on the results of the environmental assessment, the NRC is issuing a finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action would consider approval of an exemption for St. Lucie Plant, Units 1 and 2, from certain requirements of 10 CFR Part 26, "Fitness-for-Duty Rule." Specifically, the licensee requests approval of an exemption from the requirements of 10 CFR 26.205(c), "Work hours scheduling," and (d), "Work hour controls."

The licensee states that during severe weather conditions, for example, tropical storms or hurricane force winds, adherence to all work hour controls requirements could impede the licensee's ability to use whatever staff resources may be necessary to prepare the site for a pending severe weather event and ensure that the plant reaches and maintains a safe and secure status.

The exemption would only apply to severe weather conditions where tropical storm or hurricane force winds are predicted onsite requiring severe weather preparations, and activation and sequestering of the St. Lucie storm crew.

The proposed exemption will allow the licensee to not meet the requirements of 10 CFR 26.205(c) and (d), from the time severe weather site preparation begins until exit conditions are satisfied. The exemption would only apply to individuals on the storm crew who perform duties identified in 10 CFR 26.4(a)(1) through (a)(5). When storm crew sequestering exit conditions are met, full compliance with 10 CFR 26.205(c) and (d) will be required.

The proposed action does not involve any physical changes to the reactor, fuel, plant, structures, support structures, water, or land at the St. Lucie Plant, Units 1 and 2, site.

The proposed action is in accordance with the licensee's application dated October 16, 2009.

The Need for the Proposed Action

Proposed action is needed because the licensee is unable to meet the requirements of 10 CFR 26.205(c) and (d) during declarations of severe weather conditions that could result due to prevailing tropical storm or hurricane force winds impacting the facility.

Compliance with work hour control requirements could impede the

licensee's ability to use whatever staff resources may be necessary to respond to a plant emergency and ensure that the plant reaches and maintains a safe and secure status.

Environmental Impacts of the Proposed Action

The NRC staff has completed its environmental assessment of the proposed exemption. The NRC staff has concluded that the proposed exemption from the implementation of the requirements of 10 CFR 26.205(c) and (d) during declaration of severe weather conditions, would not significantly affect plant safety and would not have a significant adverse effect on the probability of occurrence of an accident.

The proposed action would not result in any increased radiological hazards beyond those previously evaluated by the NRC staff in the Safety Evaluation Reports, dated November 8 and November 7, 1974, related to operation of St. Lucie Plant, Units 1 and 2, respectively. No changes are being made in the types of effluents that may be released offsite. There is no significant increase in the amount of any effluent released offsite. There is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

The proposed action does not result in changes to land use or water use, or result in changes to the quality or quantity of non-radiological effluents. No changes to the National Pollution Discharge Elimination System permit are needed. No effects on the aquatic or terrestrial habitat in the vicinity of the plant, or to threatened, endangered, or protected species under the Endangered Species Act, or impacts to essential fish habitat covered by the Magnuson-Stevens Act are expected. There are no impacts to the air or ambient air quality. There are no impacts to historical and cultural resources. There would be no noticeable effect on socioeconomic conditions in the region. Therefore, no changes or different types of non-radiological environmental impacts are expected as a result of the proposed action. Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

The licensee currently maintains a Hurricane Plan that provides directions for activation of the storm crew. The storm crew is activated upon the direction of the Emergency Coordinator, typically the site Plant General Manager or designee. This individual is qualified as an Emergency Coordinator during a

declared emergency. The Plan provides specific entry conditions for the start of the emergency and specific conditions that will terminate the emergency. The licensee states that the impact on personnel manning for implementation of the site hurricane staffing and severe weather preparations is similar to entering the Emergency Plan. Although the proposed exemption would allow the licensee not to meet work hour controls during storm crew activation, sufficient numbers of management and supervision will be available during storm crew manning and activation to ensure that public health and safety is adequately protected.

The details of the staff's safety evaluation will be provided in the exemption that will be issued as part of the letter to the licensee approving the exemption to the regulation, if granted.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed action (*i.e.*, the "no-action" alternative). Denial of the exemption request would result in no change in current environmental impacts. If the proposed action were denied, the licensee would have to comply with the fatigue rules in 10 CFR 26.205(c) and (d). This would cause unnecessary burden on the licensee, without a significant benefit in environmental impacts. The environmental impacts of the proposed exemption and the "no action" alternative are similar.

Alternative Use of Resources

The action does not involve the use of any different resources than those considered in the Final Environmental Statement related to the St. Lucie Plant, Unit 1, dated June 1973; the Final Environmental Statement related to the operation of St. Lucie Plant, Unit 2 (NUREG-0842), dated April 1982; and, the plant-specific Supplement 11 to NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants" (GEIS). Supplement 11 of the GEIS, issued on May 16, 2003, addresses the renewal of operating licenses DPR-67 and NPF-16 for St. Lucie Plant, Units 1 and 2, for an additional 20 years of operation.

Agencies and Persons Consulted

In accordance with its stated policy, on September 7, 2010, the NRC staff consulted with the Florida State official, William A. Passetti of the Bureau of Radiation Control, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated October 16, 2009 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML092990394). Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 800-397-4209 or 301-415-4737, or send an e-mail to pdr.resource@nrc.gov.

Dated at Rockville, Maryland, this 19 day of November 2010.

For the Nuclear Regulatory Commission.

Tracy J. Orf,

Project Manager, Plant Licensing Branch II-2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2010-29935 Filed 11-26-10; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-348 and 50-364; NRC-2009-0375]

Southern Nuclear Operating Company, Inc. Joseph M. Farley Nuclear Plant, Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an Exemption, pursuant to Title 10 of the Code of Federal Regulations (10 CFR) Section 73.5, "Specific exemptions," from 10 CFR Part 73, "Physical protection of plants and materials," for Facility Operating License Nos. NPF-2 and NPF-8, issued to Southern Nuclear Operating Company, Inc. (SNC, the licensee), for operation of the Joseph M. Farley Nuclear Plant, Units 1 and 2 (FNP), located in Houston County, Alabama. In accordance with 10 CFR 51.21, the NRC

prepared an environmental assessment documenting its finding. The NRC concluded that the proposed actions will have no significant environmental impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action would exempt the FNP from the required implementation date of March 31, 2010, for several new requirements of 10 CFR Part 73. Specifically, FNP would be granted an exemption from being in full compliance with certain new requirements contained in 10 CFR 73.55 by the March 31, 2010, deadline. Instead, the licensee has proposed an alternate full compliance implementation date of July 15, 2011. The proposed action, an extension of the schedule for completion of certain actions required by the revised 10 CFR Part 73, does not involve any physical changes to the reactor, fuel, plant structures, support structures, water, or land at the FNP site.

The proposed action is in accordance with the licensee's application dated September 10, 2010, as supplemented by letter dated October 5, 2010.

The Need for the Proposed Action

The proposed action is needed to provide the licensee with additional time to perform the required upgrades to the FNP security system due to resource and logistical constraints. Previously, by letters dated June 9 and July 31, 2009, SNC submitted a request for an exemption from the compliance date identified in 10 CFR 73.55 for three specific requirements of 10 CFR 73.55. The NRC staff reviewed the request and by letter dated August 27, 2009, granted an exemption to the March 31, 2010, compliance date for the 3 specific requirements identified within the SNC exemption request until December 15, 2010. Subsequently, by letters dated September 10 and October 5, 2010, SNC submitted an additional request for an exemption to the compliance date identified in 10 CFR 73.55. The licensee has requested a further exemption from the March 31, 2010, compliance date stating that a number of issues, including unforeseen growth in the amount of design work required, design product loss due to computer hardware failures, and weather-related construction delays, will present a significant challenge to timely completion of the project related to certain requirements in 10 CFR 73.55. Specifically, the request is to extend the compliance date for three specific requirements from the current March

31, 2010 deadline, as extended for this specific licensee to December 15, 2010, by the exemption granted on August 27, 2009, until July 15, 2011. Being granted this exemption for these items will allow the licensee to complete the modifications designed to update equipment and incorporate state-of-the-art technology to meet the noted regulatory requirement.

Environmental Impacts of the Proposed Action

The NRC staff has completed its environmental assessment of the proposed exemption and has concluded that the proposed action to extend the implementation deadline would not significantly affect plant safety and would not have a significant adverse effect on the probability of an accident occurring. The proposed action would not result in an increased radiological hazard beyond those previously analyzed. There will be no change to radioactive effluents that effect radiation exposures to plant workers and members of the public. The proposed action does not involve a change to plant buildings or land areas on the FNP site. Therefore, no changes or different types of radiological impacts are expected as a result of the proposed exemption.

The proposed action does not result in changes to land use or water use, or result in changes to the quality or quantity of non-radiological effluents. No changes to the National Pollution Discharge Elimination System permit are needed. No effects on the aquatic or terrestrial habitat in the vicinity of the plant, or to threatened, endangered, or protected species under the Endangered Species Act, or impacts to essential fish habitat covered by the Magnuson-Steven's Act are expected. There are no impacts to the air or ambient air quality.

There are no impacts to historical and cultural resources. There would be no impact to socioeconomic resources. Therefore, no changes to or different types of non-radiological environmental impacts are expected as a result of the proposed exemption. Accordingly, the NRC staff concludes that there are no significant environmental impacts associated with the proposed action.

The licensee currently maintains a security system acceptable to the NRC and the NRC expects that the licensee will continue to maintain the effectiveness of the overall physical protection program and protective strategy for the duration of this exemption. Therefore, the extension of the implementation date of the new requirements of 10 CFR Part 73 to July

15, 2011, would not have any significant environmental impacts.

The NRC staff's safety evaluation will be provided in the exemption that will be issued as part of the letter to the licensee approving the exemption to the regulation.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed actions, the NRC staff considered denial of the proposed actions (*i.e.*, the "no-action" alternative). Denial of the exemption request would result in no change in current environmental impacts. The environmental impacts of the proposed exemption and technical specification change and the "no action" alternative are similar.

Alternative Use of Resources

The action does not involve the use of any different resources than those considered in the Final Environmental Statement for the FNP, as supplemented through the "Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Joseph M. Farley Nuclear Plant, Units 1 and 2—Final Report (NUREG—1437, Supplement 18)."

Agencies and Persons Consulted

In accordance with its stated policy, on November 15, 2010, the NRC staff consulted with the Alabama State official, Mr. David Walters of the Alabama Department of Public Health, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC staff has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letters dated September 10, 2010 and October 5, 2009. The licensee has provided a redacted version of the September 10, 2010 letter that is publically available and the October 5, 2010 transmittal letter is publically available. The edition of the September 10, 2010 letter and its enclosure and the enclosure to the October 5, 2010 letter that contains proprietary security-related information is not available to the public. Other parts of these documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One

White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. Publicly available records will be accessible electronically from the Agencywide Document Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site: <http://www.nrc.gov/reading-rm/adams.html>.

Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1-800-397-4209 or 301-415-4737, or send an e-mail to pdr@nrc.gov.

Dated at Rockville, Maryland, this 19th day of November, 2010.

For the Nuclear Regulatory Commission.

Robert E. Martin.

Sr. Project Manager, Plant Licensing Branch II-1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2010-29940 Filed 11-26-10; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2010-0002]

Sunshine Act Notice

DATES: Week of November 29, 2010.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

Additional Items To Be Considered

Week of November 29, 2010

Tuesday, November 30, 2010

10 a.m. Affirmation Session (Public Meeting) (Tentative).

a. *Tennessee Valley Authority* (Watts Bar Nuclear Plant, Unit 2), Southern Alliance for Clean Energy's Petition for Interlocutory Review of LBP-10-12 (Denying SACE's Waiver Petition) (July 14, 2010) (Tentative).

* * * * *

* 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 Baval, (301) 415-4651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: <http://www.nrc.gov/about-nrc/policy-making/schedule.html>.

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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 Angela Bolduc, Chief, Employee/Labor Relations and Work Life Branch, at 301-492-2230, TDD: 301-415-2100, or by e-mail at angela.bolduc@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed electronically to subscribers. If you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301-415-1969), or send an e-mail to darlene.wright@nrc.gov.

Dated: November 22, 2010.

Rochelle C. Baval,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2010-30093 Filed 11-24-10; 4:15 pm]

BILLING CODE 7590-01-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 701, OMB Control No. 3235-0522, SEC File No. 270-306.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 701 (17 CFR 230.701) under the Securities Act of 1933 ("Securities Act") (15 U.S.C. 77a *et seq.*) provides an exemption for certain issuers from the registration requirements of the Securities Act for limited offerings and sales of securities issued under compensatory benefit plans or contracts. The purpose of Rule 701 is to ensure that a basic level of information is available to employees and others when substantial amounts of securities are issued in compensatory arrangements. Approximately 300 companies annually

rely on the Rule 701 exemption. The Rule 701 disclosure takes an estimated 2 hours per response to prepare for a total annual burden of 600 hours. We estimate that 25% of the 2 hours per response (0.5 hours) is prepared by the company for a total annual reporting burden of 150 hours (0.5 hours per response × 300 responses).

Written comments are invited on: (a) Whether this 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 the burden imposed by the 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.

Please direct your written comments to Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, C/O Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an e-mail to: PRA_Mailbox@sec.gov.

Dated: November 22, 2010.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2010-29889 Filed 11-26-10; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63363; File No. S7-04-09]

Order Extending Temporary Conditional Exemption for Nationally Recognized Statistical Rating Organizations From Requirements of Rule 17g-5 Under the Securities Exchange Act of 1934 and Request for Comment

November 23, 2010.

I. Introduction

On May 19, 2010, the Securities and Exchange Commission ("Commission") conditionally exempted, with respect to certain credit ratings and until December 2, 2010, nationally recognized statistical rating organizations ("NRSROs") from certain requirements in Rule 17g-5(a)(3)¹ under the Securities Exchange Act of 1934

¹ See 17 CFR 240.17g-5(a)(3).

("Exchange Act"), which had a compliance date of June 2, 2010.² Pursuant to the Order, an NRSRO is not required to comply with Rule 17g-5(a)(3) until December 2, 2010 with respect to credit ratings where: (1) The issuer of the structured finance product is a non-U.S. person; and (2) the NRSRO has a reasonable basis to conclude that the structured finance product will be offered and sold upon issuance, and that any arranger linked to the structured finance product will effect transactions of the structured finance product after issuance, only in transactions that occur outside the U.S. ("covered transactions").³ The Commission is extending the temporary conditional exemption exempting NRSROs from complying with Rule 17g-5(a)(3) with respect to rating covered transactions until December 2, 2011.

II. Background

Rule 17g-5 identifies, in paragraphs (b) and (c) of the rule, a series of conflicts of interest arising from the business of determining credit ratings.⁴ Paragraph (a) of Rule 17g-5⁵ prohibits an NRSRO from issuing or maintaining a credit rating if it is subject to the conflicts of interest identified in paragraph (b) of Rule 17g-5 unless the NRSRO has taken the steps prescribed in paragraph (a)(1) (*i.e.*, disclosed the type of conflict of interest in Exhibit 6 to Form NRSRO in accordance with Section 15E(a)(1)(B)(vi) of the Exchange Act⁶ and Rule 17g-1⁷ and paragraph (a)(2) (*i.e.*, established and is maintaining and enforcing written policies and procedures to address and manage conflicts of interest in accordance with Section 15E(h) of the Exchange Act).⁸ Paragraph (c) of Rule 17g-5 specifically prohibits seven types of conflicts of interest. Consequently, an NRSRO is prohibited from issuing or maintaining a credit rating when it is subject to these conflicts regardless of whether it had disclosed them and established procedures reasonably designed to address them.

In December 2009, the Commission adopted subparagraph (a)(3) to Rule 17g-5. This provision requires an NRSRO that is hired by an arranger to determine an initial credit rating for a structured finance product to take

² See Securities Exchange Act Release No. 62120 (May 19, 2010), 75 FR 28825 (May 24, 2010) ("Order").

³ See *id.* at 28827-28 (setting forth conditions of relief).

⁴ 17 CFR 240.17g-5(b) and (c).

⁵ 17 CFR 240.17g-5(a).

⁶ 15 U.S.C. 78o-7(a)(1)(B)(vi).

⁷ 17 CFR 240.17g-1.

⁸ 15 U.S.C. 78o-7(h).

certain steps designed to allow an NRSRO that is not hired by the arranger to nonetheless determine an initial credit rating—and subsequently monitor that credit rating—for the structured finance product.⁹ In particular, under Rule 17g-5(a)(3), an NRSRO is prohibited from issuing or maintaining a credit rating when it is subject to the conflict of interest identified in paragraph (b)(9) of Rule 17g-5 (*i.e.*, being hired by an arranger to determine a credit rating for a structured finance product)¹⁰ unless it has taken the steps prescribed in paragraphs (a)(1) and (2) of Rule 17g-5 (discussed above) and the steps prescribed in new paragraph (a)(3) of Rule 17g-5.¹¹ Rule 17g-5(a)(3), among other things, requires that the NRSRO must:

- Maintain on a password-protected Internet Web site a list of each structured finance product for which it currently is in the process of determining an initial credit rating in chronological order and identifying the type of structured finance product, the name of the issuer, the date the rating process was initiated, and the Internet Web site address where the arranger represents the information provided to the hired NRSRO can be accessed by other NRSROs;

- Provide free and unlimited access to such password-protected Internet Web site during the applicable calendar year to any NRSRO that provides it with a copy of the certification described in paragraph (e) of Rule 17g-5 that covers that calendar year;¹² and

⁹ See 17 CFR 240.17g-5(a)(3); *see also* Securities Exchange Act Release No. 61050 (November 23, 2009), 74 FR 63832 (“Adopting Release”) at 63844–45.

¹⁰ Paragraph (b)(9) of Rule 17g-5 identifies the following conflict of interest: issuing or maintaining a credit rating for a security or money market instrument issued by an asset pool or as part of any asset-backed or mortgage-backed securities transaction that was paid for by the issuer, sponsor, or underwriter of the security or money market instrument. 17 CFR 240.17g-5(b)(9).

¹¹ 17 CFR 240.17g-5(a)(3).

¹² Paragraph (e) of Rule 17g-5 requires that an NRSRO seeking to access the hired NRSRO’s Internet website during the applicable calendar year must furnish the Commission with the following certification:

The undersigned hereby certifies that it will access the Internet Web sites described in 17 CFR 240.17g-5(a)(3) solely for the purpose of determining or monitoring credit ratings. Further, the undersigned certifies that it will keep the information it accesses pursuant to 17 CFR 240.17g-5(a)(3) confidential and treat it as material nonpublic information subject to its written policies and procedures established, maintained, and enforced pursuant to section 15E(g)(1) of the Act (15 U.S.C. 78o-7(g)(1)) and 17 CFR 240.17g-4. Further, the undersigned certifies that it will determine and maintain credit ratings for at least 10% of the issued securities and money market instruments for which it accesses information pursuant to 17 CFR 240.17g-5(a)(3)(iii), if it accesses such information

- Obtain from the arranger a written representation that can reasonably be relied upon that the arranger will, among other things, disclose on a password-protected Internet web site the information it provides to the hired NRSRO to determine the initial credit rating (and monitor that credit rating) and provide access to the web site to an NRSRO that provides it with a copy of the certification described in paragraph (e) Rule 17g-5.¹³

The Commission stated in the Adopting Release that subparagraph Rule 17g-5(a)(3) is designed to address

for 10 or more issued securities or money market instruments in the calendar year covered by the certification. Further, the undersigned certifies one of the following as applicable: (1) In the most recent calendar year during which it accessed information pursuant to 17 CFR 240.17g-5(a)(3), the undersigned accessed information for [Insert Number] issued securities and money market instruments through Internet Web sites described in 17 CFR 240.17g-5(a)(3) and determined and maintained credit ratings for [Insert Number] of such securities and money market instruments; or (2) The undersigned previously has not accessed information pursuant to 17 CFR 240.17g-5(a)(3) 10 or more times during the most recently ended calendar year.

¹³ In particular, under paragraph (a)(3)(iii) of Rule 17g-5, the arranger must represent to the hired NRSRO that it will:

- (1) Maintain the information described in paragraphs (a)(3)(iii)(C) and (a)(3)(iii)(D) of Rule 17g-5 available at an identified password-protected Internet Web site that presents the information in a manner indicating which information currently should be relied on to determine or monitor the credit rating;

- (2) Provide access to such password-protected Internet Web site during the applicable calendar year to any NRSRO that provides it with a copy of the certification described in paragraph (e) of Rule 17g-5 that covers that calendar year, provided that such certification indicates that the nationally recognized statistical rating organization providing the certification either: (i) Determined and maintained credit ratings for at least 10% of the issued securities and money market instruments for which it accessed information pursuant to paragraph (a)(3)(iii) of Rule 17g-5 in the calendar year prior to the year covered by the certification, if it accessed such information for 10 or more issued securities or money market instruments; or (ii) has not accessed information pursuant to paragraph (a)(3) of Rule 17g-5 10 or more times during the most recently ended calendar year.

- (3) Post on such password-protected Internet Web site all information the arranger provides to the NRSRO, or contracts with a third party to provide to the NRSRO, for the purpose of determining the initial credit rating for the security or money market instrument, including information about the characteristics of the assets underlying or referenced by the security or money market instrument, and the legal structure of the security or money market instrument, at the same time such information is provided to the NRSRO; and

- (4) Post on such password-protected Internet Web site all information the arranger provides to the NRSRO, or contracts with a third party to provide to the NRSRO, for the purpose of undertaking credit rating surveillance on the security or money market instrument, including information about the characteristics and performance of the assets underlying or referenced by the security or money market instrument at the same time such information is provided to the NRSRO.

conflicts of interest and improve the quality of credit ratings for structured finance products by making it possible for more NRSROs to rate structured finance products.¹⁴ For example, the Commission noted that when an NRSRO is hired to rate a structured finance product, some of the information it relies on to determine the rating is generally not made public.¹⁵ As a result, structured finance products frequently are issued with ratings from only the one or two NRSROs that have been hired by the arranger, with the attendant conflict of interest that creates.¹⁶ The Commission stated that subparagraph Rule 17g-5(a)(3) was designed to increase the number of credit ratings extant for a given structured finance product and, in particular, to promote the issuance of credit ratings by NRSROs that are not hired by arrangers.¹⁷ The Commission’s goal in adopting the rule was to provide users of credit ratings with more views on the creditworthiness of structured finance products.¹⁸ In addition, the Commission stated that Rule 17g-5(a)(3) was designed to reduce the ability of arrangers to obtain better than warranted ratings by exerting influence over NRSROs hired to determine credit ratings for structured finance products.¹⁹ Specifically, by opening up the rating process to more NRSROs, the Commission intended to make it easier for the hired NRSRO to resist such pressure by increasing the likelihood that any steps taken to inappropriately favor the arranger could be exposed to the market through the credit ratings issued by other NRSROs.²⁰

Rule 17g-5(a)(3) became effective on February 2, 2010, and the compliance date for Rule 17g-5(a)(3) was June 2, 2010.

III. Extension of Conditional Temporary Extension

In the Order, the Commission requested comment generally, but also on a number of specific issues.²¹ The Commission received six comments in response to this solicitation of comment.²² The commenters continue

¹⁴ Adopting Release at 63844.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ See Order, *supra* note 2, at 28828.

²² Letter from Masanichi Kono, Vice Commissioner for International Affairs, Financial Services Agency, Japan, to Elizabeth Murphy, Secretary, Commission, dated Nov. 12, 2010 (“Japan FSA Letter”); Letter from Masaru Ono, Executive Director, Securitization Forum of Japan, to Elizabeth Murphy, Secretary, Commission, dated

to express concern that the extraterritorial application of Rule 17g-5(a)(3) could, in the commenter's view, among other things, disrupt local securitization markets,²³ inhibit the ability of local firms to raise capital,²⁴ and conflict with local laws.²⁵ Several commenters also requested that the conditional temporary exemption be extended or made permanent.²⁶ Given the continued concerns about potential disruptions of local securitization markets, and because the Commission's consideration of the issues raised will benefit from additional time to engage in further dialogue with interested parties and to monitor market and regulatory developments, the Commission believes extending the conditional temporary exemption until December 2, 2011 is necessary or appropriate in the public interest, and is consistent with the protection of investors.

IV. Request for Comment

The Commission believes that it would be useful to continue to provide interested parties opportunity to comment. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/exorders.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number S7-04-09 on the subject line; or

Nov. 12, 2010 ("SFJ Letter"); Letter from Rick Watson, Managing Director, Association for Financial Markets in Europe/European Securitisation Forum, to Elizabeth Murphy, Secretary, Commission, dated Nov. 11, 2010 ("AFME Letter"); Letter from Jack Rando, Director, Capital Markets, Investment Industry Association of Canada, to Randall Roy, Assistant Director, Division, Commission, dated Sep. 22, 2010 ("IIAC Letter"); Letter from Christopher Dalton, Chief Executive Officer, Australian Securitisation Forum, to Randall Roy, Assistant Director, Division, Commission, dated Jun. 27, 2010 ("AuSF Letter"); Letter from Takefumi Emori, Managing Director, Japan Credit Rating Agency, Ltd. ("JCR") to Elizabeth Murphy, Secretary, Commission, dated Jun. 25, 2010 ("JCR Letter").

²³ See Japan FSA Letter; SFJ Letter; AFME Letter; JCR Letter, AuSF Letter.

²⁴ See AFME Letter; JCR Letter; AuSF Letter.

²⁵ See Japan FSA Letter; AFME Letter; JCR Letter; AuSF Letter; IIAC Letter. With respect to local laws, we note that the European Commission in recent months has issued a relevant proposal for amendments to the European Union Regulation on Credit Ratings. See "Regulation of the European Parliament and of the Council on amending Regulation (EC) No 1060/2009 on credit rating agencies" (available at http://ec.europa.eu/internal_market/securities/docs/agencies/100602_proposal_en.pdf).

²⁶ See Japan FSA Letter; SFJ Letter; AFME Letter; JCR Letter.

- Use the Federal eRulemaking Portal (<http://www.regulations.gov>). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F St., NE., Washington, DC 20549-1090.

All submissions should refer to File Number S7-04-09. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet website (<http://www.sec.gov/rules/exorders.shtml>). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F St. NE., Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. 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.

V. Conclusion

For the foregoing reasons, the Commission believes it would be necessary or appropriate in the public interest and consistent with the protection of investors to extend the conditional temporary exemption exempting NRSROs from complying with Rule 17g-5(a)(3) with respect to rating covered transactions until December 2, 2011.

Accordingly

It is hereby ordered, pursuant to Section 36 of the Exchange Act, that a nationally recognized statistical rating organization is exempt until December 2, 2011 from the requirements in Rule 17g-5(a)(3) (17 CFR 240.17g-5(a)(3)) for credit ratings where:

(1) The issuer of the security or money market instrument is not a U.S. person (as defined under Securities Act Rule 902(k)); and

(2) The nationally recognized statistical rating organization has a reasonable basis to conclude that the structured finance product will be offered and sold upon issuance, and that any arranger linked to the structured finance product will effect transactions of the structured finance product after issuance, only in transactions that occur outside the U.S.

By the Commission.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2010-29929 Filed 11-26-10; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, December 2, 2010 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Casey, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting scheduled for Thursday, December 2, 2010 will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

An adjudicatory matter; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551-5400.

Dated: November 24, 2010.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2010-30055 Filed 11-24-10; 11:15 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63351; File No. SR-Phlx-2010-154]

Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Fees for the PHOTO Historical Data Product

November 19, 2010.

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 November 8, 2010, NASDAQ OMX PHLX, Inc. ("Phlx" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III 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 amend its fee schedule by establishing fees for a new market data product, PHLX Options Trade Outline ("PHOTO") Historical Data. PHOTO Historical Data provides subscribers with historical information about the past activity on the Exchange during a particular calendar month, broken down by each option series traded on the Exchange.³ The proposed fees would become effective on and after November 15, 2010. PHOTO Historical Data is available only for internal use and distribution by subscribers.

The text of the proposed rule change is available on the Exchange's Web site at <http://nasdaqtrader.com/micro.aspx?id=PHLXfilings>, 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to establish fees for the PHOTO Historical Data market data product.

PHOTO

In September 2010, the Exchange established fees for its PHOTO market data product.⁴ PHOTO is a market data product offered by the Exchange that is designed to provide proprietary electronic trade data to subscribers. PHOTO is available as either an "End-of-Day" data product or an "Intra-Day" data product, as described more fully below. PHOTO Historical Data will permit a subscriber to select a particular prior calendar month or months and receive the "End of Day" or "Intra-Day" data for each trading session conducted during the calendar month(s) selected. Like PHOTO, the PHOTO Historical Data product is available to any person who wishes to subscribe to it, regardless of whether or not they are a member of the Exchange. The fees for the PHOTO Historical Data product are uniform for all subscribers.

PHOTO Historical Data

PHOTO Historical Data provides information about the past activity of all option series for each trading session conducted during a particular prior calendar month, as selected by the subscriber. PHOTO Historical Data subscribers will receive the following data:

- Aggregate number of buy and sell transactions in the affected series for each trading session conducted during the specified calendar month(s);
- Aggregate volume traded electronically on the Exchange in the affected series for each trading session conducted during the specified calendar month(s);
- Aggregate number of trades effected on the Exchange to open a position⁵ for

each trading session conducted during the specified calendar month(s);

- Aggregate number of trades effected on the Exchange to close a position⁶ for each trading session conducted during the specified calendar month(s);
- Origin of the orders involved in trades on the Exchange in the affected series for each trading session conducted during the specified calendar month(s), specifically aggregated in the following categories of participants: Customers, broker-dealers, market makers (including specialists, Registered Options Traders ("ROTs"), Streaming Quote Traders ("SQTs")⁷ and Remote Streaming Quote Traders ("RSQTs")⁸, and professionals.⁹

transactions" in the affected series for each trading session conducted during the calendar month(s) selected. An opening purchase transaction is an Exchange options transaction in which the purchaser's intention is to create or increase a long position in the series of options involved in such transaction. See Exchange Rule 1000(b)(24). PHOTO Historical Data will also provide subscribers with the aggregate number of "opening writing transactions" in the affected series for each trading session conducted during the calendar month(s) selected. An opening writing transaction is an Exchange options transaction in which the seller's (writer's) intention is to create or increase a short position in the series of options involved in such transaction. See Exchange Rule 1000(b)(25).

⁶ PHOTO Historical Data will provide subscribers with the aggregate number of "closing purchase transactions" in the affected series for each trading session conducted during the calendar month(s) selected. A closing purchase transaction is an Exchange options transaction in which the purchaser's intention is to reduce or eliminate a short position in the series of options involved in such transaction. See Exchange Rule 1000(b)(27). PHOTO Historical Data will also provide subscribers with the aggregate number of "closing sale transactions" in the affected series for each trading session conducted during the calendar month(s) selected. A closing sale transaction is an Exchange options transaction in which the seller's intention is to reduce or eliminate a long position in the series of options involved in such transaction. See Exchange Rule 1000(b)(26).

⁷ An SQT is an Exchange Registered Options Trader ("ROT") who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned. See Exchange Rule 1014(b)(ii)(A).

⁸ An RSQT is an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange. See Exchange Rule 1014(b)(ii)(B).

⁹ The term "professional" means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). A professional will be treated in the same manner as an off-floor broker-dealer for purposes of Rules 1014(g) (except with respect to all-or-none orders, which will be treated like customer orders), 1033(e), 1064.02 (except professional orders will be considered customer orders subject to facilitation), and 1080.08 as well as Options Floor Procedure Advices B-6, B-11 and F-5. Member organizations must indicate whether orders are for professionals. See Exchange Rule 1000(b)(14).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ PHOTO Historical Data will be available for the month of August 2010 and for each calendar month dating back to January 2009. PHOTO Historical Data will not be available for any calendar month prior to January 2009.

⁴ See Securities Exchange Act Release No. 62887 (September 10, 2010), 75 FR 57092 (September 17, 2010) (SR-Phlx-2010-121).

⁵ PHOTO Historical Data will provide subscribers with the aggregate number of "opening purchase

End of Day Product

The End-of-Day product includes the aggregate data described above representing the entire trading session. It is calculated during an overnight process after each trading session and is available to subscribers for download the following morning at approximately 7 a.m., ET. PHOTO Historical Data will provide this data for each trading session conducted during the calendar month(s) selected by the subscriber.

The fee for the PHOTO Historical Data End of Day product for subscribers is \$400.00 per calendar month selected.¹⁰

Intra-Day Product

The Intra-Day product includes periodic, cumulative data for a particular trading session. The Intra-Day product is produced and updated every ten minutes during the trading day. Data is captured in "snapshots" taken every 10 minutes throughout the trading day and is available to subscribers within 5 minutes of the conclusion of each 10-minute period. For example, subscribers to the Intra-Day product will receive the first calculation of intra-day data at 9:44 a.m. ET, which represents data captured from 9:30 a.m. to 9:39 a.m. Subscribers will receive the next update at 9:54 a.m., representing the data previously provided together with data captured from 9:40 a.m. through 9:49 a.m., and so forth. Each update will represent the aggregate data captured from the current "snapshot" and all previous "snapshots."

PHOTO Historical Data will provide this regularly updated data for each trading session conducted during the specified calendar month(s) selected by the subscriber. The fee for the PHOTO Historical Data Intra-Day product subscribers is \$750.00 per calendar month selected.¹¹

PHOTO Historical Data provides subscribers data that should enhance their ability to analyze option trade and volume data, to evaluate historical trends in the trading activity of a particular option series, and to create and test trading models and analytical

strategies. The Exchange believes that PHOTO Historical Data is a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series.

2. Statutory Basis

PHLX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,¹² in general, and with Section 6(b)(4) of the Act,¹³ in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of PHLX data. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

The Commission concluded that Regulation NMS—by deregulating the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

"[E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data."¹⁴

By removing "unnecessary regulatory restrictions" on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to broker-dealers at all, it follows that the price at which such data is sold should be set by the market as well. PHOTO is precisely the sort of market data product that the Commission envisioned when it adopted Regulation NMS.

On July 21, 2010, President Barack Obama signed into law H.R. 4173, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank Act"), which amended Section 19 of the Act. Among other things, Section 916 of the Dodd-Frank Act amended paragraph (A) of Section 19(b)(3) of the Act by inserting the phrase "on any person, whether or not the person is a member of the self-

regulatory organization" after "due, fee or other charge imposed by the self-regulatory organization." As a result, all SRO rule proposals establishing or changing dues, fees, or other charges are immediately effective upon filing regardless of whether such dues, fees, or other charges are imposed on members of the SRO, non-members, or both. Section 916 further amended paragraph (C) of Section 19(b)(3) of the Exchange Act to read, in pertinent part, "At any time within the 60-day period beginning on the date of filing of such a proposed rule change in accordance with the provisions of paragraph (1) [of Section 19(b)], the Commission summarily may temporarily suspend the change in the rules of the self-regulatory organization made thereby, 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 this title. If the Commission takes such action, the Commission shall institute proceedings under paragraph (2)(B) [of Section 19(b)] to determine whether the proposed rule should be approved or disapproved."

PHLX believes that these amendments to Section 19 of the Act reflect Congress' intent to allow the Commission to rely upon the forces of competition to ensure that fees for market data are reasonable and equitably allocated. Although Section 19(b) had formerly authorized immediate effectiveness for a "due, fee or other charge imposed by the self-regulatory organization," the Commission adopted a policy and subsequently a rule stipulating that fees for data and other products available to persons that are not members of the self-regulatory organization must be approved by the Commission after first being published for comment. At the time, the Commission supported the adoption of the policy and the rule by pointing out that unlike members, whose representation in self-regulatory organization governance was mandated by the Act, non-members should be given the opportunity to comment on fees before being required to pay them, and that the Commission should specifically approve all such fees.

PHLX believes that the amendment to Section 19 reflects Congress' conclusion that the evolution of self-regulatory organization governance and competitive market structure have rendered the Commission's prior policy on non-member fees obsolete.

Specifically, many exchanges have evolved from member-owned not-for-profit corporations into for-profit investor-owned corporations (or subsidiaries of investor owned

¹⁰ For example, a subscriber who requests End of Day PHOTO Historical Data for the month of March, 2009 would be charged \$400.00. A subscriber who requests End of Day PHOTO Historical Data for the months of March, 2009 and April, 2009 would be charged \$400.00 for the March, 2009 End of Day PHOTO Historical Data and \$400.00 for the April, 2009 End of Day PHOTO Historical Data, for a total of \$800.00, etc.

¹¹ For example, a subscriber who requests Intra-Day PHOTO Historical Data for the Month of March, 2009 would be charged \$750.00. A subscriber who requests Intra-Day PHOTO Historical Data for the months of March, 2009 and April, 2009 would be charged \$750.00 for the March, 2009 Intra-Day PHOTO Historical Data and \$750.00 for the April, 2009 Intra-Day PHOTO Historical Data, for a total of \$1,500.00, etc.

¹² 15 U.S.C. 78f.

¹³ 15 U.S.C. 78f(b)(4).

¹⁴ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

corporations). Accordingly, exchanges no longer have narrow incentives to manage their affairs for the exclusive benefit of their members, but rather have incentives to maximize the appeal of their products to all customers, whether members or nonmembers, so as to broaden distribution and grow revenues. Moreover, we believe that the change also reflects an endorsement of the Commission's determinations that reliance on competitive markets is an appropriate means to ensure equitable and reasonable prices. Simply put, the change reflects a presumption that all fee changes should be permitted to take effect immediately, since the level of all fees are constrained by competitive forces.

The recent decision of the *United States Court of Appeals for the District of Columbia Circuit in NetCoalition [sic] v. SEC, No. 09-1042 (DC Cir. 2010)*, although reviewing a Commission decision made prior to the effective date of the Dodd-Frank Act, upheld the Commission's reliance upon competitive markets to set reasonable and equitably allocated fees for market data. "In fact, the legislative history indicates that the Congress intended that the market system 'evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed' and that the SEC wield its regulatory power 'in those situations where competition may not be sufficient,' such as in the creation of a 'consolidated transactional reporting system.'" ¹⁵

The court's conclusions about Congressional intent are therefore reinforced by the Dodd-Frank Act amendments, which create a presumption that exchange fees, including market data fees, may take effect immediately, without prior Commission approval, and that the Commission should take action to suspend a fee change and institute a proceeding to determine whether the fee change should be approved or disapproved only where the Commission has concerns that the change may not be consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

PHLX 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. Notwithstanding its determination that

the Commission may rely upon competition to establish fair and equitably allocated fees for market data, the NetCoalition [sic] court found that the Commission had not, in that case, compiled a record that adequately supported its conclusion that the market for the data at issue in the case was competitive.

For the reasons discussed above, PHLX believes that the Dodd-Frank Act amendments to Section 19 materially alter the scope of the Commission's review of future market data filings, by creating a presumption that all fees may take effect immediately, without prior analysis by the Commission of the competitive environment.

Even in the absence of this important statutory change, however, PHLX believes that a record may readily be established to demonstrate the competitive nature of the market in question.

There is intense competition between trading platforms that provide transaction execution and routing services and proprietary data products. Transaction execution and proprietary data products are complementary in that market data is both an input and a by-product of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which platform to post an order will depend on the attributes of the platform where the order can be posted, including the execution fees, data quality and price and distribution of its data products. Without the prospect of a taking order seeing and reacting to a posted order on a particular platform, the posting of the order would accomplish little.

Without trade executions, exchange data products cannot exist. Data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, an exchange's customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A broker-dealer will direct orders to a particular exchange only if

the expected revenues from executing trades on the exchange exceed net transaction execution costs and the cost of data that the broker-dealer chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected value, the broker-dealer will choose not to buy it. Moreover, as a broker-dealer chooses to direct fewer orders to a particular exchange, the value of the product to that broker-dealer decreases, for two reasons. First, the product will contain less information, because executions of the broker-dealer's orders will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that broker-dealer because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the broker-dealer is directing orders will become correspondingly more valuable.

Thus, a super-competitive increase in the fees charged for either transactions or data has the potential to impair revenues from both products. "No one disputes that competition for order flow is 'fierce'." ¹⁶ However, the existence of fierce competition for order flow implies a high degree of price sensitivity on the part of broker-dealers with order flow, since they may readily reduce costs by directing orders toward the lowest-cost trading venues. A broker-dealer that shifted its order flow from one platform to another in response to order execution price differentials would both reduce the value of that platform's market data and reduce its own need to consume data from the disfavored platform. Similarly, if a platform increases its market data fees, the change will affect the overall cost of doing business with the platform, and affected broker-dealers will assess whether they can lower their trading costs by directing orders elsewhere and thereby lessening the need for the more expensive data.

Analyzing the cost of market data distribution in isolation from the cost of all of the inputs supporting the creation of market data will inevitably underestimate the cost of the data. Thus, because it is impossible to create data without a fast, technologically robust, and well-regulated execution system, system costs and regulatory costs affect the price of market data. It would be equally misleading, however, to attribute all of the exchange's costs to the market data portion of an exchange's

¹⁵ NetCoalition [sic], at 15 (quoting H.R. Rep. No. 94-229, at 92 (1975), as reprinted in 1975 U.S.C.C.A.N. 321, 323).

¹⁶ NetCoalition at 24.

joint product. Rather, all of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

Competition among trading platforms can be expected to constrain the aggregate return each platform earns from the sale of its joint products, but different platforms may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some platforms may choose to pay rebates to attract orders, charge relatively low prices for market information (or provide information free of charge) and charge relatively high prices for accessing posted liquidity. Other platforms may choose a strategy of paying lower rebates (or no rebates) to attract orders, setting relatively high prices for market information, and setting relatively low prices for accessing posted liquidity. In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering. This would be akin to strictly regulating the price that an automobile manufacturer can charge for car sound systems despite the existence of a highly competitive market for cars and the availability of aftermarket alternatives to the manufacturer-supplied system.

The market for market data products is competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market. Broker-dealers currently have numerous alternative venues for their order flow, including ten self-regulatory organization ("SRO") markets, as well as internalizing broker-dealers ("BDs") and various forms of alternative trading systems ("ATSs"), including dark pools and electronic communication networks ("ECNs"). Each SRO market competes to produce transaction reports via trade executions, and two FINRA regulated Trade Reporting Facilities ("TRFs")

compete to attract internalized transaction reports. Competitive markets for order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products. For example, the Exchange notes that at least one other U.S. options exchange offers a market data product that is substantially similar to the PHOTO Historical Data product, which the PHLX must consider in its pricing discipline in order to compete for listings, trades, and the market data itself.¹⁷

The large number of SROs, TRFs, BDs, and ATSs that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, TRF, ATS, and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including PHLX, NASDAQ, NYSE, NYSE Amex, NYSEArca, and BATS.

Any ATS or BD can combine with any other ATS, BD, or multiple ATSs or BDs to produce joint proprietary data products. Additionally, order routers and market data vendors can facilitate single or multiple broker-dealers' production of proprietary data products. The potential sources of proprietary products are virtually limitless.

The fact that proprietary data from ATSs, BDs, and vendors can by-pass SROs is significant in two respects. First, non-SROs can compete directly with SROs for the production and sale of proprietary data products, as BATS and Arca did before registering as exchanges by publishing proprietary book data on the Internet. Second, because a single order or transaction report can appear in an SRO proprietary product, a non-SRO proprietary product, or both, the data available in proprietary products is exponentially greater than the actual number of orders and transaction reports that exist in the marketplace.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end users:

¹⁷The International Securities Exchange, Inc. ("ISE") Open/Close Trade Profile and the ISE Open/Close Trade Profile Intra-Day contain substantially similar data to that included in PHOTO End of Day and PHOTO Intra-Day. See Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR-ISE-2007-70). ISE currently sells the ISE Open/Close Trade Profile with historical data available back to May 2005, and sells the ISE Open/Close Trade Profile Intraday with historical data available separately back to October 2009. See Securities Exchange Act Release No. 61317 (January 8, 2010), 75 FR 2915 (January 19, 2010) (SR-ISE-2009-103).

Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end users will not purchase in sufficient numbers. Internet portals, such as Yahoo, impose a discipline by providing only data that will enable them to attract "eyeballs" that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: They can simply refuse to purchase any proprietary data product that fails to provide sufficient value. PHLX and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully.

In addition to the competition and price discipline described above, the market for proprietary data products is also highly contestable because market entry is rapid, inexpensive, and profitable. The history of electronic trading is replete with examples of entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TracECN, BATS Trading and Direct Edge. A proliferation of dark pools and other ATSs operate profitably with fragmentary shares of consolidated market volume.

Regulation NMS, by deregulating the market for proprietary data, has increased the contestability of that market. While broker-dealers have previously published their proprietary data individually, Regulation NMS encourages market data vendors and broker-dealers to produce proprietary products cooperatively in a manner never before possible. Multiple market data vendors already have the capability to aggregate data and disseminate it on a profitable scale, including Bloomberg, and Thomson-Reuters.

The court in NetCoalition concluded that the Commission had failed to demonstrate that the market for market data was competitive based on the reasoning of the Commission's NetCoalition order because, in the court's view, the Commission had not adequately demonstrated that the depth-of-book data at issue in the case is used to attract order flow. PHLX believes, however, that evidence not before the

court clearly demonstrates that availability of depth data attracts order flow.

Competition among platforms has driven PHLX continually to improve its platform data offerings and to cater to customers' data needs. For example, PHLX offers front end applications such as its Top of PHLX Options ("TOPO") and TOPO Plus Orders data products to help customers utilize data.

For the foregoing reasons, PHLX 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 purpose of the Act.

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 foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁸ 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 e-mail to rule-comments@sec.gov. Please include File Number SR-Phlx-2010-154 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-2010-154. This file number should be included on the subject line if e-mail 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 a.m. and 3 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-2010-154 and should be submitted on or before December 20, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Elizabeth M. Murphy,

Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63357; File No. SR-ISE-2010-110]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Extension of a Pilot Program for Directed Orders

November 22, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Exchange Act"),¹ and Rule 19b-4

thereunder,² notice is hereby given that on November 16, 2010, 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 is proposing to extend the pilot period for the system change that identifies to a Directed Market Maker ("DMM") the identity of the firm entering a Directed Order until May 31, 2011.

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

On January 5, 2006, the ISE initiated a system change to identify to a DMM the identity of the firm entering a Directed Order. The ISE filed this system change on a pilot basis under Section 19(b)(3)(A) of the Exchange Act of 1934 (the "Exchange Act") and Rule 19b-4(f)(5) thereunder³ so that it would be effective while the Commission considered a separate proposed rule change filed under Section 19(b)(2) of the Exchange Act to amend the ISE's rules to reflect the system change on a permanent basis (the "Permanent Rule Change").⁴ The current pilot expires on

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 53104 (Jan. 11, 2006), 71 FR 2142 (Jan. 19, 2006) (Notice of Filing and Immediate Effectiveness of SR-ISE-2006-02).

⁴ See Securities Exchange Act Release No. 53103 (Jan. 11, 2006), 71 FR 3144 (Jan. 19, 2006) (Notice of Filing of SR-ISE-2006-01).

¹⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

November 30, 2010,⁵ but the Commission has not yet taken action with respect to the Permanent Rule Change. Accordingly, the Exchange proposes to extend the pilot for an additional six months, until May 31, 2011, so that the system change will remain in effect while the Commission continues to evaluate the Permanent Rule Change.⁶

2. Basis

The basis under the Exchange Act for this proposed rule change is found in Section 6(b)(5), in that the proposed rule change is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. Extension of the pilot program will allow the Exchange to continue operating under the pilot while the Commission considers the Permanent Rule Change.

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 Exchange Act.

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 written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Exchange Act⁷ and Rule 19b-4(f)(5)⁸ 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 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 Exchange 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 E-mail to rule-comments@sec.gov. Please include File No. SR-ISE-2010-110 in 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-2010-110. This file number should be included on the subject line if e-mail 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 Commissions 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the ISE. 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-2010-110 and should be submitted by December 20, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2010-29894 Filed 11-26-10; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63349; File No. SR-NYSEArca-2010-103]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Relating to the Listing and Trading of the Jefferies S&P 500[®] VIX Short-Term Futures ETF

November 19, 2010.

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 November 9, 2010, NYSE Arca, Inc. ("Exchange" or "NYSE Arca") 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 list and trade shares of the Jefferies S&P 500[®] VIX Short-Term Futures ETF under NYSE Arca Equities Rule 8.200. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and <http://www.nyse.com>.

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.

⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁵ See Securities Exchange Act Release No. 60956 (November 6, 2009), 74 FR 58674 (November 13, 2009) (Notice of Filing and Immediate Effectiveness of SR-ISE-2009-93).

⁶ The ISE anticipated that extension of the pilot might be necessary and included this in the filing for the initial pilot. See *supra* note 3, at footnote 5.

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f)(5).

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Arca Equities Rule 8.200, Commentary .02, permits the trading of Trust Issued Receipts ("TIRs") either by listing or pursuant to unlisted trading privileges ("UTP").³ The Exchange proposes to list and trade shares ("Shares") of the Jefferies S&P 500® VIX Short-Term Futures ETF ("Fund") pursuant to NYSE Arca Equities Rule 8.200.⁴ The Fund is a commodity pool and a Delaware statutory trust.⁵

Overview of the Fund

According to the Registration Statement, the Fund seeks to track changes, whether positive or negative, in the level of the S&P 500 VIX Short-Term Futures™ Index ER ("VIX Futures Index" or "Index") over time.⁶ The Fund will pursue its investment objective primarily by maintaining long futures positions corresponding to the futures contracts underlying the VIX Futures Index which trade on the CBOE Futures Exchange ("CFE") ("VIX Futures Contracts").⁷ with an aggregate notional

³ Commentary .02 to NYSE Arca Equities Rule 8.200 applies to TIRs that invest in "Financial Instruments." The term "Financial Instruments," as defined in Commentary .02(b)(4) to NYSE Arca Equities Rule 8.200, means any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars and floors; and swap agreements.

⁴ The Commission previously has approved listing on the Exchange under Commentary .02 to NYSE Arca Equities Rule 8.200 of certain securities issuers. See, e.g., Securities Exchange Act Release Nos. 58457 (September 3, 2008), 73 FR 52711 (September 10, 2008) (SR-NYSEArca-2008-91) (order granting accelerated approval to list on NYSE Arca of 14 ProShares funds); and 58983 (November 20, 2008), 73 FR 73368 (December 2, 2008) (SR-NYSEArca-2008-126) (order granting accelerated approval to list on NYSE Arca the Green Haven Continuous Commodity Index Fund). See also Securities Exchange Act Release No. 58968 (November 17, 2008), 73 FR 71082 (November 24, 2008) (SR-NYSEArca-2008-111) (order granting accelerated approval of proposed rule change to amend NYSE Arca Equities Rule 5.2(j)(6)(v) to add CBOE Volatility Index Futures to the definition of Futures Reference Asset).

⁵ The Fund has filed a Pre-Effective Amendment No. 3 to Form S-1 registration statement under the Securities Act of 1933, dated August 17, 2010 (File No. 333-166283) ("Registration Statement"). The description of the Fund and the Shares contained herein are based on the Registration Statement.

⁶ The VIX Futures Index was created by Standard & Poor's Financial Services, LLC ("Index Sponsor"). The VIX Futures Index is the excess return version of the S&P 500 VIX Short-Term Futures™ Index. The Index Sponsor has implemented procedures designed to prevent the use and dissemination of material, non-public information regarding the Index.

⁷ As of June 14, 2010, there was VIX Futures Contracts open interest of 88,366 contracts with a

amount equal to the Fund's total capital. In certain circumstances, as described below, the Fund may invest in one or more forward agreements or swaps ("Futures-Linked Investments"). The Fund is also intended to reflect the excess, if any, of its interest income from its investment in U.S. Treasury bills, generally with a maturity of less than one year, and other high credit quality short-term fixed-income securities, over its expenses.⁸

Jefferies Commodity Investment Services, LLC, a Delaware limited liability company, is the Fund's promoter, and will serve as Managing Owner of the Fund. The Managing Owner will serve as the commodity pool operator and commodity trading advisor of the Fund. The Managing Owner is registered as a commodity pool operator and commodity trading advisor with the Commodity Futures Trading Commission and is a member of the National Futures Association. The Bank of New York Mellon ("Administrator") will be the administrator, custodian and transfer agent of the Fund.

According to the Registration Statement, the Index is designed to provide an exposure to one or more maturities of futures contracts on the CBOE Volatility Index ("Volatility Index"), which reflect implied volatility in the S&P 500® Index at various points along the volatility forward curve. The Volatility Index is calculated based on the prices of put and call options on the S&P 500® Index. The VIX Futures Index is intended to reflect the returns that are potentially available through an unleveraged investment in the relevant futures contract or contracts on the Volatility Index.

The Index measures the return from a daily rolling long position in the first and second month VIX Futures Contracts, targeting a constant weighted average futures maturity of one month. The Fund will acquire and roll long positions in the first and second month VIX Futures Contracts with a view to tracking the level of the Index over time. The Fund will both roll and rebalance its holdings of VIX Futures Contracts in a manner consistent with the method described in the Registration Statement.

The Index is comprised of, and the value of the Shares will be based on,

contract price of \$25.55 and value of open interest of \$2,257,751,300. Total CFE trading volume in 2009 in VIX Futures Contracts was 1,143,612 contracts, with average daily volume of 4538 contracts. Total volume year-to-date (through May 31, 2010) is 1,399,709 contracts, with average daily volume of 13,458 contracts. (Source: Bloomberg and CBOE).

⁸ Terms relating to the Fund, the Shares and the Index referred to, but not defined, herein are defined in the Registration Statement.

VIX Futures Contracts. VIX Futures Contracts are measures of the market's expectation of the level of the Volatility Index at certain points in the future, and may diverge from current, or spot, Volatility Index values. The Fund is not linked to the Volatility Index, and the value of the Index and the Shares may diverge significantly from the Volatility Index.

The Fund does not intend to outperform the Index. The Managing Owner will seek to cause the net asset value ("NAV") of the Fund to track the Index during periods in which the Index is flat or declining as well as when the Index is rising.

According to the Registration Statement, the Fund seeks to achieve its investment objective by investing under normal market conditions in VIX Futures Contracts. In the event the Fund reaches its position accountability rules with respect to VIX Futures Contracts, the Managing Owner, may, in its commercially reasonable judgment, cause the Fund to invest in a Futures-Linked Investment referencing the particular VIX Futures Contracts, or invest in other futures contracts or a Futures-Linked Investment not based on the particular VIX Futures Contracts if such instruments tend to exhibit trading prices or returns that correlate with the VIX Futures Index or any VIX Futures Contract and will further the investment objective of the Fund.⁹ The Fund may also invest in Futures-Linked Investments if the market for a specific futures contract experiences emergencies (e.g., natural disaster, terrorist attack or an act of God) or disruptions (e.g., a trading halt or a flash crash) to prevent the Fund from obtaining the appropriate amount of investment exposure to the affected VIX Futures Contract directly or other futures contract.¹⁰

The Fund will hold a portfolio of VIX Futures Contracts as well as cash and U.S. Treasury bills, generally with a maturity of less than one year, and other high credit quality short-term fixed-income securities for deposit with the Fund's Clearing Broker as margin. The Fund's portfolio will be traded with a view to tracking the Index, whether the Index is rising, falling or flat over any particular period. The Fund is not

⁹ To the extent practicable, the Fund will invest in swaps cleared through the facilities of a centralized clearing house.

¹⁰ According to the Registration Statement, the Managing Owner will also attempt to mitigate the Fund's credit risk by transacting only with large, well-capitalized institutions using measures designed to determine the creditworthiness of a counterparty. The Managing Owner will take various steps to limit counterparty credit risk, as described in the Registration Statement.

“managed” by traditional methods, which typically involve effecting changes in the composition of the Fund’s portfolio on the basis of judgments relating to economic, financial and market considerations with a view to obtaining positive results under all market conditions.

According to the Registration Statement, the Shares are designed to reflect as closely as possible the changes, whether positive or negative, in the level of the VIX Futures Index over time, through the Fund’s portfolio of VIX Futures Contracts, and/or, if applicable, Futures-Linked Investments that reference the VIX Futures Index. The value of the Shares relates directly to the changes in market value, whether positive or negative, of the Fund’s portfolio of VIX Futures Contracts and the value of the Fund’s portfolio of U.S. Treasury bills, generally with a maturity of less than one year, and other high credit quality short-term fixed-income securities, less the liabilities (including estimated accrued but unpaid expenses) of the Fund.

The Volatility Index

According to the Registration Statement, the Volatility Index is a benchmark index designed to estimate expected volatility in large cap U.S. stocks over 30 days in the future by averaging the weighted prices of certain put and call options on the S&P 500® Index. During periods of market instability, the implied level of volatility of the S&P 500® Index typically increases and, consequently, the prices of options linked to the S&P 500® Index typically increase (assuming all other relevant factors remain constant or have negligible changes). This, in turn, causes the level of the Volatility Index to increase. Because the Volatility Index may increase in times of uncertainty, the Volatility Index is commonly known as the “fear gauge” of the broad U.S. equities market. The Volatility Index has historically had negative correlations to the S&P 500® Index.

The calculation of the Volatility Index involves a formula that uses the prices of a weighted series of out-of-the-money put and call options on the level of the S&P 500® Index (“SPX Options”), with two adjacent expiry terms to derive a constant 30-day forward measure of market volatility. The Volatility Index is calculated independent of any particular option pricing model and in doing so seeks to eliminate any biases which may otherwise be included in using options pricing methodology based on certain assumptions.

According to the Registration Statement, although the Volatility Index

measures the 30-day forward volatility in the S&P 500® Index as implied by the SPX Options, 30-day options are only available once a month. To arrive at the Volatility Index level, a broad range of out-of-the money SPX Options expiring on the two closest nearby months (“near term options” and “next term options,” respectively) are selected in order to bracket a 30-day calendar period. SPX Options having a maturity of less than eight days are excluded at the outset and, when the near term options have eight days or less left to expiration, the Volatility Index rolls to the second and third contract months in order to minimize pricing anomalies that occur close to expiration. The model-free implied volatility using prices of the near term options and next term options are then calculated on a strike price weighted-average basis in order to arrive at a single average implied volatility value for each month. The results of each of the two months are then interpolated to arrive at a single value with a constant maturity of 30 days to expiration. Futures on the Volatility Index were first launched for trading by the CBOE in 2004. Volatility Index futures have expirations ranging from the front month consecutively out to the tenth month.

The VIX Futures Index is composed of one or more futures contracts on the Volatility Index. OTC derivatives and various types of electronic trading facilities and markets may offer investments linked to the Volatility Index. At present, all of the contracts included in the VIX Futures Index are exchange-traded futures contracts.

The VIX Futures Index is a rolling Index, which rolls on a daily basis. One of the effects of daily rolling is to maintain a constant weighted average maturity for the underlying futures contracts. The VIX Futures Index is composed of rolling first and second month futures contracts on the Volatility Index. Unlike equities, which typically entitle the holder to a continuing stake in a corporation, futures contracts normally specify a certain date for the delivery of the underlying asset or financial instrument or, in the case of futures contracts relating to indices such as the Volatility Index, a certain date for payment in cash of an amount determined by the level of the underlying index. The VIX Futures Index operates by selling futures contracts on the Volatility Index on a daily basis, specifying cash settlement on a nearby date and purchasing futures contracts on the Volatility Index on a daily basis specifying cash settlement on a later date. The roll for each VIX Futures

Contract occurs on each index business day according to a pre-determined schedule that has the effect of keeping constant the weighted average maturity of the relevant VIX Futures Contract. This process is known as “rolling” a futures position, and the VIX Futures Index is a “rolling index.” The constant weighted average maturity for the futures contracts underlying the VIX Futures Index is one month.¹¹

Because the Index incorporates this process of rolling futures positions on a daily basis, and the Fund, in general, also rolls its positions on a daily basis, the daily roll is not anticipated to be a significant source of tracking error between the Fund and its Index. The Index is based on VIX Futures Contracts and not the Volatility Index, and as such neither the Fund nor the Index are expected to track the Volatility Index.

Creation and Redemption of Shares

The Fund creates and redeems Shares from time-to-time in one or more Baskets. A Basket is a block of 20,000 Shares. Baskets may be created or redeemed only by Authorized Participants, except that the initial Baskets in the Fund will be created by the Initial Purchaser. Except when aggregated in Baskets, the Shares are not redeemable securities. Authorized Participants pay a transaction fee in connection with each order to create or redeem a Basket.

The total cash payment required to create each Basket is the NAV of 20,000 Shares on the purchase order date.¹² Baskets are issued as of noon, E.T., on the business day immediately following the purchase order date at the applicable NAV per Share on the purchase order date, but only if the required payment has been timely received. Purchase and redemption orders must be placed by noon, E.T.

The procedures by which an Authorized Participant can redeem one or more Baskets mirror the procedures for the creation of Baskets. On any business day, an Authorized Participant may place an order with the Managing Owner to redeem one or more Baskets.

¹¹ It is anticipated that, near expiration, the performance of a VIX Futures Contract will be close to that of the Volatility Index, while longer term futures (not close to expiration) reflect the long term expectations of the value of the Volatility Index plus a risk premium and may not closely track the performance of the Volatility Index. The Exchange notes that the Fund seeks results that match the performance of the VIX Futures Index and should not be expected to match the performance of the Volatility Index.

¹² E-mail from Michael Cavalier, Chief Counsel, NYSE Euronext, to Edward Y. Cho, Special Counsel, Division of Trading and Markets, Commission, dated November 15, 2010 (“Exchange Confirmation”).

The redemption proceeds from the Fund consist of the cash redemption amount. The cash redemption amount is equal to the NAV of the number of Baskets of the Fund requested in the Authorized Participant's redemption order on the redemption order date.

Availability of Information Regarding the Shares

The NAV for the Fund will be calculated by the Administrator once a day at or after 4:15 p.m., E.T., and will be disseminated daily to all market participants at the same time.¹³ The Exchange will make available on its Web site daily trading volume of each of the Shares, closing prices of such Shares, and number of Shares outstanding.

The closing prices and settlement prices of VIX Futures Contracts are also readily available from the Web sites of the CFE, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. Complete real-time data for VIX Futures Contracts is available by subscription from Reuters and Bloomberg. The CFE also provides delayed futures information on current and past trading sessions and market news free of charge on its Web site (<http://www.cfe.cboe.com>). The specific contract specifications for VIX Futures Contracts are also available on such Web sites, as well as other financial informational sources. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. In addition, the Fund's Web site at <http://www.jamfunds.com/jcis> will display the end of day closing Index levels and NAV. The level of the Volatility Index as calculated by CBOE, updated every 15 seconds from 9:30 a.m. to 4:15 p.m., E.T., is disseminated on the CBOE Web site at <http://www.cboe.com> and through major market data vendors.

The Fund will provide Web site disclosure of portfolio holdings daily and will include, as applicable, the names and value (in U.S. dollars) of VIX Futures Contracts, Futures-Linked Investments and other futures contracts, if any, and characteristics of such investments and cash equivalents, and amount of cash held in the portfolio of the Fund. This Web site disclosure of the portfolio composition of the Fund

will occur at the same time as the disclosure by the Managing Owner of the portfolio composition to Authorized Participants so that all market participants are provided portfolio composition information at the same time. Therefore, the same portfolio information will be provided on the public Web site as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current portfolio composition of the Fund through the Fund's Web site.

Dissemination of Indicative Trust Value and Index Value

In addition, in order to provide updated information relating to the Fund for use by investors and market professionals, an updated Indicative Trust Value ("ITV") will be calculated. The ITV is calculated by using the prior day's closing NAV per share of the Fund as a base and updating that value throughout the NYSE Arca Core Trading Session of 9:30 a.m. to 4 p.m. E.T. each trading day to reflect current changes in the value of VIX Futures Contracts held by the Fund, as well as the value of any swap or forward contracts and other futures contracts held by the Fund. The ITV disseminated during the Core Trading Session should not be viewed as an actual real-time update of the NAV, which is calculated only once a day.

The ITV will be disseminated on a per-Share basis by one or more major market data vendors every 15 seconds during the Core Trading Session. In addition, the end-of-day NAV of the Fund will be disseminated once a day.

The Exchange believes that dissemination of the ITV provides additional information regarding the Fund that is not otherwise available to the public and is useful to professionals and investors in connection with the related Shares trading on the Exchange or the creation or redemption of such Shares.

The Index Sponsor will publish the daily closing level of the VIX Futures Index as of the close of the NYSE Arca Core Trading Session. The Managing Owner will publish the NAV of the Fund and the NAV per Share daily. The Index Sponsor will publish the intraday level of the VIX Futures Index updated every 15 seconds during the NYSE Arca Core Trading Session on the consolidated tape, Reuters and/or Bloomberg, and the Managing Owner will publish the ITV per Share once every 15 seconds during the NYSE Arca Core Trading Session on the Managing

Owner's Web site at <http://www.jamfunds.com/jcis>.¹⁴

The current trading price per Share will be published continuously as trades occur during the NYSE Arca Core Trading Session on the consolidated tape, Reuters and/or Bloomberg and on the Managing Owner's Web site. The most recent end-of-day Index closing level will be published as of the close of the NYSE Arca Core Trading Session each trading day on the consolidated tape, Reuters and/or Bloomberg and on the Managing Owner's Web site. The most recent end-of-day NAV of the Fund will be published on Reuters and/or Bloomberg and on the Managing Owner's Web site. In addition, the most recent end-of-day NAV of the Fund will be published the following morning on the consolidated tape. All of the foregoing information with respect to the VIX Futures Index will also be published at <http://www.cfe.cboe.com>.

Additional information regarding the Fund and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions and taxes is included in the Registration Statement.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m. E.T. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, Commentary .03, the minimum price variation ("MPV") for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is \$0.01, with the exception of securities that are priced less than \$1.00 for which the MPV for order entry is \$0.0001.

The trading of the Shares will be subject to NYSE Arca Equities Rule 8:200, Commentary .02(e), which sets forth certain restrictions on ETP Holders acting as registered Market Makers in Trust Issued Receipts to facilitate surveillance. See "Surveillance" below for more information.

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may

¹³ According to the Registration Statement, net asset value means the total assets of the Fund including, but not limited to, all cash and cash equivalents or other debt securities less total liabilities of the Fund, each determined on the basis of generally accepted accounting principles in the United States, consistently applied under the accrual method of accounting.

¹⁴ See Exchange Confirmation, *supra* note 12.

include: (1) The extent to which trading is not occurring in the underlying futures contracts; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, trading in Shares will be subject to trading halts caused by extraordinary market volatility pursuant to the Exchange's "circuit breaker" rule¹⁵ or by the halt or suspension of trading of the underlying futures contracts.

The Exchange represents that the Exchange may halt trading during the day in which the interruption to the dissemination of the ITV, the VIX Futures Index, the Volatility Index or the value of the underlying futures contracts occurs. If the interruption to the dissemination of the ITV, the VIX Futures Index, the Volatility Index or the value of the underlying futures contracts persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

The Fund will meet the initial and continued listing requirements applicable to Trust Issued Receipts in NYSE Arca Equities Rule 8.200 and Commentary .02 thereto. With respect to application of Rule 10A-3 under the Act,¹⁶ the Trust relies on the exception contained in Rule 10A-3(c)(7).¹⁷ A minimum of 100,000 Shares of the Fund will be outstanding as of the start of trading on the Exchange.

Surveillance

The Exchange intends to utilize its existing surveillance procedures applicable to derivative products, including Trust Issued Receipts, to monitor trading in the Shares. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws.

The Exchange's current trading surveillances focus on detecting securities trading outside their normal patterns. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of

all relevant parties for all relevant trading violations. The Exchange is able to obtain information regarding trading in the Shares, or options, futures or options on futures on, Shares through ETP Holders, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market. The Exchange can obtain market surveillance information, including customer identity information, with respect to transactions occurring on the exchanges that are members of the Intermarket Surveillance Group ("ISG"), including CBOE and CFE. A list of ISG members is available at <http://www.isgportal.org>.¹⁸

In addition, with respect to Fund components traded on exchanges, not more than 10% of the weight of such components in the aggregate shall consist of components whose principal trading market is not a member of ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement.

The Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) The risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated ITV will not be calculated or publicly disseminated; (2) the procedures for purchases and redemptions of Shares in Creation Baskets and Redemption Baskets (and that Shares are not individually redeemable); (3) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (4) how information regarding the ITV is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Bulletin will advise ETP Holders, prior to the commencement of trading, of the prospectus delivery requirements

¹⁸ The Exchange notes that not all investments held by the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

applicable to the Fund. The Exchange notes that investors purchasing Shares directly from the Fund will receive a prospectus. ETP Holders purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Bulletin will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Bulletin will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Bulletin will also reference that the CFTC has regulatory jurisdiction over futures contracts traded on U.S. markets.

The Information Bulletin will also disclose the trading hours of the Shares of the Fund and that the NAV for the Shares is calculated after 4 p.m. E.T. each trading day. The Bulletin will disclose that information about the Shares of the Fund is publicly available on the Fund's Web site.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,¹⁹ in general, and furthers the objectives of Section 6(b)(5),²⁰ 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 mechanism of a free and open market and a national market system. The Exchange believes that the proposed rule change will permit the listing of an additional issuance of Trust Issued Receipts on the Exchange that will enhance competition among market participants, to the benefit of investors and the marketplace. In addition, the listing and trading criteria set forth in Rule 8.200 are intended to protect investors and the public interest.

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.

¹⁵ See NYSE Arca Equities Rule 7.12.

¹⁶ 17 CFR 240.10A-3.

¹⁷ 17 CFR 240.10A-3(c)(7).

¹⁹ 15 U.S.C. 78f(b).

²⁰ 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

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

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 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 e-mail to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2010-103 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-2010-103. This file number should be included on the subject line if e-mail 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 20549-1090 on official business days between 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the Exchange's principal office. 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-2010-103 and should be submitted on or before December 20, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Elizabeth M. Murphy,

Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63350; File No. SR-Phlx-2010-156]

Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Extension of a Pilot Program Concerning Disseminated Quotations

November 19, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4² thereunder, notice is hereby given that on November 10, 2010, NASDAQ OMX PHLX, Inc. ("Phlx" or "Exchange") 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 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 amend Exchange Rules 1017, Openings in Options, and 1082, Firm Quotations, to extend, through March 31, 2011, a pilot

program (the "pilot") under which the Exchange's rules describe the manner in which the PHLX XL[®] automated options trading system³ disseminates quotations when (i) there is an opening imbalance in a particular series, and (ii) there is a Quote Exhaust (as described below) or a Market Exhaust (as described below) quote condition present in a particular series.

The current pilot is scheduled to expire November 30, 2010.

The text of the proposed rule change is available on the Exchange's Web site at <http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings>, 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 purpose of the proposed rule change is to extend the pilot through March 31, 2011.—

Background

In June, 2009, the Exchange added several significant enhancements to its automated options trading platform (now known as PHLX XL) and adopted rules to reflect those enhancements.⁴ As part of the system enhancements, the Exchange proposed to disseminate a "non-firm" quote condition on a bid or offer whose size is exhausted in certain situations. The non-exhausted side of

³ This proposal refers to "PHLX XL" as the Exchange's automated options trading system. In May 2009 the Exchange enhanced the system and adopted corresponding rules referring to the system as "Phlx XL II." See Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR-Phlx-2009-32). The Exchange intends to submit a separate technical proposed rule change that would change all references to the system from "Phlx XL II" to "PHLX XL" for branding purposes.

⁴ See Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR-Phlx-2009-32).

²¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

the Exchange's disseminated quotation would remain firm up to its disseminated size. Currently, however, the Options Price Reporting Authority ("OPRA") only disseminates option quotations for which both sides of the quotation are marked "non-firm." OPRA currently does not disseminate a "non-firm" condition for one side of a quotation while the other side of the quotation remains firm.⁵

Accordingly, the Exchange proposed, for a pilot period scheduled to expire November 30, 2009, and later extended through September 30, 2010,⁶ to disseminate quotations in such a circumstance with (i) a bid price of \$0.00, with a size of one contract if the remaining size is a seller, or (ii) an offer price of \$200,000, with a size of one contract if the remaining size is a buyer.

The Exchange subsequently modified the manner in which the PHLX XL system disseminates quotes when one side of the quote is exhausted but the opposite side still has marketable size at the disseminated price, as described in detail below.⁷

On October 7, 2010, the U.S. options exchanges, as participants in the OPRA Plan, voted to make technological changes that would enable OPRA to support a one-sided non-firm quote condition. These technological changes require OPRA and the participants to design, test, and deploy modifications to their systems, and to establish connectivity with quotation vendors, that will support the one-sided non-firm quote condition. The Exchange set a target date for its completion of the changes by the end of January, 2011. The Exchange is proposing to extend the current pilot through March 31, 2011, in order to account for the time required to complete the changes, and to account for the possibility that issues could arise that might delay the process beyond the end of January target date.

Opening Imbalance

An opening "imbalance" occurs when all opening marketable size cannot be completely executed at or within an established Opening Quote Range ("OQR") for the affected series.⁸

⁵ Currently, there is no mechanism for the Options Price Reporting Authority ("OPRA") to identify only one side of a quote as non-firm. The Exchange has approached OPRA to attempt to develop the capability to identify and implement such functionality.

⁶ See *supra* note 4.

⁷ See Securities Exchange Act Release No. 63024 (September 30, 2010), 75 FR 61799 (October 6, 2010) (SR-Phlx-2010-134).

⁸ Where there is an imbalance at the price at which the maximum number of contracts can trade that is also at or within the lowest quote bid and highest quote offer, the PHLX XL system will

Currently, pursuant to Exchange Rule 1017(l)(v)(C)(7), any unexecuted contracts from the opening imbalance not traded or routed are displayed in the Exchange quote at the opening price for a period not to exceed ten seconds, and subsequently, cancelled back to the entering participant if they remain unexecuted and priced through the opening price, unless the member that submitted the original order has instructed the Exchange in writing to re-enter the remaining size, in which case the remaining size will be automatically submitted as a new order. During this display time period, the PHLX XL system disseminates, if the imbalance is a buy imbalance, an offer of \$0.00, with a size of zero contracts or, if the imbalance is a sell imbalance, a bid of \$0.00, with a size of zero contracts, on the opposite side of the market from remaining unexecuted contracts.

The purpose of this provision is to indicate that the Exchange has exhausted all marketable interest, at or within the OQR, on one side of the market during the opening process yet has remaining unexecuted contracts on the opposite side of the market that are firm at the disseminated price and size.

Rule 1017(l)(v)(C)(7) is subject to the pilot, which is scheduled to expire November 30, 2010. The Exchange proposes to extend the pilot through March 31, 2011.

Quote Exhaust

Quote Exhaust occurs when the market at a particular price level on the Exchange includes a quote, and such market is exhausted by an inbound contra-side quote or order ("initiating quote or order"), and following such exhaustion, contracts remain to be executed from the initiating quote or order.⁹

Rather than immediately executing at the next available price, the PHLX XL system employs a timer (a "Quote Exhaust Timer"), not to exceed one second; in order to allow market participants to refresh their quotes. During the Quote Exhaust Timer, PHLX XL currently disseminates the "Reference Price" (the most recent execution price) for the remaining size, provided that such price does not lock an away market, in which case, the Exchange currently disseminates a bid and offer that is one Minimum Price Variation ("MPV") from the away market price. During the Quote Exhaust Timer, the Exchange disseminates: (i) A bid

calculate an OQR for a particular series, outside of which the PHLX XL system will not execute. See Exchange Rule 1017(l)(iii) and (iv).

⁹ See Exchange Rule 1082(a)(ii)(B)(3).

price of \$0.00, with a size of zero contracts if the remaining size is a seller, or (ii) an offer price of \$0.00, with a size of zero contracts if the remaining size is a buyer.

Currently, Exchange Rules 1082(a)(ii)(B)(3)(g)(iv)(A)(3), 1082(a)(ii)(B)(3)(g)(iv)(A)(4), 1082(a)(ii)(B)(3)(g)(iv)(B)(2), and 1082(a)(ii)(B)(3)(g)(iv)(C) describe various scenarios under which the PHLX XL system trades, routes, or posts unexecuted contracts after determining the "Best Price" following a Quote Exhaust. These rules permit an up to 10 second time period during which participants may revise their quotes prior to the PHLX XL system taking action. In all of these scenarios, during the up to 10 second time period, the PHLX XL system currently disseminates an offer of \$0.00, with a size of zero contracts if the remaining size is a buyer or, if the remaining size is a seller, a bid of \$0.00, with a size of zero contracts, on the opposite side of the market from remaining unexecuted contracts.

Exchange Rules 1082(a)(ii)(B)(3)(g)(iv)(A)(3), 1082(a)(ii)(B)(3)(g)(iv)(A)(4), 1082(a)(ii)(B)(3)(g)(iv)(B)(2), and 1082(a)(ii)(B)(3)(g)(iv)(C) are subject to the pilot, which is scheduled to expire November 30, 2010. The Exchange proposes to extend the pilot through March 31, 2011.

Current Rule 1082(a)(ii)(B)(3)(g)(vi) describes what the PHLX XL system does if, after trading at the PHLX and/or routing, there are unexecuted contracts from the initiating order that are still marketable. In this situation, remaining contracts are posted for a period of time not to exceed 10 seconds and then cancelled after such period of time has elapsed, unless the member that submitted the original order has instructed the Exchange in writing to re-enter the remaining size, in which case the remaining size will be automatically submitted as a new order. During the up to 10 second time period, the Exchange will disseminate, on the opposite side of the market from remaining unexecuted contracts: (i) A bid price of \$0.00, with a size of zero contracts if the remaining size is a seller, or (ii) an offer price of \$0.00, with a size of zero contracts if the remaining size is a buyer.

Rule 1082(a)(ii)(B)(3)(g)(vi) is subject to the pilot. The Exchange proposes to extend the pilot through March 31, 2011.

Market Exhaust

Market Exhaust occurs when there are no PHLX XL participant quotations in the Exchange's disseminated market for a particular series and an initiating

order in the series is received. In such a circumstance, the PHLX XL system initiates a "Market Exhaust Auction" for the initiating order.¹⁰

In this situation, the PHLX XL system will first determine if the initiating order, or a portion thereof, can be executed on the PHLX. Thereafter, if there are unexecuted contracts remaining in the initiating order the PHLX XL system will initiate a Market Exhaust Timer. During the Market Exhaust Timer, the Exchange disseminates any unexecuted size of the initiating order at the "Reference Price," which is the execution price of a portion of the initiating order, or one MPV from a better-priced away market price if the Reference Price would lock the away market. The PHLX XL system currently disseminates, on the opposite side of the market from the remaining unexecuted contracts: (i) A bid price of \$0.00, with a size of zero contracts if the remaining size is a seller, or (ii) an offer price of \$0.00, with a size of zero contracts if the remaining size is a buyer. This provision is subject to the pilot. The Exchange proposes to extend the pilot through March 31, 2011.

Provisional Auction

Exchange Rule

1082(a)(ii)(B)(4)(d)(iv)(E) describes what PHLX XL does after it has explored all alternatives and there still remain unexecuted contracts. During the "Provisional Auction," any unexecuted contracts from the initiating order are displayed in the Exchange quote for the remaining size for a brief period not to exceed ten seconds and subsequently cancelled back to the entering participant if they remain unexecuted, unless the member that submitted the original order has instructed the Exchange in writing to re-enter the remaining size, in which case the remaining size will be automatically submitted as a new order. During the brief period, the PHLX XL system currently disseminates, on the opposite side of the market from remaining unexecuted contracts: (i) A bid price of \$0.00, with a size of zero contracts if the remaining size is a seller, or (ii) an offer price of \$0.00, with a size of zero contracts if the remaining size is a buyer.

Rule 1082(a)(ii)(B)(4)(d)(iv)(E) is subject to the pilot. The Exchange proposes to extend the pilot through March 31, 2011.

The Exchange believes that the pilot benefits customers and the marketplace as a whole by enabling PHLX to effectively reflect the market interest the

Exchange has that is firm and executable, while at the same time indicating the other side of the Exchange market is not firm and therefore not executable. This allows the Exchange to protect orders on its book and attempt to attract interest to execute against such order.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act¹¹ in general, and furthers the objectives of Section 6(b)(5) of the Act¹² 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 further believes that the proposal is consistent with the SEC Quote Rule's provisions regarding non-firm quotations.¹³ Specifically, Rule 602(a)(3)(i) provides that if, at any time a national securities exchange is open for trading, the exchange determines, pursuant to rules approved by the Commission, that the level of trading activities or the existence of unusual market conditions is such that the exchange is incapable of collecting, processing, and making available to vendors the data for a subject security required to be made available in a manner that accurately reflects the current state of the market on such exchange, such exchange shall immediately notify all specified persons of that determination and, upon such notification, the exchange is relieved of its obligations under paragraphs (a)(1) and (2) of Rule 602 relating to collecting and disseminating quotations, subject to certain other provisions of Rule 602(a)(3).

By disseminating a bid of \$0.00 for a size of zero contracts, or an offer of \$0.00 for a size of zero contracts in certain situations delineated above in the Exchange's rules, the Exchange believes that it is adequately communicating that it is non-firm on that side of the market in compliance with the Quote Rule.

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.

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.

II. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act¹⁴ and Rule 19b-4(f)(6)¹⁵ thereunder, the Exchange has designated this proposal as one that effects a change that: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange believes that the current pilot is "non-controversial" and therefore appropriate for filing pursuant to Rule 19b-4(f)(6).

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. Furthermore, a proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹⁶ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)¹⁷ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission notes the instant proposed rule change does not involve any substantive change to the Exchange's rules. Rather, the proposed rule change only seeks to extend the current pilot to allow time for OPRA to make technological changes that would enable OPRA to support a one-sided non-firm quote condition and allow the Exchange time to make corresponding changes to its systems. Thus, the Commission believes that the proposed rule change

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

¹³ See 17 CFR 242.602(a)(3)(i) and (ii).

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b-4(f)(6).

¹⁶ 17 CFR 240.19b-4(f)(6).

¹⁷ 17 CFR 240.19b-4(f)(6).

¹⁰ See Exchange Rule 1082(a)(ii)(B)(4)(b).

does not raise any new regulatory issues.¹⁸

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 e-mail to rule-comments@sec.gov. Please include File Number SR-Phlx-2010-156 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-2010-156. This file number should be included on the subject line if e-mail 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 a.m. and 3 p.m. Copies of such 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-2010-156 and should be submitted on or before December 20, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Elizabeth M. Murphy,
Secretary.

[FR Dqc. 2010-29907 Filed 11-26-10; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63359; File No. SR-BATS-2010-033]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by BATS Exchange, Inc. to Modify the Minor Rule Violation Plan for BATS Options

November 22, 2010.

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 November 18, 2010, 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 Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(6)(iii) thereunder,⁴ which renders it effective upon filing with the Commission. 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 is proposing to amend BATS Rule 25.3, entitled "Penalty for

Minor Rule Violations", to expand the list of violations eligible for disposition under the Exchange's Minor Rule Violation Plan ("MRVP") as it relates to the equity options platform operated by the Exchange ("BATS Options").

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, on the Commission's Web site at <http://www.sec.gov> 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.

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 amend Rule 25.3, entitled "Penalty for Minor Rule Violations", to expand the list of violations eligible for disposition under the Exchange's Minor Rule Violation Plan ("MRVP") as it relates to options in order to improve the consistency of the Exchange's MRVP with other options exchanges. All options exchanges have entered into a plan pursuant to Rule 17d-2 of the Act (the "Plan") under which the exchanges have agreed to allocate regulatory responsibility for certain rules common to all options exchanges, which Plan is administered by a committee known as the Options Surveillance Group (the "OSG"). Adding the proposed rules to the MRVP makes the Exchange's MRVP more consistent with the minor rule violation plans of other self-regulatory organizations, including with respect to rules that are classified as common rules pursuant to the Plan (the "OSG 17d-2"). The Exchange believes that its MRVP with respect to violations of rules that are common rules pursuant to the OSG 17d-2 should be consistent with the other options exchanges that are parties to the OSG 17d-2.

Consistent with the goal of improved consistency between the Exchange's

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(6)(iii).

¹⁸ For the 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. 78(c)(f).

MRVP and the MRVPs of other options exchanges, the proposed additions include Rules 18.9, 18.10, 23.1(a) through (k), 23.1(l), and 24.4, each of which is described below.

- Rule 18.9 provides that no Options Member may directly or indirectly exceed exercise limits established by the Chicago Board Options Exchange, BATS Options, or another exchange, as the limits apply to options trading on BATS Options.

- Rule 18.10 provides the requirements for accurately reporting position and account information to the Exchange.

- Rule 23.1(a) through (k) relates to expiring exercise declarations and the timely submission of "Advice Cancel" or exercise instruction relating to the exercise or non-exercise of non-cash-settled equity options.

- Rule 23.1(l) relates to the failure to submit an Exercise Advice; the submission of an advice and no subsequent exercise; the submission of an Exercise Advice after the designated cut-off time; the submission of an Exercise Advice for an amount different than the amount exercised; and the time-stamping of an advice or exercise instruction memorandum prior to purchasing contracts.

- Lastly, Rule 24.4 covers requests by the Exchange for submission of trade data.

The proposed changes would allow the Exchange to impose a fine of at least \$500 per violation of the above-listed rules, with a maximum fine amount of \$5,000. By promptly imposing a meaningful financial penalty for such violations, the MRVP focuses on correcting conduct before it gives rise to more serious enforcement action. The MRVP provides a reasonable means of addressing rule violations that do not necessarily rise to the level of requiring formal disciplinary proceedings, while also providing a greater flexibility in handling certain violations. Adopting a provision that would allow the Exchange to sanction violators under the MRVP by no means minimizes the importance of compliance with these rules. The Exchange believes that the violation of any of its rules is a serious matter. The addition of a sanction under the MRVP simply serves to add an additional method for disciplining violators of the additional rules. The Exchange will continue to conduct surveillance with due diligence and make its determination, on a case by case basis, whether a violation of these additional rules should be subject to formal disciplinary proceedings.

In addition to the changes proposed above, the Exchange proposes to modify

its MRVP sanction for a violation of Exchange position limit rules (Rule 18.7) in order to conform to the sanctions imposed by a majority of other options exchanges. The Exchange's current MRVP sanction for violations of position limits differs depending on whether a violation occurs in an Options Member's account or a customer account, a distinction not present in the rules of most other options exchanges. Furthermore, the Exchange's current MRVP sanction for violations of position limits is based on a per contract amount, whereas most options exchanges would impose a flat amount as the fine. Consistent with the other changes proposed above, the Exchange believes that conforming changes are appropriate, especially due to the fact that position limit rules are subject to the OSG 17d-2.

Finally, the Exchange also proposes modifying the headings of the sub-parts in its existing Rule 25.3 to correct typographical errors. Specifically, in each heading the "Number of Cumulative Violations Within One Period" and "Fine Amount" language is currently commingled into one heading.

2. Statutory Basis

Approval of the rule change 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.⁵ In particular, the proposed change is consistent with Section 6(b)(5) of the Act,⁶ 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, by giving the Exchange the ability to promptly impose a meaningful financial penalty for such violations before there is a need for more serious enforcement action. The Exchange believes that the proposed rule meets these requirements in that it promotes transparency and uniformity across markets concerning enforcement of common rules contained in the OSG 17d-2.

B Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

⁵ 15 U.S.C. 78f(b).

⁶ 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

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

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 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) of the Act⁷ and Rule 19b-4(f)(6)(iii) thereunder.⁸

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 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 e-mail to rule-comments@sec.gov. Please include File No. SR-BATS-2010-033 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-BATS-2010-033. This file number should be included on the subject line

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 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 Commission notes that the Exchange satisfied this five-day pre-filing requirement.

if e-mail 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 a.m. and 3 p.m. Copies of such 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 No. SR-BATS-2010-033 and should be submitted on or before December 20, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2010-29895 Filed 11-26-10; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63352; File No. SR-CBOE-2010-046]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Granting Approval of Proposed Rule Change To Amend Certain Rules Pertaining to Credit Options

November 19, 2010.

I. Introduction

On September 20, 2010, the Chicago Board Options Exchange, Incorporated ("CBOE" or "Exchange") 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 to amend its rules relating to Credit Options. The proposed rule change was published for comment in the **Federal Register** on October 7, 2010.³ The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

The Exchange proposes to amend its rules governing Credit Options⁴ to make three substantive changes. First, CBOE proposes to permit the Exchange to fix the exercise settlement value for Credit Default Options, on a class-by-class basis, at \$1 or \$100, or at a value between those two points. Currently, the exercise settlement value is fixed at \$100. Since the cash settlement amount for Credit Default Options is the product of the exercise settlement value multiplied by a contract multiplier that may be fixed by the Exchange on a class-by-class basis within a range of 1 to 1,000, this change will enable the Exchange to list a Credit Default Option contract with a cash settlement amount that could be arrived at in different ways.⁵ Second, the proposal would permit the Exchange to establish the minimum price variation ("MPV") for all Credit Options, which is currently \$0.05, on a class-by-class basis, at an increment no less than \$0.01, which would permit more pricing points, such as when lower exercise settlement values are designated. Third, the proposal would give the Exchange authority to list Credit Options that contemplate only a single credit event. Currently, CBOE rules for Credit Options enumerate several potential credit events, the occurrence of any one of which could allow the Credit Option

to be exercised. For example, a failure-to-pay default will always be a designated credit event for each class, and the Exchange may, on a class-by-class basis, specify other events of default or a restructuring.⁶ The Exchange proposes to amend its rules to permit it to list Credit Options designating a single credit event, such as a failure-to-pay default, another event of default, or a restructuring. The Exchange also proposes to make a technical, non-substantive change to one of its rules governing Credit Options, Rule 29.3.

III. Discussion and Commission's Findings

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.⁷ In particular, the Commission finds that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act,⁸ 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 foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and 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.

The Commission believes that the proposal to authorize the Exchange to list Credit Options that contemplate only a single credit event is consistent with the Act. In addition, the Commission believes that the proposal to allow the Exchange flexibility to fix the exercise settlement value for Credit Default Options within a range of \$1 to \$100 is consistent with the Act. With this change, the Exchange could list a contract with a cash settlement value of \$10,000 with a multiplier of 1,000 and an exercise settlement amount of \$10, or with a multiplier of 100 and an exercise settlement amount of \$100. There could be concerns if the Exchange were to seek to list Credit Default Options having the same cash settlement value but with different combinations of multiplier and cash settlement amount.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 63026 (October 1, 2010), 75 FR 62167 ("Notice").

⁴ Credit Options include Credit Default Options and Credit Default Basket Options. Credit Default Options are cash-settled binary options that are automatically exercised upon the occurrence of specified credit events or expire worthless. See CBOE Rule 29.1(b); Securities Exchange Act Release No. 55871 (June 6, 2007), 72 FR 32372 (June 12, 2007) (SR-CBOE-2006-84) (order approving CBOE's proposed rules to list and trade Credit Default Options). Credit Default Basket Options are cash-settled binary options based on a basket of at least two reference entities. See CBOE Rule 29.1(h); Securities Exchange Act Release No. 56275 (August 17, 2007), 72 FR 47097 (August 22, 2007) (SR-CBOE-2007-26) (order approving CBOE's proposed rules to list and trade Credit Default Basket Options).

⁵ The Exchange has represented that it will not list more than one Credit Default Option contract with a cash settlement amount arrived at in different ways. See Notice at note 8 and accompanying text.

⁶ See CBOE Rules 29.2 and 29.2A.

⁷ In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁸ 15 U.S.C. 78b(5).

⁹ 17 CFR 200.30-3(a)(12).

This could fragment the market and dilute the liquidity of economically identical products. The Exchange has represented, however, that it will not list more than one Credit Default Option contract with a cash settlement value that has been arrived at in multiple ways.⁹ The Commission's approval of this aspect of the proposal incorporates that representation.¹⁰

Finally, the Commission believes that the proposal to use an MPV of as little as \$0.01 for all Credit Options is consistent with the Act. With exercise settlement values as low as \$1, the ability to set the MPV at \$0.01 would make available 100 price points for quoting bids and offers in the range of \$0 to \$1, as opposed to only 20 price points under the current MPV of \$0.05. The CBOE has represented that it has analyzed its capacity and believes that it and the Options Price Reporting Authority have the necessary systems capacity to handle the additional traffic associated with the ability to designate \$0.01 as the MPV for Credit Options; and that the Exchange believes that the change will not lead to a proliferation of quotes and thus do not have multiple series with different strike prices, because Credit Options do not have strike prices.¹¹

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,¹² that the proposed rule change (SR-CBOE-2010-046), be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2010-29893 Filed 11-26-10; 8:45 am]
BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

⁹ See *supra* note 5.

¹⁰ The Commission also notes that the CBOE currently has the flexibility to set the exercise settlement value for binary options listed on the Exchange on a class-by-class basis. See CBOE Rule 22.1(e). See also Notice at note 9 and accompanying text.

¹¹ See Notice. The Commission also notes that the Exchange has the discretion to establish the MPV on a class-by-class basis for binary options at an increment no less than \$0.01. See CBOE Rule 22.13(b).

¹² 15 U.S.C. 78s(b)(2).

¹³ 17 CFR 200.30-3(a)(12).

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new and/or currently approved information collection.

DATES: Submit comments on or before January 28, 2011.

ADDRESSES: Send all comments regarding whether this information collection is necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collection, to Dean Koppel, Assistant Administrator, Office of Policy and Research, Small Business Administration, 409 3rd Street, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Dean Koppel, Assistant Administrator, Office of Policy and Research, 202-205-7332, dean.koppel@sba.gov Curtis B. Rich, Management Analyst, 202-205-7030 curtis.rich@sba.gov.

SUPPLEMENTARY INFORMATION: A small business determined to be non responsible for award of a specific prime Government contract by a Government contracting office has the right to appeal that decision through the Small Business Administration (SBA). The information contained on this form, as well as, other information developed by SBA, is used in the evaluation process.

Title: "SBA Application for Certificate of Competency."

Description of Respondents: Prime Government Contractors.

Form Number: 1531.

Annual Responses: 275.

Annual Burden: 2,200.

Jacqueline White,
Chief, Administrative Information Branch.

[FR Doc. 2010-29946 Filed 11-26-10; 8:45 am]
BILLING CODE 8025-01-P

DEPARTMENT OF STATE

[Public Notice: 4728]

The Amended Designation of Lashkar-e-Tayyiba (LT, LeT), aka Lashkar-e-Toiba, aka Lashkar-i-Taiba, aka al Mansoorian, aka al Mansooreen, aka Army of the Pure, aka Army of the Righteous, aka Army of the Pure and Righteous as a Foreign Terrorist Organization pursuant to Section 219(b) of the Immigration and Nationality Act

Based upon a review of the administrative record assembled in this matter, and in consultation with the

Attorney General and the Secretary of the Treasury, the Secretary of State has concluded that there is a sufficient factual basis to find that Lashkar-e-Tayyiba, also known under the aliases listed above, uses or has used additional aliases, namely, Falah-I-Insaniat Foundation, FiF, Falah-e-Insaniat Foundation, Falah-e-Insaniyat, Falah-i-Insaniyat, Falah Insania, Welfare of Humanity, Humanitarian Welfare Foundation. Human Welfare Foundation.

Therefore, effective upon the date of publication in the **Federal Register**, the Secretary of State hereby amends the 2003 redesignation of Lashkar-e-Tayyiba as a foreign terrorist organization, pursuant to § 219(b) of the INA (8 U.S.C. 1189(b)), to include the following new aliases and other possible transliterations thereof: Falah-I-Insaniat Foundation, FiF, Falah-e-Insaniat Foundation, Falah-e-Insaniyat, Falah-i-Insaniyat, Falah Insania, Welfare of Humanity, Humanitarian Welfare Foundation, Human Welfare Foundation.

Dated: September 28, 2010.

Hillary Rodham Clinton,
Secretary of State.

[FR Doc. 2010-29807 Filed 11-26-10; 8:45 am]
BILLING CODE 4710-10-P

DEPARTMENT OF STATE

[Public Notice 7249]

Bureau of Western Hemisphere Affairs; Executive Order 11423, as Amended; Notice of Receipt of Application for a Presidential Permit To Renovate and Expand the San Ysidro Land Port of Entry on the U.S.-Mexico Border at San Diego, CA and Tijuana, Baja CA, Mexico

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State hereby gives notice that, on November 10, 2010, it received an application for a Presidential Permit to authorize the renovation and expansion of the San Ysidro border crossing facility on the U.S.-Mexico border at San Diego, California and Tijuana, Baja California; Mexico. The General Services Administration (GSA) filed this application and is acting as the project's sponsor. The Department of State's jurisdiction over this application is based upon Executive Order 11423 of August 16, 1968, as amended. As provided in E.O. 11423, the Department is circulating this application to relevant federal and state agencies for review and

comment. Under E.O. 11423, the Department has the responsibility to determine, taking into account input from these agencies and other stakeholders, whether this proposed border crossing is in the U.S. national interest.

DATES: Interested members of the public are invited to submit written comments regarding this application on or before February 28, 2011 to Mr. Stewart Tuttle, U.S.-Mexico Border Affairs Coordinator, via e-mail at WHA-BorderAffairs@state.gov or by mail at WHA/MEX—Room 3908, Department of State, 2201 C St. NW., Washington, DC 20520.

FOR FURTHER INFORMATION CONTACT: Mr. Stewart Tuttle, U.S.-Mexico Border Affairs Coordinator, via e-mail at WHA-BorderAffairs@state.gov; by phone at 202-647-6356; or by mail at WHA/MEX—Room 3908, Department of State, 2201 C St. NW., Washington, DC 20520. General information about Presidential Permits is available on the Internet at <http://www.state.gov/p/whu/rt/permit/>.

SUPPLEMENTARY INFORMATION: This application and related environmental assessment documents are available for review in the Office of Mexican Affairs, Border Affairs Unit, Department of State, during normal business hours.

Dated: 11-19-2010.

Edward Alexander Lee,
Director, Office of Mexican Affairs,
Department of State.

[FR Doc. 2010-29873 Filed 11-26-10; 8:45 am]
BILLING CODE 4710-10-P

DEPARTMENT OF STATE

[Public Notice: 7247]

The Designation of Falah-i-Insaniat (and Other Aliases) as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, Executive Order 13284 of January 23, 2003, and Executive Order 13372 of February 16, 2005, I hereby determine that the organization known as Falah-i-Insaniat (and other aliases) has committed, or poses 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.

Consistent with the determination in section 10 of Executive Order 13224 that

“for those persons * * * determined to be subject to the order who might have a constitutional presence in the United States * * * prior notice to such persons of measures to be taken pursuant to this order would render these measures ineffectual,” I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: September 28, 2010.

Hillary Rodham Clinton,
Secretary of State, Department of State.
[FR Doc. 2010-29872 Filed 11-26-10; 8:45 am]
BILLING CODE 4710-10-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Certification: Mechanics, Repairmen, and Parachute Riggers, FAR 65

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 27, 2010, vol. 75, no. 166, page 52802. FAR part 65 prescribes requirements for mechanics, repairmen, parachute riggers, and inspection authorizations. The information collected shows applicant eligibility for certification.

DATES: Written comments should be submitted by December 29, 2010.

FOR FURTHER INFORMATION CONTACT: Carla Scott on (202) 267-9895, or by e-mail at: Carla.Scott@faa.gov.

SUPPLEMENTARY INFORMATION: OMB Control Number: 2120-0022.

Title: Certification: Mechanics, Repairmen, and Parachute Riggers, FAR 65.

Form Numbers: FAA Forms 8610-1, 8610-2.

Type of Review: Renewal of an information collection.

Background: FAR Part 65 prescribes, among other things, rules governing the issuance of certificates and associated rating for mechanic, repairman, parachute riggers, and issuance of inspection authorizations. The information collected on the forms submitted for renewal is used for evaluation by the FAA, which is necessary for issuing a certificate and/or rating. Certification is necessary to ensure qualifications of the applicant.

Respondents: An estimated 66,153 mechanics, repairmen, and parachute riggers.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 20 minutes.

Estimated Total Annual Burden: 44,841 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to oir_submission@omb.eop.gov, or faxed to (202) 395-6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC on November 19, 2010.

Carla Scott,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES-200.

[FR Doc. 2010-29900 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****Executive Committee of the Aviation Rulemaking Advisory Committee; Meeting**

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Executive Committee of the Aviation Rulemaking Advisory Committee.

DATES: The meeting will be held on December 16, 2010, at 10 a.m.

ADDRESSES: The meeting will take place at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, 10th floor, MacCracken Room.

FOR FURTHER INFORMATION CONTACT: Renee Butner, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267-5093; fax (202) 267-5075; e-mail Renee.Butner@faa.gov.

SUPPLEMENTARY INFORMATION: Under section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), we are giving notice of a meeting of the Executive Committee of the Aviation Rulemaking Advisory Committee taking place on December 16, 2010, at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC, 20591. The Agenda includes:

1. Updates on:
 - a. Commercial Air Tour Maintenance (CATM) Working Group
 - b. Process Improvement Working Group (PIWG)
 - c. Charter Renewal
 - d. "One Stop Shopping" Web Site
 - e. Committee Manual Revisions
2. Issue Area Status Reports from Assistant Chairs
3. Remarks from other EXCOM members

Attendance is open to the interested public but limited to the space available. The FAA will arrange teleconference service for individuals wishing to join in by teleconference if we receive notice by December 7. Arrangements to participate by teleconference can be made by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Callers outside the Washington metropolitan area are responsible for paying long-distance charges.

The public must arrange by December 7 to present oral statements at the meeting. The public may present written statements to the executive committee by providing 25 copies to the

Executive Director, or by bringing the copies to the meeting.

If you are in need of assistance or require a reasonable accommodation for this meeting, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Washington, DC on November 22, 2010.

Dennis Pratte,

Acting Deputy Director, Office of Rulemaking.

[FR Doc. 2010-29922 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Railroad Administration**

[Docket No. FRA-2000-7257; Notice No. 64]

Railroad Safety Advisory Committee; Notice of Meeting

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Announcement of Railroad Safety Advisory Committee (RSAC) Meeting.

SUMMARY: FRA announces the forty-third meeting of the RSAC, a Federal advisory committee that develops railroad safety regulations through a consensus process. The RSAC meeting topics will include opening remarks from the FRA Administrator, and status reports will be provided by the Passenger Hours of Service, Training Standards, Track Safety Standards, Passenger Safety, and Medical Standards Working Groups. Further discussions will also be held on the previously accepted RSAC Task 10-02 regarding the Development, Use, and Implementation of Rail Safety Technology in Dark Territory. This agenda is subject to change, including the possible addition of further proposed tasks under the Rail Safety Improvement Act of 2008.

DATES: The meeting of the RSAC is scheduled to commence at 9:30 a.m. on Tuesday, December 14, 2010, and will adjourn by 4:30 p.m.

ADDRESSES: The RSAC meeting will be held at the National Association of Home Builders National Housing Center, 1201 15th Street, NW., Washington, DC 20005. The meeting is open to the public on a first-come, first-served basis, and is accessible to individuals with disabilities. Sign and oral interpretation can be made available if requested 10 calendar days before the meeting.

FOR FURTHER INFORMATION CONTACT: Larry Woolverton, RSAC Administrative

Officer/Coordinator, FRA, 1200 New Jersey Avenue, SE., Mailstop 25, Washington, DC 20590, (202) 493-6212; or Robert Lauby, Deputy Associate Administrator for Regulatory and Legislative Operations, FRA, 1200 New Jersey Avenue, SE., Mailstop 25, Washington, DC 20590, (202) 493-6474.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), FRA is giving notice of a meeting of the RSAC. The RSAC was established to provide advice and recommendations to FRA on railroad safety matters. The RSAC is composed of 54 voting representatives from 31 member organizations, representing various rail industry perspectives. In addition, there are non-voting advisory representatives from the agencies with railroad safety regulatory responsibility in Canada and Mexico, the National Transportation Safety Board, and the Federal Transit Administration. The diversity of the Committee ensures the requisite range of views and expertise necessary to discharge its responsibilities. See the RSAC Web site for details on prior RSAC activities and pending tasks at: <http://rsac.fra.dot.gov/>. Please refer to the notice published in the **Federal Register** on March 11, 1996 (61 FR 9740), for additional information about the RSAC.

Issued in Washington, DC, on November 22, 2010.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2010-29870 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION**Federal Railroad Administration**

[Docket Number FRA-2010-0027]

Notice of Petition for Waiver of Compliance; Notice of Petition for Statutory Exemption

In accordance with 49 U.S.C. 21102(b), Cargill Incorporated (CI), on behalf of its employees performing work governed by the hours of service law (HSL) (49 U.S.C. Chapter 211) at its Channelview, TX, facility, has petitioned the Federal Railroad Administration (FRA) for an exemption from certain provisions of the HSL. Specifically, CI requests an exemption from the requirements of 49 U.S.C. 21103(a)(1) and 21103(a)(4) as it applies to employees at its Channelview facility. In a separate petition, which CI requests that FRA consider in the event that FRA

denies its exemption petition, CI seeks a waiver from the requirements of 49 U.S.C. 21103(a)(1) as it applies to employees performing covered service at its Channelview facility, for the purpose of conducting a pilot project. Both petitions may be viewed at <http://www.regulations.gov> under the docket number listed above.

CI's Petition for Statutory Exemption

In its petition for statutory exemption, CI seeks an exemption from the statutory requirement contained in 49 U.S.C. 21103(a)(1), limiting train employees to a total of 276 on-duty hours per calendar month, awaiting or in deadhead transportation from a duty assignment to a place of final release, and in any other mandatory service for a railroad carrier, and from 49 U.S.C. 21103(a)(4), which requires railroads to provide train employees 48 hours of rest after an employee has initiated an on-duty period on 6 consecutive days and 72 hours of rest after an employee has initiated an on-duty period on 7 consecutive days. In support of its exemption request, CI states that its Channelview facility has 15 or fewer employees covered by the HSL and that the facility is operated independently of other CI facilities. CI further explains that its employees subject to the HSL spend the majority of their on-duty time performing non-covered service (e.g., unloading grain from stationary railcars, general housekeeping duties in accordance with the Occupational Safety and Health Administration's combustible dust standards) and that covered service accounts for less than 12 percent of covered employees' monthly hours worked. CI also explains that with certain seasonal exceptions, employees at its Channelview facility generally work in two shifts that rotate every 2 weeks; from 7 a.m.–3 p.m. and from 3 p.m.–11 p.m. (extended to 3 a.m. if needed). CI asserts that the employees' current work schedules ensure safe operations by providing the employees greater control over rest periods and the scheduling of personal affairs and that the statutory restrictions of 49 U.S.C. 21103(a)(1) and 21103(a)(4) unnecessarily lower the earning potential of employees subject to the HSL as compared to other workers at the facility.

CI's Petition for Waiver

In its petition for waiver, in lieu of using a calendar month for measuring the on-duty hours of an employee pursuant to 49 U.S.C. 21103(a)(1), CI proposes to implement a pilot program for establishing an alternative calculation period for the 276-hour

monthly limitation. CI and its employees propose a pilot program that would divide a "calendar month" into two measuring periods or groups. The first group would calculate its time toward the 276-hour monthly limitation from the first day of each month to the last day of each month. The second group would calculate its time toward the 276-hour monthly limitation from the 15th day of a month to the 14th day of the following month. By staggering the calculation of the 276-hour monthly limitation, CI notes that the pilot program would ensure that not all employees reach the monthly limitation at the same time.

CI included with its petitions, documentation indicating that its employees supported the request for relief. (49 U.S.C. 21103(a)(1) and 21103(a)(4)). As previously stated, the requests for relief are specially limited to CI's Channelview, TX, facility and, as such, the other facilities of CI are not covered by the requests.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA-2010-0027) and may be submitted by any of the following methods:

- *Web site:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12-140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet

at the docket facility's Web site at <http://www.regulations.gov>.

Anyone is able to search the electronic form of any written communications and 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 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC, on November 22, 2010.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

{FR Doc. 2010-29826 Filed 11-26-10; 8:45 am}

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2010-0153; Notice 1]

Continental Tire North America, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

Continental Tire North America, Inc., (Continental),¹ has determined that certain passenger car replacement tires manufactured in 2009 do not fully comply with paragraph S5.5(b) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles*. Continental has filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports*, dated August 10, 2010.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Continental has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Continental's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Affected are approximately 17,121 size 235/45ZR17 94W Continental brand Extremecontact DWS model passenger car tires manufactured from March 2009

¹Continental Tire North America Inc. (Continental) is a replacement equipment manufacturer and importer that is incorporated in the State of Ohio.

to October 2009 at Continental's plant located in Camaçari- BA, Brasil. A total of approximately 16,325 of these tires have been delivered to Continental's customers in the United States and Canada.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, these provisions only apply to the 16,325² tires that have already passed from the manufacturer to an owner, purchaser, or dealer.

Paragraph S5.5(b) of FMVSS No. 139 requires in pertinent part:

S5.5 Tire markings. Except as specified in paragraphs (a) through (i) of S5.5, each tire must be marked on each sidewall with the information specified in S5.5(a) through (d) and on one sidewall with the information specified in S5.5(e) through (i) according to the phase-in schedule specified in S7 of this standard. The markings must be placed between the maximum section width and the bead on at least one sidewall, unless the maximum section width of the tire is located in an area that is not more than one-fourth of the distance from the bead to the shoulder of the tire. If the maximum section width falls within that area, those markings must appear between the bead and a point one-half the distance from the bead to the shoulder of the tire, on at least one sidewall. The markings must be in letters and numerals not less than 0.078 inches high and raised above or sunk below the tire surface not less than 0.015 inches* * *

(b) The tire size designation as listed in the documents and publications specified in S4.1.1 of this standard;

Continental explains that the noncompliance is that, due to a mold labeling error, the sidewall marking on the reference side of the tires incorrectly identifies the tire size code as "658R 3VR" when in fact it should be identified as "658P 3VR" in the tread

² Continental's petition, which was filed under 49 CFR Part 556, requests an agency decision to exempt Continental as a replacement equipment manufacturer from the notification and recall responsibilities of 49 CFR Part 573 for the 16,325 tires that were delivered to its customers in the United States. However, the agency cannot relieve Continental distributors of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after Continental recognized that the subject noncompliance existed. Those tires must be brought into conformance, exported, or destroyed. In addition, any of the affected tires that Continental has not delivered to its customers must be brought into compliance, exported or destroyed.

area of the tires as required by paragraph S5.5(b).

Continental also explains that while the non-compliant tires are mislabeled, all of the tires included in this petition meet or exceed the performance requirements of FMVSS No. 139.

Continental argues that this noncompliance is inconsequential to motor vehicle safety because the noncompliant sidewall marking does not create an unsafe condition and all other labeling requirements have been met.

Continental points out that NHTSA has previously granted similar petitions for non-compliances in sidewall marking.

Continental additionally states that it has corrected the affected tire molds and all future production will have the correct material shown on the sidewall.

In summation, Continental believes that the described noncompliance of its tires to meet the requirements of FMVSS No. 139 is inconsequential to motor vehicle safety, and that its petition, to exempt from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance.

Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. *By mail addressed to:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

b. *By hand delivery to U.S.* Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. *Electronically:* By logging onto the Federal Docket Management System (FDMS) Web site at <http://www.regulations.gov/>. Follow the online

instructions for submitting comments. Comments may also be faxed to 1-202-493-2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at <http://www.regulations.gov> by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477-78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: December 29, 2010.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at CFR 1.50 and 501.8.

Issued on: November 19, 2010.

Claude H. Harris,
Acting Associate Administrator for Enforcement.

[FR Doc. 2010-29879 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2010-0354]

Pipeline Safety: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration, DOT.
ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995,

PHMSA invites comments on an information collection under Office of Management and Budget (OMB) Control No. 2137-0578, titled "Reporting Safety-Related Conditions on Gas, Hazardous Liquid, and Carbon Dioxide Pipelines and Liquefied Natural Gas Facilities." PHMSA is preparing to request approval from OMB for a renewal of the current information collection.

DATES: Interested persons are invited to submit comments on or before January 28, 2011.

ADDRESSES: Comments may be submitted in the following ways:

E-Gov Web Site: <http://www.regulations.gov>. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.

Fax: 1-202-493-2251.

Mail: Docket Management Facility; U.S. DOT, 1200 New Jersey Avenue, SE., West Building, Room W12-140, Washington, DC 20590-0001.

Hand Delivery: 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.

Instructions: Identify the docket number, PHMSA-2010-0354, at the beginning of your comments. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. You should know that 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.). Therefore, you may want to review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477) or visit <http://www.regulations.gov> before submitting any such comments.

Docket: For access to the docket or to read background documents or comments, go to <http://www.regulations.gov> at any time or to 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. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: "Comments on PHMSA-2010-0354."

The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to delays in the delivery of U.S. mail to

Federal offices in Washington, DC, we recommend that persons consider an alternative method (Internet, fax, or professional delivery service) of submitting comments to the docket and ensuring their timely receipt at DOT.

FOR FURTHER INFORMATION CONTACT: Cameron Satterthwaite by telephone at 202-366-1319, by fax at 202-366-4566, or by mail at U.S. DOT, PHMSA, 1200 New Jersey Avenue, SE., PHP-30, Washington, DC 20590-0001.

SUPPLEMENTARY INFORMATION: Section 1320.8(d), Title 5, Code of Federal Regulations requires PHMSA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies an information collection request that PHMSA will be submitting to OMB for renewal and extension. The information collection expires February 28, 2011, and is identified under Control No. 2137-0578, titled: "Reporting Safety-Related Conditions on Gas, Hazardous Liquid, and Carbon Dioxide Pipelines and Liquefied Natural Gas Facilities." The Pipeline Safety Laws (49 U.S.C. 60132) require each operator of a pipeline facility (except master meter operators) to submit to DOT a written report on any safety-related condition that causes or has caused a significant change or restriction in the operation of a pipeline facility or a condition that is a hazard to life, property or the environment. The following information is provided for this information collection: (1) Title of the information collection; (2) OMB control number; (3) Type of request; (4) Abstract of the information collection activity; (5) Description of affected public; (6) Estimate of total annual reporting and recordkeeping burden; and (7) Frequency of collection. PHMSA will request a three-year term of approval for this information collection activity.

PHMSA requests comments on the following information collection:

Title: Reporting Safety-Related Conditions on Gas, Hazardous Liquid, and Carbon Dioxide Pipelines and Liquefied Natural Gas Facilities.

OMB Control Number: 2137-0578.

Type of Request: Renewal of a currently approved information collection.

Abstract: Each operator of a pipeline facility (except master meter operators) must submit to DOT a written report on any safety-related condition that causes or has caused a significant change or restriction in the operation of a pipeline facility or a condition that is a hazard to life, property or the environment.

Affected Public: Operators of pipeline facilities (except master meter operators).

Estimated number of responses: 142.
Estimated annual burden hours: 852 hours.

Frequency of collection: On occasion. Comments are invited on:

(a) The need for the proposed collection of information 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 the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Issued in Washington, DC on November 23, 2010.

Linda Daugherty,

Deputy Associate Administrator for Policy and Programs.

[FR Doc. 2010-29960 Filed 11-26-10; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 384 (Sub-No. 2X)]

Delta Southern Railroad, Inc.— Abandonment Exemption—In East Carroll Parish, LA

Delta Southern Railroad, Inc. (DSR) filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments* to abandon 8 miles of rail line extending from milepost 463.0, near Shelburn, to milepost 471.0, which is approximately a mile south of Lake Providence, in East Carroll Parish, La.¹ The line traverses United States Postal Service Zip Code 71254.

DSR has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line to be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or

¹ On November 16, 2010, DSR supplemented its notice of exemption.

with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on December 29, 2010, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,² formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),³ and trail use/rail banking requests under 49 CFR 1152.29 must be filed by December 9, 2010. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by December 20, 2010, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423-0001.

A copy of any petition filed with the Board should be sent to DSR's representative: Thomas F. McFarland, P.C., 208 South LaSalle Street, Suite 1890, Chicago, IL 60604-1112.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

DSR has filed a combined environmental and historic report which addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by December 3, 2010. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423-0001) or by calling OEA, at (202)

² The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

³ Each OFA must be accompanied by the filing fee, which is currently set at \$1,500. See 49 CFR 1002.2(f)(25).

245-0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1-800-877-8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), DSR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by DSR's filing of a notice of consummation by November 29, 2011, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at <http://www.stb.dot.gov>.

Decided: November 22, 2010.

By the Board.

Rachel D. Campbell,
Director, Office of Proceedings.
Andrea Pope-Matheson,
Clearance Clerk.

[FR Doc. 2010-29834 Filed 11-26-10; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 19, 2010.

The Department of the Treasury will submit the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13 on or after the date of publication of this notice. A copy of the submissions may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

DATES: Written comments should be received on or before December 29, 2010 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545-1614.
Type of Review: Extension without change to a currently approved collection.

Title: REG-106177-97 (NPRM) Qualified State Tuition Programs.

Abstract: Respondents are States and eligible educational institutions that establish and maintain qualified State tuition programs. Respondents include distributors who receive benefits under the programs. Information verifies that programs are qualified and that distribution are used for qualified educational expenses.

Respondents: State, Local, and Tribal Governments.

Estimated Total Burden Hours: 4,258,260 hours.

OMB Number: 1545-21.75.

Type of Review: Extension without change to a currently approved collection.

Title: Form 8942—Application for Certification of Qualified Investments Eligible for Credits; Notice 2010-45—Qualifying Therapeutic Discovery Project Credit.

Abstract: On March 23, 2010, the President signed the Patient Protection and Affordable Care Act (Act) (Pub. L. 111-148). Section 9023(a) of the Act adds section 48D to the Internal Revenue Code. Section 48D provides a 50-percent nonrefundable investment tax credit, and corresponding grant in lieu of a tax credit, for qualified investments in qualifying therapeutic discovery projects. The credit and grant are designed to encourage investments in new therapies relating to diseases. Form 8942 will be used to apply for certification and credit.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 14,545 hours.

OMB Number: 1545-0029.

Type of Review: Extension without change of a currently approved collection.

Title: Employer's Quarterly Federal Tax Return.

Form: 941 series and schedules.

Abstract: Form 941 is used by employers to report payments made to employees subject to income and social security/Medicare taxes and the amounts of these taxes. Form 941-PR is used by employers in Puerto Rico to report social security and Medicare taxes only. Form 941-SS is used by employers in the U.S. possessions to report social security and Medicare taxes only. Schedule B is used by employers to record their employment tax liability.

Respondents: Private sector; Businesses or other for-profits.

Estimated Total Burden Hours: 388,256,964 hours.

OMB Number: 1545-2173.

Type of Review: Extension without change to a currently approved collection.

Title: Hiring Incentives to Restore Employment (HIRE) Act Employee Affidavit.

Abstract: This form was created in response to the Hiring Incentives to Restore Employment (HIRE) Act, which was signed on March 18, 2010. The form was developed as a template for the convenience of employers who must collect affidavits from qualifying employees. The form is not filed, rather an employer must retain the affidavit in order to justify claiming certain HIRE Act benefits. A model form is needed as soon as possible so that employers can begin confidently claiming payroll exemptions. The useful life of the form is only from March 18, 2010 to December 31, 2010.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 227,000 hours.

OMB Number: 1545-2174.

Type of Review: Extension without change to a currently approved collection.

Title: Form 14134, Application for Certificate of Subordination of Federal Tax Lien, and Form 14135, Application for Certificate of Discharge of Property from Federal Tax Lien.

Form: 14134, 14135.

Abstract: The collection of information is required by 26 CFR 301.6325-1(b)(5) for consideration of the United States discharging property from the Federal tax lien and is required by 26 CFR 301.6325-1(d)(4) for consideration that the United States subordinate its interest in property. These forms will provide guidance to ensure proper documentation is submitted to the Agency.

Respondents: Businesses or other for-profits, farms, not-for-profit institutions.

Estimated Total Burden Hours: 22,665 hours.

OMB Number: 1545-2090.

Type of Review: Extension without change to a currently approved collection.

Title: REG-143797-06 (Final), Health Savings Plan Notice.

Abstract: The information is needed in cases where an employee establishes an HSA after the end of the calendar year but before the last day of February and will be used by employees for purposes of making up HSA contributions to those employees. The respondents are employees of employers who contribute to employees' HSAs.

Respondents: Businesses or other for-profits and not-for-profit institutions.

Estimated Total Burden Hours: 1,250,000 hours.

OMB Number: 1545-1892.

Type of Review: Extension without change to a currently approved collection.

Title: REG-153841-02 (TD 9208) (Final), Election Out of GST Deemed Allocations.

Abstract: The information collected will be used by the IRS to identify the trusts to which the election or termination of election will apply. The collection of information in this proposed regulation is in sections 26.2632-1(b)(2)(ii), 26.2632-1(b)(2)(iii), and 26.2632-1(b)(2). This information is required by the IRS for taxpayers who elect to have the automatic allocation rules not apply to the current transfer and/or to future transfers to the trust or to terminate such election. This information is also required by the IRS for taxpayers who elect to treat trusts described in section 2632(c)(3)(B)(i) through (vi) as GST trusts or to terminate such election.

Respondents: Individuals or households.

Estimated Total Burden Hours: 12,500 hours.

OMB Number: 1545-1430.

Type of Review: Extension without change to a currently approved collection.

Title: Form 945 and 945V: Annual Return of Withheld Federal Income Tax/Voucher; Form 945-A: Annual Record of Federal Tax Liability; Form 945-X: Annual Return of Withheld Federal Income Tax, Claim, Refund.

Form: 945, 945V, 945-X.

Abstract: Form 945 is used to report income tax withholding on nonpayroll payments including backup withholding and withholding on pensions, annuities, IRA's military retirement and gambling winnings. Form 945-V, Payment Voucher, is used if you are making a payment with Form 945, Annual Return of Withheld Federal Income Tax. Form 945-A is used to report nonpayroll tax liabilities. Form 945-X is used to correct errors made on Form 945, Annual Return of Withheld Federal Income Tax, for one year only.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 3,596,690 hours.

OMB Number: 1545-1081.

Type of Review: Extension without change to a currently approved collection.

Title: Application for Extension of Time to File Information Returns.

Form: 8809.

Abstract: Form 8809 is used to request an extension of time to file Forms W-2, W-2G, 1042-S, 1097, 1098, 1099, 3921, 3922, 5498, and 8027. The IRS reviews the information contained on

the form to determine whether an extension should be granted.

Respondents: Businesses or other for-profits, farms, not-for-profit institutions.

Estimated Total Burden Hours: 192,000 hours.

OMB Number: 1545-0985.

Type of Review: Extension without change to a currently approved collection.

Title: PS-128-86, PS-127-86, and PS-73-88 (Final)(TD 8644) Generation-Skipping Transfer Tax.

Abstract: This regulation provides rules relating to the effective date, return requirements, definitions, and certain special rules covering the generation-skipping transfer tax. The information required by the regulation will require individuals and/or fiduciaries to report information on Form 706NA, 706, 706GS (D), 706GS(D-1), 706GS(T), 709 and 843 in connection with the generation skipping transfer tax. The information will facilitate the assessment of the tax and taxpayer examinations.

Respondents: Individuals or households.

Estimated Total Burden Hours: 3,750 hours.

Bureau Clearance Officer: Allan M. Hopkins, Internal Revenue Service, 1111 Constitution Avenue, NW., Room 6129, Washington, DC 20224; (202) 622-3634.

OMB Reviewer: Shagufia Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395-7873.

Celina Elphage,

Treasury PRA Clearance Officer.

[FR Doc. 2010-29829 Filed 11-26-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 23, 2010.

The Department of the Treasury will submit the following public information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13 on or after the date of publication of this notice. A copy of the submission may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

DATES: Written comments should be received on or before December 29, 2010 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545-0199.

Type of Review: Extension without change to a currently approved collection.

Title: Application for Approval of Prototype Simplified Employee Pension (SEP) or Savings Incentive Match Plan for Employees of Small Employers (SIMPLE IRA Plan).

Form: 5306-A.

Abstract: This form is used by banks, credit unions, insurance companies, and trade or professional associations to apply for approval of a Simplified Employee Pension Plan or Savings Incentive Match Plan to be used by more than one employer. The data collected is used to determine if the prototype plan submitted is an approved plan.

Respondents: Private sector: Businesses or other for-profits.

Estimated Total Burden Hours: 94,400 hours.

Bureau Clearance Officer: Allan Hopkins, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224; (202) 622-6665.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395-7873.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2010-29931 Filed 11-26-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 22, 2010.

The Department of the Treasury will submit the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13 on or after the date of publication of this notice. A copy of the submissions may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

DATES: Written comments should be received on or before December 29, 2010.

Internal Revenue Service (IRS)

OMB Number: 1545-0035.

Type of Review: Extension without change to a currently approved collection.

Title: Employer's Annual Tax Return for Agricultural Employees.

Form: 943, 943-PR, 943-A, 943A-PR, 943-X, 943 X-PR.

Abstract: Sections 3101(a) and (b), and 3111(a) and (b), 3402(p), and 6011(a) and (b) of the Internal Revenue Code and sections 31.6011(a)-1 and 31.6011(a)-4 of the Employment Tax Regulations require agricultural employers to report (a) The employees' and employers' FICA taxes on wages and (b) the amounts withheld for income tax. Form 943 is used for this purpose. Sections 3101(a) and (b), 3111(a) and (b), and 6011(a) and (b) of the Internal Revenue Code and section 31.6011(a)-1 of the Employment Tax Regulations require agricultural employers in Puerto Rico to report the employees' and employers' FICA taxes on wages. Form 943-PR is used for this purpose. Section 6302(c) of the Internal Revenue Code and section 31.6302-l(g) of the Employment Tax Regulations require agricultural employers who are semiweekly depositors to deposit the taxes accumulated during the semiweekly period within 3 banking days of the end of the period. Section 31.6302-l(c)(3) of the Employment Tax Regulations requires that agricultural employers, who on any day within a deposit period accumulate \$100,000 or more of employment taxes, must deposit them by the close of the next banking day. Forms 943-A and 943A-PR are optional forms that may be used by agricultural employers to show their tax liabilities for the semiweekly periods and \$100,000 one-day rule. Form 943-X is used to correct errors made on Form 943, Employer's Annual Federal Tax Return for Agricultural Employees, for one year only. Form 943-X-PR, for use in Puerto Rico, is used to correct errors made on Form 943, Employer's Annual Federal Tax Return for Agricultural Employees, for one year only.

Respondents: Businesses or other for-profits and Farms.

Estimated Total Burden Hours: 10,880,812 hours.

Bureau Clearance Officer: Allan M. Hopkins, Internal Revenue Service, 1111 Constitution Avenue, NW., Room 6129, Washington, DC 20224; (202) 622-3634.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New

Executive Office Building, Room 10235, Washington, DC 20503; (202) 395-7873.

Celina Elphage,

Treasury PRA Clearance Officer.

[FR Doc. 2010-29930 Filed 11-26-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 22, 2010.

The Department of the Treasury will submit the following public information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13 on or after the date of publication of this notice. A copy of the submission may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

DATES: Written comments should be received on or before December 29, 2010 to be assured of consideration.

Bureau of the Public Debt (BPD)

OMB Number: 1535-0122.

Type of Review: Extension without change of a currently approved collection.

Title: Voluntary Customer Satisfaction Survey To Implement Executive Order 12862.

Abstract: Voluntary surveys to determine customer satisfaction with BPD products and services.

Respondents: Individuals and Households.

Estimated Total Burden Hours: 876 hours.

Bureau Clearance Officer: Bruce Sharp, Bureau of the Public Debt, 200 Third Street, Parkersburg, West Virginia 26106; (304) 480-8112.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395-7873.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. 2010-29926 Filed 11-26-10; 8:45 am]

BILLING CODE 4810-39-P

DEPARTMENT OF THE TREASURY**Alcohol and Tobacco Tax and Trade Bureau****Proposed Information Collections; Comment Request**

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the proposed or continuing information collections listed below in this notice.

DATES: We must receive your written comments on or before January 28, 2011.

ADDRESSES: You may send comments to Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, at any of these addresses:

- P.O. Box 14412, Washington, DC 20044-4412;
- 202-453-2686 (facsimile); or
- formcomments@ttb.gov (e-mail).

Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form or recordkeeping requirement number, and OMB number (if any) in your comment. If you submit your comment via facsimile, send no more than five 8.5 x 11 inch pages in order to ensure electronic access to our equipment.

FOR FURTHER INFORMATION CONTACT: To obtain additional information, copies of the information collection and its instructions, or copies of any comments received, contact Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412; or telephone 202-453-2265.

SUPPLEMENTARY INFORMATION:**Request for Comments**

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this notice will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information

collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether this information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection's burden 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 the requested information.

Information Collections Open for Comment

Currently, we are seeking comments on the following forms and recordkeeping requirements:

Title: Notice of Change in Status of Plant.

OMB Control Number: 1513-0044.

TTB Form Numbers: 5110.34.

Abstract: TTB F 5110.34 is necessary to show the use of the distilled spirits plant (DSP) premises for other activities or by alternating proprietors. It describes proprietor's use of plant premises and other information to show that the change in plant status is in conformity with law and regulations. It also shows what bond covers the activities of the DSP at a given time.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 100.

Estimated Total Annual Burden Hours: 1,000.

Title: Tax Deferral Bond—Distilled Spirits (Puerto Rico).

OMB Control Number: 1513-0050.

TTB Form Number: 5110.50.

Abstract: TTB F 5110.50 is the bond to secure payment of excise taxes on distilled spirits shipped from Puerto Rico to the U.S. on deferral of the tax. The form identifies the principal, the surety, purpose of bond, and allocation of the penal sum among the principal's locations.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 10.

Estimated Total Annual Burden Hours: 10.

Title: Tobacco Products Manufacturers—Supporting Records for Removal for the Use of the United States.

OMB Number: 1513-0069.

TTB Recordkeeping Requirement Number: 5210/6.

Abstract: Tobacco products have historically been a major source of excise tax revenues for the Federal Government. In order to safeguard these taxes, tobacco products manufacturers are required to maintain a system of records designed to establish accountability over the tobacco products and cigarette papers and tubes produced. However, these items can be removed without the payment of tax if they are for the use of the United States. Records must be retained by the manufacturer for 3 years following the close of the year covered therein and must be made available for inspection by any TTB officer upon his/her request.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 101.

Estimated Total Annual Burden Hours: 505.

Titles: Statement of Ultimate Vendor. Exemption Certificate (Use on Certain Vessels or Aircraft).

Exemption Certificate (Use by State or local Governments).

Statement of Manufacturer's Vendee (For Export).

Statement of Manufacturer's Vendee (Use in Further Manufacture).

OMB Control Number: 1513-0128.

TTB Form Numbers: 5600.33, 5600.34, 5600.35, 5600.36, 5600.37, respectively.

Abstract: Title 27, CFR, part 53 requires that, in some cases, persons who sell firearms or ammunition tax-free use specific exemption certificates

or statements to support the tax-free sales. In addition, 27 CFR part 53 requires a specific statement from the ultimate vendor to support claims for certain tax refunds or credits. Although the regulations require firearms and ammunition excise taxpayers to design and reproduce these certificates or statements as specified in the regulations, in order to promote uniformity among excise taxpayers and compliance with regulations, these certificates and statements are needed.

Current Actions: We are submitting this information collection request for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit; individuals or households; State or Local Governments.

Estimated Number of Respondents: 7,000.

Estimated Total Annual Burden Hours: 52,500.

Dated: November 19, 2010.

Gerald Isenberg,

Director, Regulations and Rulings Division.

[FR Doc. 2010-29863 Filed 11-26-10; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Art Advisory Panel—Closed Meeting

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of Closed Meeting of Art Advisory Panel for Decorative Art.

SUMMARY: A closed meeting of the Art Advisory Panel will be held in Washington, DC.

DATES: The meeting will be held December 8, 2010.

ADDRESSES: The closed meeting of the Art Advisory Panel for Decorative Art will be held on December 8, 2010, in the Appeals Media Center beginning at 9:30 a.m., Franklin Court Building, 1099 14th Street, NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Joseph E. Bothwell, C:AP:PV:ART, 1099 14th Street, NW., Washington, DC 20005. Telephone (202) 435-5611 (not a toll free number).

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App., that a closed meeting of the Art Advisory

Panel for Decorative Art will be held on December 8, 2010, beginning at 9:30 a.m., in room 4112, Appeals Large Conference Room, Franklin Court Building, 1099 14th Street, NW., Washington, DC 20005.

The agenda will consist of the review and evaluation of the acceptability of fair market value appraisals of works of art involved in Federal income, estate, or gift tax returns. This will involve the discussion of material in individual tax returns made confidential by the provisions of 26 U.S.C. 6103.

A determination as required by section 10(d) of the Federal Advisory Committee Act has been made that this meeting is concerned with matters listed in section 552b(c)(3), (4), (6), and (7), and that the meeting will not be open to the public.

Diane S. Ryan,
Chief, Appeals.

[FR Doc. 2010-30049 Filed 11-24-10; 11:15 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of the Tier 2 Tax Rates

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice.

SUMMARY: Publication of the tier 2 tax rates for calendar year 2011 as required by section 3241(d) of the Internal Revenue Code (26 U.S.C. section 3241). Tier 2 taxes on railroad employees, employers, and employee representatives are one source of funding for benefits under the Railroad Retirement Act.

DATES: The tier 2 tax rates for calendar year 2011 apply to compensation paid in calendar year 2011.

FOR FURTHER INFORMATION CONTACT: Kathleen Edmondson, CC:TEGE:EOEG:ET1, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, Telephone Number (202) 622-0047 (not a toll-free number).

TIER 2 TAX RATES: The tier 2 tax rate for 2011 under section 3201(b) on employees is 3.9 percent of compensation. The tier 2 tax rate for 2011 under section 3221(b) on employers is 12.1 percent of compensation. The tier 2 tax rate for 2011 under section 3211(b) on employee representatives is 12.1 percent of compensation.

Dated: November 17, 2010.

Nancy Marks,

Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities).

[FR Doc. 2010-29887 Filed 11-26-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0060]

Agency Information Collection (Claim for One Sum Payment (Government Life Insurance)) Activities under OMB Review

AGENCY: Veterans Benefits 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 Benefits Administration (VBA), 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; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 29, 2010.

ADDRESSES: Submit written comments on the collection of information through <http://www.Regulations.gov>; or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395-7316. Please refer to "OMB Control No. 2900-0060" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-7485, fax (202) 273-0443 or e-mail denise.mclamb@mail.va.gov. Please refer to "OMB Control No. 2900-0060."

SUPPLEMENTARY INFORMATION:

Titles:

a. Claim for One Sum Payment (Government Life Insurance), VA Form 29-4125.

b. Claim for Monthly Payments (National Service Life Insurance), VA Form 29-4125a.

c. Claim for Monthly Payments (United States Government Life Insurance, (USGLI)), VA Form 29-4125k.

OMB Control Number: 2900-0060.

Type of Review: Extension of a currently approved collection.

Abstract: Beneficiaries of deceased veterans must complete VA Form 29-4125 to apply for proceeds of the veteran's Government Insurance policies. If the beneficiary desires monthly installment in lieu of one lump payment he or she must complete VA Forms 29-4125a and 29-4125k. VA uses the information to determine the claimant's eligibility for payment of insurance proceeds and to process monthly installment payments.

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 September 16, 2010, at page 56664.

Affected Public: Individuals or households.

Estimated Annual Burden:

- a. VA Form 29-4125—8,200 hours.
- b. VA Form 29-4125a—185 hours.
- c. VA Form 4125k—125 hours.

Estimated Average Burden per Respondents:

- a. VA Form 29-4125—6 minutes.
- b. VA Form 29-4125a—6 minutes.
- c. VA Form 4125k—15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents:

- a. VA Form 29-4125—82,000.
- b. VA Form 29-4125a—1,850.
- c. VA Form 4125k—500.

Dated: November 23, 2010.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2010-29933 Filed 11-26-10; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0613]

Proposed Information Collection (Recordkeeping at Flight Schools); Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to

publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to this notice. This notice solicits comments on the information needed to determine if courses offered by a flight school should be approved.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 28, 2011.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov> or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail nancy.kessinger@va.gov. Please refer to "OMB Control No. 2900-0613" in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461-9769 or FAX (202) 275-5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104-13; 44 U.S.C. 3501-3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Recordkeeping at Flight Schools (38 U.S.C. 21.4263 (h)(3)).

OMB Control Number: 2900-0613.

Type of Review: Extension of a previously approved collection.

Abstract: Flight schools are required to maintain records on students to support continued approval of their courses. VA uses the data collected to determine whether the courses and

students meet the requirements for flight training benefits and to properly pay students.

Affected Public: Business or other for-profit and Not-for-profit institutions.

Estimated Annual Burden: 274 hours.

Estimated Average Burden Per Respondent: 20 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 394.

Estimated Annual Responses: 821.

Dated: November 23, 2010.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Services.

[FR Doc. 2010-29913 Filed 11-26-10; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0180]

Proposed Information Collection (Compliance Report of Proprietary Institutions) Activity; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine whether proprietary schools receiving Federal financial assistance from VA and the Department of Education are in compliance with equal opportunity laws.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 28, 2011.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>; or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC

20420 or e-mail nancy.kessinger@va.gov. Please refer to "OMB Control No. 2900-0180" in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT:

Nancy J. Kessinger at (202) 461-9769 or FAX (202) 275-5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104-13; 44 U.S.C. 3501-3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary

for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Compliance Report of Proprietary Institutions, VA Form 20-4274.

OMB Control Number: 2900-0180.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 20-4274 is used to determine whether proprietary

educational institutions receiving Federal financial assistance comply with applicable civil rights statute and regulations. The collected information is used to identify areas that may indicate, statistically, disparate treatment of minority group members.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 155 hours.

Estimated Average Burden per Respondent: 75 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 124.

Dated: November 23, 2010.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2010-29914 Filed 11-26-10; 8:45 am]

BILLING CODE 8320-01-P



Federal Register

Monday,
November 29, 2010

Part II

Department of Health and Human Services

Center for Medicare & Medicaid Services

42 CFR Parts 405, 409, 410 et al.
Medicare Program; Payment Policies
Under the Physician Fee Schedule and
Other Revisions to Part B for CY 2011;
Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 405, 409, 410, 411, 413, 414, 415, and 424
[CMS-1503-FC]
RIN 0938-AP79
Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011
AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It finalizes the calendar year (CY) 2010 interim relative value units (RVUs) and issues interim RVUs for new and revised procedure codes for CY 2011. It also addresses, implements, or discusses certain provisions of both the Affordable Care Act (ACA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition, this final rule with comment period discusses payments under the Ambulance Fee Schedule (AFS), the Ambulatory Surgical Center (ASC) payment system, and the Clinical Laboratory Fee Schedule (CLFS), payments to end-stage renal disease (ESRD) facilities, and payments for Part B drugs. Finally, this final rule with comment period also includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (CBP DMEPOS), and provider and supplier enrollment issues associated with air ambulances.

DATES: *Effective date:* These regulations are effective on January 1, 2011.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 3, 2011.

ADDRESSES: In commenting, please refer to file code CMS-1503-FC. 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 for "submitting a comment."

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-1503-FC, 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-1503-FC, 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) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Sara Vitolo, (410) 786-5714, for issues related to malpractice RVUs.

Erin Smith, (410) 786-0763, for issues related to end-stage renal disease-related services for home dialysis.

Michael Moore, (410) 786-6830, for issues related to geographic practice cost indices.

Ken Marsalek, (410) 786-4502, for issues related to the physician practice information survey, the multiple procedure payment reduction, and payment for the technical component of pathology services.

Regina Walker-Wren, (410) 786-9160, for issues related to outpatient mental health add-on provision and increased payment for certified nurse-midwife services.

Elizabeth Truong, (410) 786-6005, or Sara Vitolo, (410) 786-5714, for issues related to potentially misvalued services.

Elizabeth Truong, (410) 786-6005, for issues related to the sustainable growth rate or anesthesia or physician fee schedule conversion factors.

Dorothy Shannon, (410) 786-3396, for issues related to outpatient therapy services.

Pamela West, (410) 786-2302, for issues related to payment for diabetes self-management training programs and kidney disease education services.

Ryan Howe, (410) 786-3355, for issues related to direct practice expense inputs and telehealth services.

Sara Vitolo, (410) 786-5714, for issues related to pulmonary rehabilitation services, application of skin substitutes, canalith repositioning, intranasal/oral immunization, and the refinement panel.

Roberta Epps, (410) 786-4503, for issues related to portable x-ray and bone density tests.

Chava Sheffield, (410) 786-2298, for issues related to equipment utilization rate assumption for advanced imaging services.

Chava Sheffield, (410) 786-2298, or Larry Chan, (410) 786-6864, for issues related to the physician fee schedule practice expense methodology.

Stephanie Frilling, (410) 786-4507, or Erin Smith, (410) 786-0763, for issues related to the incentive payment programs for primary care and general surgery services, and payment for the annual wellness visit and preventive services.

Cheryl Gilbreath, (410) 786-5919, for issues related to payment for covered outpatient drugs and biologicals.

Rochel Kujawa, (410) 786-9111, for issues related to ambulance services.

Glenn McQuirk, (410) 786-5723, for clinical laboratory issues.

Randall Ricktor, (410) 786-4632, for Federally Qualified Health Center Issues.

Pauline Lapin, (410) 786-6883, for issues related to the chiropractic services demonstration BN issue.

Troy Barsky, (410) 786-8873, or Kristin Bohl, (410) 786-8680, for issues related to physician self-referral.

Troy Barsky, (410) 786-8873, or Fred Grabau (410) 786-0206, for issues related to timely filing rules.

Henry Richter, (410) 786-4562, or Lisa Hubbard, (410) 786-5472, for issues related to renal dialysis provisions and payments for end-stage renal disease facilities.

Diane Stern, (410) 786-1133, for issues related to the physician quality reporting initiative and incentives for e-prescribing.

Sheila Roman, (410) 786-6004, or Pamela Cheetham, 410-786-2259, for issues related to the Physician Resource Use Feedback Program and value-based purchasing.

Joel Kaiser, (410) 786-4499, for issues related to the DME provisions.

Sandra Bastinelli, (410) 786-3630, for issues related to provider and supplier enrollment issues.

Rebecca Cole, (410) 786-4497, for issues related to physician payment not identified above.

SUPPLEMENTARY INFORMATION: Comment Subject Areas: We will consider comments on the following subject areas discussed in this final rule with comment period that are received by the date and time indicated in the **DATES** section of this final rule with comment period:

(1) The interim final work, practice expense, and malpractice RVUs (including the direct practice expense (PE) inputs and the equipment utilization rate assumption, and the applicability of a multiple procedure payment reduction (MPPR)), for new and revised CY 2011 HCPCS codes. These codes and their CY 2011 interim final RVUs are listed in Addendum C to this final rule with comment period.

(2) The physician self-referral designated health services codes listed in Tables 98 and 99.

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.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a table of contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

Information on the regulations impact appears throughout the preamble and, therefore, is not discussed exclusively in section XI. of this final rule with comment period.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

- AA Anesthesiologist assistant
- AACVPR American Association of Cardiovascular and Pulmonary Rehabilitation
- AANA American Association of Nurse Anesthetists
- ABMS American Board of Medical Specialties
- ABN Advanced Beneficiary Notice
- ACA “Affordable Care Act”
- ACC American College of Cardiology
- ACGME Accreditation Council on Graduate Medical Education
- ACLS Advanced cardiac life support
- ACP American College of Physicians
- ACR American College of Radiology
- ACS American Community Survey
- AED Automated external defibrillator
- AFROC Association of Freestanding Radiation Oncology Centers
- AFS Ambulance Fee Schedule
- AHA American Heart Association

- AHFS—DI American Hospital Formulary Service-Drug Information
- AHRQ [HHS] Agency for Healthcare Research and Quality
- AMA American Medical Association
- AMA—DE American Medical Association Drug Evaluations
- AACE American Association of Clinical Endocrinologists
- AADE American Association of Diabetes Educators
- AMP Average manufacturer price
- AO Accreditation organization
- AOA American Osteopathic Association
- APA American Psychological Association
- APC Administrative Procedures Act
- APTA American Physical Therapy Association
- ARRA American Recovery and Reinvestment Act (Pub. L. 111–5)
- ASC Ambulatory surgical center
- ASP Average sales price
- ASRT American Society of Radiologic Technologists
- ASTRO American Society for Therapeutic Radiology and Oncology
- ATA American Telemedicine Association
- AWP Average wholesale price
- AWV Annual Wellness Visit
- BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
- BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
- BPM Benefit Policy Manual
- BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
- BLS Bureau of Labor Statistics
- BN Budget neutrality
- BPM Benefit Policy Manual
- CABG Coronary artery bypass graft
- CAD Coronary artery disease
- CAH Critical access hospital
- CAHEA Committee on Allied Health Education and Accreditation
- CAP Competitive acquisition program
- CARE Continuity Assessment Record and Evaluation
- CBIC Competitive Bidding Implementation Contractor
- CBP Competitive Bidding Program
- CBSA Core-Based Statistical Area
- CDC Centers for Disease Control and Prevention
- CEM Cardiac Event Monitoring
- CF Conversion factor
- CFC Conditions for Coverage
- CFR Code of Federal Regulations
- CKD Chronic kidney disease
- CLFS Clinical laboratory fee schedule
- CMA California Medical Association
- CMD Contractor Medical Director
- CMHC Community mental health center
- CMP Civil-money penalty
- CMS Centers for Medicare & Medicaid Services
- CNS Clinical nurse specialist
- CoP Condition of participation
- COPD Chronic obstructive pulmonary disease
- CORF Comprehensive Outpatient Rehabilitation Facility
- COS Cost of service
- CPEP Clinical Practice Expert Panel

- CPI Consumer Price Index
- CPI-U Consumer price index for urban consumers
- CPR Cardiopulmonary resuscitation
- CPT [Physicians] Current Procedural Terminology (4th Edition, 2002, copyrighted by the American Medical Association)
- CR Cardiac rehabilitation
- CRNA Certified registered nurse anesthetist
- CRP Canalith repositioning
- CRT Certified respiratory therapist
- CSW Clinical social worker
- CT Computed Tomography
- CTA Computed Tomography Angiography
- CSC Computer Sciences Corporation
- CWF Common Working File
- CY Calendar year
- DEA Drug Enforcement Agency
- DOTPA Development of Outpatient Therapy Alternatives
- DHS Designated health services
- DHHS Department of Health and Human Services
- DME Durable medical equipment
- DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
- DOQ Doctors Office Quality
- DOS Date of service
- DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
- DSMT Diabetes self-management training
- EGC Electrocardiogram
- E/M Evaluation and management
- EDI Electronic data interchange
- EEG Electroencephalogram
- EHR Electronic health record
- EKG Electrocardiogram
- EMG Electromyogram
- EMTALA Emergency Medical Treatment and Active Labor Act
- EOG Electro-oculogram
- EPO Erythropoietin
- eRx Electronic Prescribing
- ESO Endoscopy Supplies
- ESRD End-stage renal disease
- FAA Federal Aviation Administration
- FAX Facsimile
- FDA Food and Drug Administration (HHS)
- FFS Fee-for-service
- FOTO Focus On Therapeutic Outcomes
- FQHC Federally Qualified Health Center
- FR **Federal Register**
- GAF Geographic adjustment factor
- GAO General Accounting Office
- GEM Generating Medicare [Physician Quality Performance Measurement Results]
- GFR Glomerular filtration rate
- GPRO Group Practice Reporting Option
- GPO Group purchasing organization
- GPCI Geographic practice cost index
- GPS Geographic Positioning System
- GSA General Services Administration
- HAC Hospital-acquired conditions
- HBAI Health and behavior assessment and intervention
- HCC Hierarchal Condition Category
- HCPAC Health Care Professional Advisory Committee
- HCPCS Healthcare Common Procedure Coding System
- HCRIS Healthcare Cost Report Information System
- HEMS Helicopter Emergency Medical Services
- HDRT High dose radiation therapy

- HH PPS Home Health Prospective Payment System
- HHA Home health agency
- HHRG Home health resource group
- HHS [Department of] Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)
- HIT Health information technology
- HITECH Health Information Technology for Economic and Clinical Health Act (Title IV of Division B of the Recovery Act, together with Title XIII of Division A of the Recovery Act)
- HITSP Healthcare Information Technology Standards Panel
- HIV Human immunodeficiency virus
- HOPD Hospital outpatient department
- HPSA Health Professional Shortage Area
- HRA Health Risk Assessment
- HRSA Health Resources Services Administration (HHS)
- HSIP HPSA Surgical Incentive Program
- HUD Housing and Urban Development
- IACS Individuals Access to CMS Systems
- ICD International Classification of Diseases
- ICF Intermediate care facilities
- ICF International Classification of Functioning, Disability and Health
- ICR Intensive cardiac rehabilitation
- ICR Information collection requirement
- IDTF Independent diagnostic testing facility
- IGI IHS Global Insight, Inc.
- IFC Interim final rule with comment period
- IMRT Intensity-Modulated Radiation Therapy
- IOM Internet Only Manual
- IPCI indirect practice cost index
- IPPE Initial preventive physical examination
- IPPS Inpatient prospective payment system
- IRS Internal Revenue Service
- ISO Insurance services office
- IVD Ischemic Vascular Disease
- IVIG Intravenous immune globulin
- IWP/UT Intra-service work per unit of time
- JTC Joint Commission
- JRCERT Joint Review Committee on Education in Radiologic Technology
- KDE Kidney disease education
- LCD Local coverage determination
- MA Medicare Advantage
- MA-PD Medicare Advantage-Prescription Drug Plans
- MAC Medicare Administrative Contractor
- MAV Measure Applicability Validation
- MCMP Medicare Care Management Performance
- MCP Monthly Capitation Payment
- MDRD Modification of Diet in Renal Disease
- MedCAC Medicare Evidence Development and Coverage Advisory Committee (formerly the Medicare Coverage Advisory Committee (MCAC))
- MedPAC Medicare Payment Advisory Commission
- MGMA Medical Group Management Association
- MEI Medicare Economic Index
- MIEA-TRHCA Medicare Improvements and Extension Act of 2006 (that is, Division B of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109-432)
- MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275)
- MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173)
- MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173)
- MNT Medical nutrition therapy
- MOC Maintenance of certification
- MP Malpractice
- MPC Multispecialty Points of Comparison
- MPPR Multiple procedure payment reduction
- MQSA Mammography Quality Standards Act of 1992 (Pub. L. 102-539)
- MRA Magnetic Resonance Angiography
- MRI Magnetic Resonance Imaging
- MSA Metropolitan Statistical Area
- MSP Medicare Secondary Payer
- MUE Medically Unlikely Edit
- NCCI National Correct Coding Initiative
- NCD National Coverage Determination
- NCQA National Committee for Quality Assurance
- NCQDIS National Coalition of Quality Diagnostic Imaging Services
- NDC National drug code
- NF Nursing facility
- NISTA National Institute of Standards and Technology Act
- NP Nurse practitioner
- NPI National Provider Identifier
- NPP Nonphysician practitioner
- NQF National Quality Forum
- NBRC National Board for Respiratory Care
- NRC Nuclear Regulatory Commission
- NTSB National Transportation Safety Board
- NUBC National Uniform Billing Committee
- OACT [CMS] Office of the Actuary
- OBRA Omnibus Budget Reconciliation Act
- OCR Optical Character Recognition
- ODF Open door forum
- OES Occupational Employment Statistics
- OGPE Oxygen generating portable equipment
- OIG Office of Inspector General
- OMB Office of Management and Budget
- ONC [HHS] Office of the National Coordinator for Health IT
- OPPS Outpatient prospective payment system
- OSCAR Online Survey and Certification and Reporting
- PA Physician assistant
- PACE Program of All-inclusive Care for the Elderly
- PAT Performance assessment tool
- PC Professional component
- PCI Percutaneous coronary intervention
- PCIP Primary Care Incentive Payment Program
- PDP Prescription drug plan
- PE Practice expense
- PE/HR Practice expense per hour
- PEAC Practice Expense Advisory Committee
- PECOS Provider Enrollment Chain and Ownership System
- PERC Practice Expense Review Committee
- PFS Physician Fee Schedule
- PGP [Medicare] Physician Group Practice
- PHI Protected health information
- PHP Partial hospitalization program
- PIM [Medicare] Program Integrity Manual
- PLI Professional liability insurance
- POA Present on admission
- POC Plan of care
- PPI Producer price index
- PPIS Physician Practice Information Survey
- PPPS Personalized Prevention Plan Services
- PPS Prospective payment system
- PPTA Plasma Protein Therapeutics Association
- PQRI Physician Quality Reporting Initiative
- PR Pulmonary rehabilitation
- PRA Paperwork Reduction Act
- PSA Physician scarcity areas
- PT Physical therapy
- PTCA Percutaneous transluminal coronary angioplasty
- PTA Physical therapy assistant
- PVBP Physician and Other Health Professional Value-Based Purchasing Workgroup
- QDCs (Physician Quality Reporting System) Quality Data Codes
- RA Radiology assistant
- RAC Medicare Recovery Audit Contractor
- RBMA Radiology Business Management Association
- RFA Regulatory Flexibility Act
- RHC Rural health clinic
- RHQDAPU Reporting Hospital Quality Data Annual Payment Update Program
- RIA Regulatory impact analysis
- RN Registered nurse
- RNAC Reasonable net acquisition cost
- RPA Radiology practitioner assistant
- RRT Registered respiratory therapist
- RUC [AMAs Specialty Society] Relative (Value) Update Committee
- RVRBS Resource-Based Relative Value Scale
- RVU Relative value unit
- SBA Small Business Administration
- SCHIP State Children's Health Insurance Programs
- SDW Special Disability Workload
- SGR Sustainable growth rate
- STATS Short Term Alternatives for Therapy Services
- SLP Speech-language pathology
- SMS [AMAs] Socioeconomic Monitoring System
- SNF Skilled nursing facility
- SOR System of record
- SRS Stereotactic radiosurgery
- SSA Social Security Administration
- SSI Social Security Income
- STARS Services Tracking and Reporting System
- STATS Short Term Alternative Therapy Services
- TC Technical Component
- TIN Tax identification number
- TRHCA Tax Relief and Health Care Act of 2006 (Pub. L. 109-432)
- TTO Transtracheal oxygen
- UAF Update Adjustment Factor
- UPMC University of Pittsburgh Medical Center
- URAC Utilization Review Accreditation Committee
- USDE United States Department of Education
- USP-DI United States Pharmacopoeia-Drug Information
- VA Veterans Administration
- VBP Value-based purchasing
- WAC Wholesale Acquisition Cost

WAMP Widely available market price
WHO World Health Organization

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2010 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable FARS/DFARS apply.

I. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), "Payment for Physicians' Services." The Act requires that payments under the physician fee schedule (PFS) are based on national uniform relative value units (RVUs) based on the relative resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice expense. Before the establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges. We note that throughout this final rule with comment period, unless otherwise noted, the term "practitioner" is used to describe both physicians and eligible nonphysician practitioners (such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, psychologists, or social workers) that are permitted to furnish and bill Medicare under the PFS for the services under discussion.

A. Development of the Relative Value System

1. Work RVUs

The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101-239), and OBRA 1990, (Pub. L. 101-508). The final rule, published on November 25, 1991 (56 FR 59502), set forth the fee schedule for payment for physicians' services beginning January 1, 1992. Initially, only the physician work RVUs were resource-based, and the PE and malpractice RVUs were based on average allowable charges.

The physician work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician

work RVUs for most codes in a cooperative agreement with the Department of Health and Human Services (DHHS). In constructing the code-specific vignettes for the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the Federal government, and obtained input from numerous physician specialty groups.

Section 1848(b)(2)(B) of the Act specifies that the RVUs for anesthesia services are based on RVUs from a uniform relative value guide, with appropriate adjustment of the conversion factor (CF), in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. We established a separate CF for anesthesia services, and we continue to utilize time units as a factor in determining payment for these services. As a result, there is a separate payment methodology for anesthesia services.

We establish physician work RVUs for new and revised codes based on our review of recommendations received from the American Medical Association's (AMA) Specialty Society Relative Value Update Committee (RUC).

2. Practice Expense Relative Value Units (PE RVUs)

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103-432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs.

Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), amended section 1848(c)(2)(C)(ii) of the Act to delay implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based PE RVUs to resource-based RVUs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published November 2, 1998 (63 FR 58814), effective for services furnished in 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, resource-based PE RVUs did not become fully effective until 2002.

This resource-based system was based on two significant sources of actual PE data: the Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System

(SMS) data. The CPEP data were collected from panels of physicians, practice administrators, and nonphysicians (for example, registered nurses (RNs)) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physicians' service in both the office setting and out-of-office setting. We have since refined and revised these inputs based on recommendations from the RUC. The AMA's SMS data provided aggregate specialty-specific information on hours worked and PEs.

Separate PE RVUs are established for procedures that can be performed in both a nonfacility setting, such as a physician's office, and a facility setting, such as a hospital outpatient department (HOPD). The difference between the facility and nonfacility RVUs reflects the fact that a facility typically receives separate payment from Medicare for its costs of providing the service, apart from payment under the PFS. The nonfacility RVUs reflect all of the direct and indirect PEs of providing a particular service.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the calendar year (CY) 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007 and provided for a 4-year transition for the new PE RVUs under this new methodology. This transition ended in CY 2010 and direct PE RVUs are calculated in CY 2011 using this methodology, unless otherwise noted.

In the CY 2010 PFS final rule with comment period, we updated the PE/hour (HR) data that are used in the

calculation of PE RVUs for most specialties (74 FR 61749). For this update, we used the Physician Practice Information Survey (PPIS) conducted by the AMA. The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) using a survey instrument and methods highly consistent with those of the SMS and the supplemental surveys used prior to CY 2010. We note that in CY 2010, for oncology, clinical laboratories, and independent diagnostic testing facilities (IDTFs), we continued to use the supplemental survey data to determine PE/HR values (74 FR 61752).

3. Resource-Based Malpractice (MP) RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act requiring us to implement resource-based malpractice (MP) RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule published November 2, 1999 (64 FR 59380). The MP RVUs were based on malpractice insurance premium data collected from commercial and physician-owned insurers from all the States, the District of Columbia, and Puerto Rico.

4. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less often than every 5 years. The first Five-Year Review of the physician work RVUs was published on November 22, 1996 (61 FR 59489) and was effective in 1997. The second Five-Year Review was published in the CY 2002 PFS final rule with comment period (66 FR 55246) and was effective in 2002. The third Five-Year Review of physician work RVUs was published in the CY 2007 PFS final rule with comment period (71 FR 69624) and was effective on January 1, 2007. (Note: Additional codes relating to the third Five-Year Review of physician work RVUs were addressed in the CY 2008 PFS final rule with comment period (72 FR 66360).) The fourth Five-Year Review of physician work RVUs was initiated in the CY 2010 PFS final rule with comment period where we solicited candidate codes from the public for this review (74 FR 61941). Changes due to the fourth Five-Year Review of physician work RVUs will be effective January 1, 2012.

In 1999, the AMA RUC established the Practice Expense Advisory Committee (PEAC) for the purpose of refining the direct PE inputs. Through March 2004, the PEAC provided recommendations to CMS for over 7,600

codes (all but a few hundred of the codes currently listed in the AMAS Current Procedural Terminology (CPT) codes). As part of the CY 2007 PFS final rule with comment period (71 FR 69624), we implemented a new bottom-up methodology for determining resource-based PE RVUs and transitioned the new methodology over a 4-year period. A comprehensive review of PE was undertaken prior to the 4-year transition period for the new PE methodology from the top-down to the bottom-up methodology, and this transition was completed in CY 2010. In CY 2010, we also incorporated the new PPIS data to update the specialty-specific PE/HR data used to develop PE RVUs. Therefore, the next Five-Year Review of PE RVUs will be addressed in CY 2014.

In the CY 2005 PFS final rule with comment period (69 FR 66236), we implemented the first Five-Year Review of the MP RVUs (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). The second Five-Year Review and update of resource-based malpractice RVUs was published in the CY 2010 PFS final rule with comment period (74 FR 61758) and was effective in CY 2010.

5. Adjustments to RVUs Are Budget Neutral

Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than \$20 million from what they would have been if the adjustments were not made. In accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures to change by more than \$20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than \$20 million.

For CY 2010, we adopted a number of new payment policies for which we estimated the potential for a redistributive effect under the PFS, including the use of the new PPIS data to develop the specialty-specific PE/HR used for the PE RVUs (74 FR 61749 through 61752) and the elimination of the reporting of all CPT consultation codes in order to allow for correct and consistent coding and appropriate payment for evaluation and management services under the PFS (74 FR 61767 through 61775). In the CY 2011 PFS proposed rule (75 FR 40047), we acknowledged that clinical experience with these new PFS policies has been growing over the first 6 months of CY 2010 and noted that as we seek to improve future PFS payment

accuracy for services, we were interested in public comments on the perspectives of physicians and nonphysician practitioners caring for Medicare beneficiaries under the current PFS coding and payment methodologies for physicians' services.

Comment: Many commenters expressed various concerns regarding new Medicare coding and payment methodologies adopted for CY 2010 and continuing in CY 2011. Some commenters indicated that the effects of using PPIS data to develop the specialty-specific practice expense per hour (PE/HR) significantly reduced the payment for certain services and procedures. Commenters were concerned that the reductions in practice costs reflected in the PPIS data were inaccurate and that CMS reliance on the PPIS data caused undue hardship to certain specialties. Some commenters requested that CMS utilize new PE survey data for specific specialties.

A number of commenters were also particularly concerned with the decision by CMS to no longer recognize the CPT consultation codes for Part B payment of evaluation and management (E/M) services beginning in CY 2010. Many commenters recommended resuming payment for consultation codes under the PFS to recognize the unique physician work and practice expenses when consultation services are furnished at the request of other practitioners. Several commenters argued that consultation services were especially important to ensuring high-quality, coordinated care for complex patients and to prevent unnecessary, expensive tests. Based on findings from a survey of affected specialties, these commenters expressed concern that CMS policy decision to no longer recognize the CPT consultation codes for PFS payment purposes resulted in: (1) A reduction in the number of new Medicare patients seen by specialists; (2) a reduction in overall specialist time spent with individual Medicare patients; (3) a reduction in the number of consultations provided to hospital inpatients; (4) diminished continuity and coordination of care; and (5) the elimination of physicians' office staff and postponement of physicians purchasing new equipment because of practice cost concerns. Finally, other commenters requested that, in the absence of recognition of the CPT consultation codes for PFS payment, CMS should revise the current prolonged services and new patient definitions in order to allow for higher payments for services that, prior to CY 2010, would have been billed using the CPT consultation codes. Specifically,

the commenters believe that CMS should adopt the current CPT policy of identifying patients seen by physicians in a different subspecialty within a group practice as "new" patients, rather than continuing to use the same physician specialty as the decision point. In addition, some commenters encouraged CMS to adopt the CPT inpatient setting guidelines for determining whether a service meets the prolonged service criteria, which allow physicians to include time spent on a patient's floor or unit performing tasks related to the patient's care, rather than just face-to-face time as specified under current CMS policy.

Response: We appreciate the concerns of the commenters regarding current PFS coding and payment methodologies. We welcome the perspective of physicians and nonphysician practitioners caring for Medicare beneficiaries. We understand that in some cases, recent policy changes under the PFS reduced payments for certain professional services, albeit with the goal of providing payment for services that appropriately reflects their relative value in the context of PFS payment for all other services. It is in the nature of any budget neutral payment system for changes, such as the use of PPIS data and the elimination of PFS payment for the CPT consultation codes, to have a somewhat differential impact on various groups of physicians and/or nonphysician practitioners. Furthermore, we note that all physicians benefited from the budget neutral increase in the payment levels for the other evaluation and management (E/M) CPT codes that resulted from the consultation code policy change.

For CY 2010, we adopted the PPIS data for developing the PE RVUs as the most recent data on physicians office practice expenses that used a consistent survey instrument across all specialty and healthcare professional groups. The PPIS was a nationally representative survey providing the most up-to-date and comprehensive data available from 51 specialties, using a survey instrument that was carefully designed, tested, and implemented. As discussed in the CY 2010 PFS final rule with comment period (75 FR 61751), because we recognized that some specialties would likely experience significant payment reductions with the use of the PPIS data, we adopted a 4-year transition from the previous PE RVUs to the PE RVUs developed using the new PPIS data in order to allow physicians and others time to adjust to the payment changes. We note that CY 2010 was the first year of the transition, with payment

based upon 75 percent of the previous PE RVUs and 25 percent of the PE RVUs using the new PPIS data. This blend will move to 50/50 in CY 2011, and we intend to continue to closely monitor Medicare PFS utilization data to detect any emerging issues that may be of concern during this transition period, such as access problems for Medicare beneficiaries. To date, we have identified no specific problems that would warrant our proposal of a change with respect to the final CY 2010 policy regarding development of the PE RVUs based on the PPIS data. Going forward, as discussed further in section II.A.2.f. of this final rule with comment period, we remain interested in the thoughts of stakeholders regarding the MedPAC comment that "CMS should consider alternatives to collecting specialty-specific cost data or options to decrease the reliance on such data." We encourage interested parties to contact us at any time if they have information to share or discuss in this regard.

In response to extensive public comment on the CY 2010 PFS proposal to eliminate payment for the CPT consultation codes, we explained our rationale in detail in the CY 2010 PFS final rule with comment period (75 FR 61767 through 61775). Prior to the CY 2010 PFS rulemaking cycle, we had made numerous attempts to resolve issues related to the reporting of the CPT consultation codes, including developing and implementing relevant guidance and educating physicians regarding documentation, transfer of care, and consultation policy. Despite these efforts, there was still substantial disagreement and inconsistency within the physician community regarding these issues. In addition, we believe that in most cases there is no substantial difference in physician work between E/M visits and services that would otherwise be reported with CPT consultation codes. Therefore, we continue to believe that E/M services that could previously have been reported using the CPT consultation codes may now be appropriately reported and paid using other E/M codes, specifically office and other outpatient, initial hospital and nursing facility care, and subsequent hospital and nursing facility care E/M codes. This policy allows for correct and consistent coding for E/M services furnished by physicians and nonphysician practitioners, as well as provides for appropriate payment for the specific services that were previously billed using the CPT consultation codes.

While we continue to believe that promoting effective coordination of care

must be an essential goal of our payment systems, we are currently not aware of any evidence that the CY 2010 policy change to no longer recognize the CPT consultation codes is creating problems regarding care coordination and communication among physicians that negatively impact the health of Medicare beneficiaries. As we stated in the CY 2010 PFS final rule with comment period in response to similar hypothetical concerns expressed by some commenters (75 FR 61774), if we become aware of such evidence in the future, we would certainly consider whether there is an appropriate policy response to promote more effective coordination of care. However, we continue to believe it is premature to consider what the appropriate responses might be unless specific evidence of an issue affecting the health of Medicare beneficiaries comes to our attention. We will continue to be attentive to any concerns that develop about the effects of the policy on the goal of promoting effective coordination of care.

In the CY 2010 PFS final rule with comment period (75 FR 61772), we explained that, although we estimated that there would be redistributional effects among specialties, we did not believe the estimated impacts of the change in consultation code policy were disproportionate to the goals we sought to achieve in finalizing the proposal. While we understand that commenters are concerned with the effects of this policy change and that these comments were submitted after only a half year's experience with the revised policy, the commenters on the CY 2011 proposed rule did not fundamentally address the underlying issues that led to our decision to no longer recognize the consultation codes for PFS payment purposes.

We appreciate the suggestions of the commenters regarding policy changes to the definitions of new patients and prolonged services. Regarding the definition of "new" patient, we note that we continue to consider requests on an ongoing basis for new Medicare physician specialty codes and may establish new codes upon evaluating the submissions based on the criteria listed in the Medicare Claims Processing Manual, Pub. 100-04, chapter 26, section 10.8. In fact, we have approved four new Medicare physician specialty codes in the past 2 years. These additions allow more patients of those subspecialties to be considered new based on the narrower range of services provided by the subspecialty within a broader specialty group practice. We encourage interested stakeholders to submit requests for new specialty codes

if they desire a specific code for a different medical specialty or subspecialty. We do not believe it is necessary to change our current policy to one that would routinely adopt the CPT policy of identifying patients seen by physicians in a different subspecialty as "new" patients because our current criteria for establishing new Medicare physician specialty codes already accounts for many of these scenarios. Medicare physician specialty codes describe the unique types of medicine that physicians practice. Therefore, we believe our current definition of "new" for reporting office visits to a group practice appropriately relies upon the Medicare definition of a different specialty so that that the differential physician resources required to care for a patient who is truly new to the physician's unique type of medical practice are appropriately recognized.

Finally, we note that our prolonged service criterion that allows counting only of face-to-face time for inpatients, as it does for outpatients, is longstanding. Given that the highest level initial hospital care E/M visit by a physician typically extends for 70 minutes, in order to report the prolonged physician service CPT code in the inpatient setting, a physician would need to spend at least an additional 30 minutes caring for the patient. We are uncertain whether many inpatient E/M services that would otherwise be reported as CPT consultation codes extend beyond 100 minutes, even if we were to consider adopting a policy change to allow counting of unit/floor time in addition to face-to-face time. If we were to consider such a policy change in the counting of physician time, we are also concerned that available documentation in the medical record could make evaluating the medical necessity of a prolonged service especially problematic. Therefore, we do not believe it would be appropriate to modify our interpretation of the counting of time for purposes of reporting the prolonged service inpatient codes. In most cases, we believe that the additional time that may be required for an E/M visit to a hospital inpatient that would otherwise be reported by a CPT consultation code may be appropriately paid through the Medicare payment for the level of initial or subsequent hospital care E/M code that is reported that takes into consideration the face-to-face time the consulting physician spends with the patient.

We appreciate the commenters' varied perspectives on caring for Medicare beneficiaries under the recent PFS

coding and payment changes adopted for CY 2010 and continuing in CY 2011. While we did not make CY 2011 proposals to modify our established policies regarding the use of the PPIS data to calculate the PE RVUs or the reporting of E/M visits that would otherwise be reported under the CPT consultation codes, and we are not modifying them for CY 2011, we will continue to monitor the impact of these policies. We look forward to continuing our dialogue with stakeholders regarding these and future policy changes under the PFS.

B. Components of the Fee Schedule Payment Amounts

To calculate the payment for every physician's service, the components of the fee schedule (physician work, PE, and MP RVUs) are adjusted by a geographic practice cost index (GPCI). The GPCIs reflect the relative costs of physician work, PE, and malpractice expense in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which is calculated by CMS Office of the Actuary (OACT).

The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = \{[\text{RVU work} \times \text{GPCI work}] + [\text{RVU PE} \times \text{GPCI PE}] + [\text{RVU malpractice} \times \text{GPCI malpractice}]\} \times \text{CF}.$$

C. Most Recent Changes to the Fee Schedule

The CY 2010 PFS final rule with comment period (74 FR 61738) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized some of the CY 2009 interim RVUs and implemented interim RVUs for new and revised codes for CY 2010 to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. The CY 2010 PFS final rule with comment period also addressed other policies, as well as certain provisions of the MIPPA.

As required by the statute at the time of its issuance on October 30, 2009, the CY 2010 PFS final rule with comment period announced the following for CY 2010: The PFS update of -21.2 percent; the initial estimate for the sustainable growth rate of -8.8 percent; and the CF of \$28.4061.

On December 10, 2009, we published a correction notice (74 FR 65449) to correct several technical and typographical errors that occurred in the

CY 2010 PFS final rule with comment period. This correction notice announced a revised CF for CY 2010 of \$28.3895.

On December 19, 2009, the Department of Defense Appropriations Act, 2010 (Pub. L. 111-118) was signed into law. Section 1011 of Public Law 111-118 provided a 2-month zero percent update to the CY 2010 PFS effective only for dates of service from January 1, 2010 through February 28, 2010.

On March 2, 2010, the Temporary Extension Act of 2010 (Pub. L. 111-144) was signed into law. Section 2 of Public Law 111-144 extended through March 31, 2010 the zero percent update to the PFS that was in effect for claims with dates of service from January 1, 2010 through February 28, 2010.

In addition, on April 15, 2010, the Continuing Extension Act of 2010 (Pub. L. 111-157) was signed into law. Section 4 of Public Law 111-157 extended through May 31, 2010 the zero percent update to the PFS that was in effect for claims with dates of services from January 1, 2010 through March 31, 2010. The provision was retroactive to April 1, 2010.

In the May 11, 2010 **Federal Register** (75 FR 26350), we published a subsequent correction notice to correct several technical and typographical errors that occurred in the CY 2010 PFS final rule with comment period and the December 10, 2009 correction notice. The May 11, 2010 correction notice announced a revised CF for CY 2010 of \$28.3868.

On June 25, 2010, the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111-192) was signed into law. This law required application of a 2.2 percent update to the PFS for claims with dates of services from June 1, 2010 through November 30, 2010. As a result of this change, the PFS conversion factor was revised to \$36.8729 for services furnished during this time period.

On March 23, 2010 the Patient Protection and Affordable Care Act (Pub. L. 111-148) was signed into law. Shortly thereafter, on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was signed into law. These two laws are discussed in this final rule with comment period and are collectively referred to as the "Affordable Care Act" (ACA) throughout this final rule with comment period.

D. Public Comments Received in Response to the CY 2011 PFS Proposed Rule

We received approximately 8,500 timely pieces of correspondence containing multiple comments on the CY 2011 PFS proposed rule. We note that we received some comments that were outside the scope of the CY 2011 PFS proposed rule, including public comments on new CY 2011 HCPCS codes that were not presented in the CY 2011 PFS proposed rule and existing CY 2010 HCPCS codes with final values for which we made no proposals for CY 2011. These comments are not addressed in this CY 2011 PFS final rule with comment period. New and revised CY 2011 HCPCS codes and their CY 2011 interim PFS work, malpractice, and PE RVUs are displayed in Addendum C to this final rule with comment period, and these values are open to public comment on this final rule with comment period. Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule with comment period under the appropriate headings.

II. Provisions of the Final Rule for the Physician Fee Schedule

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing the service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. Section 121 of the Social Security Amendments of 1994 (Pub. L. 103-432), enacted on October 31, 1994, required CMS to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by looking at the direct and indirect physician practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. In addition, we note that section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may

not cause total PFS payments to differ by more than \$20 million from what they would have been if the adjustments were not made. Therefore, if revisions to the RVUs cause expenditures to change by more than \$20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than \$20 million. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed history of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We use a bottom-up approach to determine the direct PE by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically required to provide each service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the American Medical Association's (AMA's) Relative Value Update Committee (RUC). For a detailed explanation of the bottom-up direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units Under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect practice expenses incurred per hour worked (PE/HR) in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). These surveys were conducted from 1995 through 1999. For several specialties that collected additional PE/HR data through supplemental surveys, we incorporated these data in developing the PE/HR values used annually.

While the SMS was not specifically designed for the purpose of establishing PE RVUs, we found these data to be the best available at the time. The SMS was a multispecialty survey effort conducted using a consistent survey instrument and method across specialties. The survey sample was randomly drawn from the AMA Physician Master file to ensure national representativeness. The AMA discontinued the SMS survey in 1999.

As required by the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), we also established a process by which specialty groups could submit supplemental PE data. In the May 3, 2000 **Federal Register**, we issued the Medicare Program; Criteria for Submitting Supplemental Practice Expense Survey Data interim final rule (65 FR 25664) in which we established criteria for acceptance of supplemental data. The criteria were modified in the CY 2001 and CY 2003 PFS final rules with comment period (65 FR 65380 and 67 FR 79971, respectively). In addition to the SMS, we previously used supplemental survey data for the following specialties: Cardiology; dermatology; gastroenterology; radiology; cardiothoracic surgery; vascular surgery; physical and occupational therapy; independent laboratories; allergy/immunology; independent diagnostic testing facilities (IDTFs); radiation oncology; medical oncology; and urology.

Because the SMS data and the supplemental survey data were from different time periods, we historically inflated them by the Medicare Economic Index (MEI) to put them on a comparable a time basis as we could when calculating the PE RVUs. This MEI proxy was necessary in the past due to the lack of contemporaneous, consistently collected, and comprehensive multispecialty survey data.

The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS), which was expanded (relative to the SMS) to include nonphysician practitioners (NPPs) paid under the PFS. The PPIS was designed to update the specialty-specific PE/HR data used to develop PE RVUs. The AMA and the CMS contractor, The Lewin Group (Lewin), analyzed the PPIS data and calculated the PE/HR for physician and nonphysician specialties, respectively. The AMA's summary worksheets and Lewin's final report are available on the CMS Web site at <http://www.cms.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=descending&itemID=CMS1223902&intNumPerPage=10>. (See downloads labeled AMA PPIS Worksheets 1-3 and Physician Practice Expense non MDDO Final Report)

The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs using a consistent survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information

from 3,656 respondents across 51 physician specialty and healthcare professional groups.

We believe the PPIS is the most comprehensive source of PE survey information available to date. Therefore, we used the PPIS data to update the PE/HR data for almost all of the Medicare-recognized specialties that participated in the survey for the CY 2010 PFS. When we changed over to the PPIS data beginning in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we finalized a 4-year transition (75/25 for CY 2010, 50/50 for CY 2011, 25/75 for CY 2012, and 0/100 for CY 2013) from the previous PE RVUs to the PE RVUs developed using the new PPIS data.

Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added section 1848(c)(2)(H)(i) of the Act, which requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

We do not use the PPIS data for reproductive endocrinology, sleep medicine, and spine surgery since these specialties are not separately recognized by Medicare, and we do not know how to blend these data with Medicare-recognized specialty data.

Supplemental survey data on independent labs, from the College of American Pathologists, were implemented for payments in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing IDTFs, were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Finally, consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for medical oncology, independent laboratories, and IDTFs were updated to CY 2006 using the MEI to put them on

a comparable basis with the PPIS data. In the CY 2010 PFS final rule with comment period (74 FR 61753), we miscalculated the indirect PE/HR for IDTFs as part of this update process. Therefore, for CY 2011, we are using a revised indirect PE/HR of \$479.81 for IDTFs, consistent with our final policy to update the indirect PE/HR values from prior supplemental survey data that we are continuing to use in order to put these data on a comparable basis with the PPIS data. This revision changes the IDTF indirect percentage from 51 percent to 50 percent for CY 2011.

Previously, we had established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead use the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other with respect to physician time.

In the CY 2010 PFS final rule with comment period (74 FR 61752), we agreed that, under the current PE methodology, the PPIS data for registered dietitians should not be used in the calculation of PE RVUs since these dietitians are paid 85 percent of what a physician would be paid for providing the service. To include their survey data in the PE calculation would influence the ratesetting by incorporating what the services would be paid if performed by registered dietitians and not strictly what the payment rates would be if provided by physicians. We further stated that we would utilize the "All Physicians" PE/HR, as derived from the PPIS, in the calculation of resource-based PE RVUs in lieu of the PE/HR associated with registered dietitians. In the resource-based PE methodology for CY 2010, while we removed the specialty of registered dietitians from the ratesetting step we did not assign the "All Physicians" PE/HR to services furnished by registered dietitians. Instead, we allowed the PE/HR for those services to be generated by a weighted average of all the physician specialties that also furnished the services. This method was consistent with our policy to not use the registered dietitian PPIS PE/HR in calculating the PE RVUs for services furnished by registered dietitians but

we did not actually crosswalk the specialty of registered dietitian to the "All Physicians" PE/HR data as we had intended according to the final policy. Nevertheless, we are affirming for CY 2011 that the final resource-based PE RVUs have been calculated in accordance with the final policy adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) for registered dietitian services that crosswalks the specialty to the "All Physicians" PE/HR data.

As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), CY 2011 is the second year of the 4-year transition to the PE RVUs calculated using the PPIS data. Therefore, in general, the CY 2011 PE RVUs are a 50/50 blend of the previous PE RVUs based on the SMS and supplemental survey data and the new PE RVUs developed using the PPIS data as described above. Note that the reductions in the PE RVUs for expensive diagnostic imaging equipment attributable to the change to an equipment utilization rate assumption of 75 percent (see 74 FR 61753 through 61755 and section II.A.3. of this final rule with comment period) are not subject to the transition.

CMS' longstanding policy in a PFS transition payment year is that if the CPT Editorial Panel creates a new code for that year, the new code would be paid at its fully implemented PFS amount and not at a transition rate for that year. Consistent with this policy, all new CY 2011 CPT codes will not be paid based on transitional PE RVUs in CY 2011. Instead, we will pay these services based on the fully implemented PE RVUs in CY 2011. Additionally, existing CPT codes for which the global period has changed in CY 2011 will not be subject to the PPIS PE RVU transition. We believe that changing the global period of a code results in the CPT code describing a different service to which the previous PE RVUs would no longer be relevant when the code is reported for a service furnished in CY 2011. The five CY 2011 existing CPT codes with global period changes from CY 2010 to CY 2011 are: 11043 (Debridement, muscle, and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less); 11044 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less); 57155 (Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy); 97597 (Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors,

scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 square centimeters or less); and 97598 (Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instructions(s) for ongoing care, per session, total wound(s) surface area; each additional 20 square centimeters, or part thereof (List separately in addition to code for primary procedure)).

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(i) *Direct costs.* The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, equipment, and supplies) typically required to provide the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of \$400 from our PE database and another service has a direct cost sum of \$200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(ii) *Indirect costs.* Section II.A.2.b. of this final rule with comment period describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocate the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the physician work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is described below.

• For a given service, we use the direct portion of the PE RVUs calculated as described above and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that perform the service to determine an initial indirect

allocator. For example, if the direct portion of the PE RVUs for a given service were 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that performed the service, the initial indirect allocator would be 6.00 since 2.00 is 25 percent of 8.00.

• We then add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 6.00 plus 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

• We next incorporate the specialty-specific indirect PE/HR data into the calculation. As a relatively extreme example for the sake of simplicity, assume in our example above that, based on the survey data, the average indirect cost of the specialties performing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties performing the second service with an indirect allocator of 5.00. In this case, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

d. Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or facility setting, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because Medicare makes a separate payment to the facility for its costs of furnishing a service, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

e. Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: A professional component (PC) and a

technical component (TC), each of which may be performed independently or by different providers, or they may be performed together as a "global" service. When services have PC and TC components that can be billed separately, the payment for the global component equals the sum of the payment for the TC and PC. This is a result of using a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global components, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global components, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global under the bottom-up methodology.)

f. Alternative Data Sources and Public Comments on Final Rule for 2010

In the CY 2010 PFS final rule with comment period (74 FR 61749 through 61750), we discussed the Medicare Payment Advisory Commission's (MedPAC's) comment that in the future, "CMS should consider alternatives to collecting specialty-specific cost data or options to decrease the reliance on such data." We agreed with MedPAC that it would be appropriate to consider the future of the PE RVUs moving forward. We sought comments from other stakeholders on the issues raised by MedPAC for the future. In particular, we requested public comments regarding MedPAC's suggestion that we consider alternatives for collecting specialty-specific cost data or options to decrease the reliance on such data. We noted MedPAC's comment that, "CMS should consider if Medicare or provider groups should sponsor future data collection efforts, if participation should be voluntary (such as surveys) or mandatory (such as cost reports), and whether a nationally representative sample of practitioners would be sufficient for either a survey or cost reports." MedPAC also stated that one option for decreasing the reliance on specialty-specific cost data would be the elimination of the use of indirect PE/HR data in the last step of establishing the indirect cost portion of the PE RVUs as described previously.

Almost all of the commenters on the CY 2010 PFS final rule with comment period that addressed this issue expressed a general willingness to work with CMS on methodological improvements or future data collection efforts. Although no commenters detailed a comprehensive overall alternative methodology, several commenters did provide suggestions regarding future data collection efforts

and specific aspects of the current methodology.

The commenters on the CY 2010 PFS final rule with comment period that addressed the issue of surveys supported the use of surveys if they yielded accurate PE information. The few commenters that addressed the issue of cost reports were opposed to physician cost reports. The commenters varied with respect to their opinions regarding whether data collection efforts should be led by organized medicine, individual specialty societies, or CMS. Several commenters that addressed the issue of voluntary versus mandatory data collection efforts supported voluntary data collection efforts and opposed mandatory data collection efforts.

Some commenters recommended no changes to the methodology or PE data in the near future. Other commenters indicated that the methodology and data changes needed to be made for CY 2011. Although most commenters did not directly address the use of the indirect PE/HR data, those that did predominately opposed the elimination of the use of these data.

Many commenters addressed specifics of the PE methodology (as further described in section II.A.2.c. of this final rule with comment period). Some were opposed to the scaling factor applied in the development of the direct PE portion of the PE RVUs so that in the aggregate the direct portion of the PE RVUs do not exceed the proportion indicated by the survey data (See Step 4 in g.(ii) below). Several of these commenters advocated the elimination of this direct scaling factor, while others indicated that the issue should be examined more closely.

A few commenters recommended that physician work not be used as an allocator in the development of the indirect portion of the PE RVUs as described earlier in this section. A few indicated that physician time, but not physician work, should be used in the allocation. Other commenters suggested that indirect costs should be allocated solely on the basis of direct costs.

We note that many of the issues raised by commenters on the CY 2010 PFS final rule with comment period are similar to issues raised in the development of the original resource-based PE methodology and in subsequent revisions to the methodology, including the adoption of the bottom-up methodology. While we did not propose a broad methodological change or broad data collection effort in the CY 2011 PFS proposed rule, we invited comments on our summary of the issues raised by the commenters on

the CY 2010 PFS final rule with comment period, as discussed in the CY 2011 PFS proposed rule (75 FR 40050). The complete public comments on the CY 2010 PFS final rule with comment period are available for public review at <http://www.regulations.gov> by entering "CMS-1413-FC" in the search box on the main page.

Comment: A number of commenters believe the PPIS data are flawed and, therefore, should not be used to set the PE RVUs for all or certain categories of PFS services. Other commenters supported the adoption of the PPIS data and, whether ultimately favoring the adoption of the PPIS data or not, many commenters stated that the 4-year transition adopted by CMS is important to physicians and Medicare beneficiaries to ensure access to care. The commenters explained that the transition gives physician specialty societies the opportunity to collect new and more detailed data where appropriate for refinement and CMS the opportunity to more carefully analyze the new data and its appropriateness. Although once again the commenters did not provide specific recommendations on alternatives to a comprehensive survey of practice expenses or options to decrease the PFS reliance on specialty-specific cost data, the commenters offered the following suggestions regarding future practice expense data collection.

- Select a reputable company with experience in health care market research.
- Base changes on a comprehensive data source with adequate participation rates.
- Have data independently reviewed in order to ensure accuracy.
- Make data publicly available in time to allow for review and comment by stakeholders.

Several commenters emphasized the administrative complexity and burden if CMS were to require all physicians to submit cost reports. One commenter supported a limited study of practice costs estimated by cost reports to determine if the current PE RVUs were appropriately paying physicians for the physician's office costs of services. The commenter believes that cost reports would be more accurate than the PPIS methodology. Finally, several commenters indicated a willingness to engage CMS in more detailed discussion about potential refinements to the current PE/HR data.

Response: We appreciate the commenters' recommendations regarding factors we should consider in developing future practice expense data collection efforts in order to improve the

accuracy of the information. While we are continuing the transition that was adopted in the CY 2010 PFS final rule with comment period (74 FR 61751) under the CY 2011 PFS to full implementation of the PPIS data for the CY 2013 PFS PE RVUs, we continue to remain interested in the thoughts of stakeholders regarding the MedPAC comment that "CMS should consider alternatives to collecting specialty-specific cost data or options to decrease the reliance on such data." More specifically, we encourage stakeholders to contact us at any time if they encounter additional information to share, develop further ideas or analyses that could inform our ongoing consideration of physicians' practice expenses, or otherwise would like to discuss this topic further as part of an open dialogue with us. While to date, no stakeholders have presented a comprehensive overall alternative methodology, we remain interested in potential novel or refined approaches. We also continue to welcome more limited suggestions for improvements to our current PE methodology or future practice expense information collection activities.

g. PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period with comment period (74 FR 61745 through 61746).

(1) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data from the surveys.

(2) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the current aggregate pool of direct PE costs. This is the product of the current aggregate PE (aggregate direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data.

Step 3: Calculate the aggregate pool of direct costs. This is the sum of the product of the direct costs for each service from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3 calculate a direct PE scaling adjustment so that the aggregate direct cost pool does not exceed the current aggregate direct cost pool and apply it

to the direct costs from Step 1 for each service.

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(3) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global components.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs, the clinical PE RVUs, and the work RVUs.

For most services the indirect allocator is: Indirect percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs.

Note: For global services, the indirect allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 2, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVUs, clinical PE RVUs, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services performed by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global components, PCs, and TCs. Under this method, the

indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global component.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment, MEI rebasing adjustment, and multiple procedure payment reduction (MPPR) adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 (prior to the MEI rebasing and MPPR adjustments) to the current pool of PE RVUs. This final BN adjustment is required primarily because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but all specialties are included for purposes of calculating the final BN adjustment. (See "Specialties excluded from ratesetting calculation" below in this section.)

As discussed in section II.E.5. of this final rule with comment period, we are rebasing and revising the Medicare Economic Index (MEI) for CY 2011. As discussed in section II.C.4. of this final rule with comment period, section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service. There is inherent duplication in the PE associated with those services which are frequently furnished together, so reducing PFS payment for the second and subsequent services to account for the efficiencies in multiple service sessions may be appropriate. Consistent with this provision of the ACA, we are adopting a limited expansion of the current MPPR policy for imaging services for CY 2011 and a new MPPR policy for therapy services.

(5) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESSETTING CALCULATION

Specialty code	Specialty description
42	Certified nurse midwife.
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Individuals not included in 55, 56, or 57.
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (e.g., drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
95	Competitive Acquisition Program (CAP) Vendor.
96	Optician.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
1	Supplier of oxygen and/or oxygen related equipment.
2	Pedorthic personnel.
3	Medical supply company with pedorthic personnel.

- Crosswalk certain low volume physician specialties: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

- Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

- Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000

(Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

- Payment modifiers: Payment modifiers are accounted for in the creation of the file. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier.

- Work RVUs: The setup file contains the work RVUs from this final rule with comment period.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

$$\frac{1}{(minutes\ per\ year * usage)} * price * \left(\frac{interest\ rate}{1 - (1 / (1 + interest\ rate))} \right) +$$

$$rate) \wedge life\ of\ equipment))) + maintenance)$$

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.
 usage = equipment utilization assumption; 0.75 for certain expensive diagnostic imaging equipment (see 74 FR 61753 through 61755 and section II.A.3. of this final rule with comment period) and 0.5 for others.

price = price of the particular piece of equipment.

interest rate = 0.11.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

Note: The use of any particular conversion factor (CF) in Table 2 to illustrate the PE calculation has no effect on the resulting RVUs.

TABLE 2—CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est Non-facility	33533 CABG, arterial, single facility	71020 Chest x-ray Nonfacility	71020-TC Chest x-ray Nonfacility	71020-26 Chest x-ray Nonfacility	93000 ECG, complete Non-facility	93005 ECG, tracing Non-facility	93010 ECG, report Nonfacility
(1) Labor cost (lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	6.12	6.12	0.00
(2) Supply cost (sup)	Step 1	AMA		2.98	7.34	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (exp)	Step 1	AMA		0.19	0.65	8.17	8.17	0.00	0.12	0.12	0.00
(4) Direct cost (dir)	Step 1		$= (1) + (2) + (3)$	16.50	85.51	17.31	17.31	0.00	7.43	7.43	0.00
(5) Direct adjustment (dir adj)	Steps 2-4	See footnote*		0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
(6) Adjusted labor	Steps 2-4	=Lab * Dir adj	$= (1) * (5)$	6.68	38.87	2.88	2.88	0.00	3.07	3.07	0.00
(7) Adjusted supplies	Steps 2-4	=Sup * Dir adj	$= (2) * (5)$	1.50	3.68	1.70	1.70	0.00	0.60	0.60	0.00
(8) Adjusted equipment	Steps 2-4	=Exp * Dir adj	$= (3) * (5)$	0.10	0.33	4.10	4.10	0.00	0.06	0.06	0.00
(9) Adjusted direct	Steps 2-4		$= (6) + (7) + (8)$	8.27	42.87	8.68	8.68	0.00	3.73	3.73	0.00
(10) Conversion factor (CF)	Step 5	PFS		36.87	36.87	36.87	36.87	36.87	36.87	36.87	36.87
(11) Adj labor cost converted	Step 5	=(Lab * Dir adj)/CF	$= (6)/(10)$	0.18	1.05	0.08	0.08	0.00	0.08	0.08	0.00
(12) Adj supply cost converted	Step 5	=(Sup * Dir adj)/CF	$= (7)/(10)$	0.04	0.10	0.05	0.05	0.00	0.02	0.02	0.00
(13) Adj equipment cost converted	Step 5	=(Exp * Dir adj)/CF	$= (8)/(10)$	0.01	0.01	0.11	0.11	0.00	0.00	0.00	0.00
(14) Adj direct cost converted	Step 5		$= (11) + (12) + (13)$	0.22	1.16	0.24	0.24	0.00	0.10	0.10	0.00
(15) Work RVUs	Setup File	PFS		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir pct	Steps 6,7	Surveys		0.26	0.18	0.29	0.29	0.29	0.29	0.29	0.29
(17) Ind pct	Steps 6,7	Surveys		0.74	0.82	0.71	0.71	0.71	0.71	0.71	0.71
(18) Ind alloc formula (1st part)	Step 8	See Step 8		$((14)/(16)) * (17)$	$((14)/(16)) * (17)$	$((14)/(16)) * (17)$	$((14)/(16)) * (17)$	$((14)/(16)) * (17)$	$((14)/(16)) * (17)$	$((14)/(16)) * (17)$	$((14)/(16)) * (17)$
(19) Ind alloc (1st part)	Step 8		See (18)	0.65	5.29	0.58	0.00	0.25	0.25	0.25	0.00
(20) Ind alloc formulas (2nd part)	Step 8	See Step 8		(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
(21) Ind alloc (2nd part)	Step 8		See (20)	0.97	33.75	0.30	0.08	0.22	0.25	0.08	0.17
(22) Indirect allocator (1st + 2nd)	Step 8		$= (19) + (21)$	1.62	39.04	0.88	0.66	0.22	0.50	0.33	0.17
(23) Indirect adjustment (ind adj)	Steps 9-11	See footnote**		0.37	0.37	0.37	0.37	0.37	0.37	0.37	0.37
(24) Adjusted indirect allocator	Steps 9-11	=ind alloc * ind adj		0.60	14.47	0.33	0.24	0.08	0.19	0.12	0.06
(25) Ind. practice cost index (IPCI)	Steps 12-16	See Steps 12-16		1.11	0.83	0.90	0.90	0.90	0.92	0.92	0.92
(26) Adjusted indirect	Step 17	= Adj ind alloc * IPCI	$= (24) * (25)$	0.67	12.04	0.29	0.22	0.07	0.17	0.11	0.06
(27) MEI rebasing adjustment	Step 18	PFS		1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18
(28) MPPR adjustments	Step 18	PFS		1.01	1.01	1.01	1.01	1.01	1.01	1.01	1.01
(29) PE RVU	Step 18	=(Adj dir + Adj ind) * budn * MEI adj * MPPR adj.	$= (14) + (26) * budn * MEI adj * MPPR adj.$	1.06	15.68	0.63	0.54	0.09	0.32	0.25	0.07

Note:

PE RVUs in Table 2, row 29, may not match the values in Addendum B due to rounding.
 * The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [Step 2]/[Step 3].
 ** The indirect adj = [current pe rvus * avg ind pct]/[sum of ind allocators] = [Step 9]/[Step 10].

3. PE Revisions for CY 2011

a. Equipment Utilization Rate

As part of the PE methodology associated with the allocation of equipment costs for calculating PE RVUs, we currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment (which is equipment priced at over \$1 million, for example, computed tomography (CT) and magnetic resonance imaging (MRI) scanners), for which we adopted a 90 percent utilization rate assumption and provided for a 4-year transition beginning in CY 2010 (74 FR 61755). Therefore, CY 2010 is the first transitional payment year. Payment is made in CY 2010 for the diagnostic services listed in Table 3 (those that include expensive diagnostic imaging equipment in their PE inputs) of the CY 2011 PFS proposed rule (75 FR 40054) based on 25 percent of the new PE RVUs and 75 percent of the prior PE RVUs for those services.

Section 1848(b)(4)(C) of the Act (as added by section 3135(a) of the ACA) requires that with respect to fee schedules established for CY 2011 and subsequent years, in the methodology for determining PE RVUs for expensive diagnostic imaging equipment under the CY 2010 PFS final rule with comment period, the Secretary shall use a 75 percent assumption instead of the utilization rates otherwise established in that rule. The provision also requires that the reduced expenditures attributable to this change in the utilization rate for CY 2011 and subsequent years shall not be taken into account when applying the budget neutrality limitation on annual adjustments described in section 1848(c)(2)(B)(ii)(II) of the Act:

As a result, the 75 percent equipment utilization rate assumption will be applied to expensive diagnostic imaging equipment in a non-budget neutral manner for CY 2011, and the resulting changes to PE RVUs will not be transitioned over a period of years. We will apply the 75 percent utilization rate assumption in CY 2011 to all of the services to which we currently apply the transitional 90 percent equipment utilization rate assumption in CY 2010. These services are listed in a file on the CMS Web site that is posted under downloads for the CY 2010 PFS final rule with comment period at http://www.cms.gov/physicianfeesched/downloads/CODES_SUBJECT_TO_90PCT_USAGE_RATE.zip. These codes are also displayed in Table 3 at the end of this section.

Comment: Several commenters argued that the 75 percent utilization rate assumption should not be applied because of the imprecise data on which the policy was based. The commenters explained that based on an independent survey, actual equipment utilization rates are close to 50 percent. In addition, the commenters postulated that rural imaging centers would be adversely affected by the change due to lower equipment utilization rates than non-rural centers. The commenters requested that CMS base equipment utilization rate assumptions on actual utilization data rather than assumptions.

Several other commenters supported the implementation of the 75 percent utilization rate assumption, and MedPAC recommended that CMS explore increasing the equipment utilization rate assumption for diagnostic imaging equipment that costs less than \$1 million. Finally, several commenters clarified that certain procedures were not subject to the provision, including nuclear cardiology services and therapeutic interventional radiology.

Response: Section 1848(b)(4)(C) of the Act (as added by section 3135(a) of the ACA) requires that with respect to fee schedules established for CY 2011 and subsequent years, in the methodology for determining PE RVUs for expensive diagnostic imaging equipment under the CY 2010 PFS final rule with comment period, the Secretary shall use a 75 percent assumption instead of the utilization rates otherwise established in that rule. We acknowledge that further data regarding actual equipment utilization in the physician's office setting may be informative, but our use of such data to set the equipment utilization rate assumption for expensive diagnostic imaging equipment at a value other than 75 percent would require a statutory change.

We did not propose to expand the 75 percent equipment utilization rate assumption for CY 2011 to other procedures beyond those that use CT and MRI scanners as listed in Table 4 of the CY 2011 PFS proposed rule (75 FR 40055) and Table 3 at the end of this section. Any future changes in equipment utilization rate assumptions, including any expansion of the 75 percent equipment utilization rate assumption to additional expensive diagnostic imaging equipment, would be made through the annual PFS notice and comment rulemaking cycle. Furthermore, any changes in equipment utilization rate assumptions for less costly diagnostic imaging equipment (less than \$1 million) or for therapeutic

imaging or other equipment would not be subject to the statutory provision that specifies a 75 percent assumption. We note that we are constantly reassessing our methodology for developing the PE RVUs and would propose any changes to the equipment utilization rate assumptions for these types of equipment through the annual PFS rulemaking cycle if we determine such changes could be appropriate.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal without modification. The 75 percent equipment utilization rate assumption will be applied to expensive diagnostic imaging equipment in a non-budget neutral manner for CY 2011, and the changes to the PE RVUs will not be transitioned over a period of years. We will apply the 75 percent utilization rate assumption in CY 2011 to all of the services to which we currently apply the transitional 90 percent utilization rate assumption in CY 2010. The CY 2011 codes are displayed in Table 3 at the end of this section that lists all the codes to which the 75 percent equipment utilization rate assumption applies for CY 2011. In addition, the codes subject to this policy are posted under the downloads for the CY 2011 PFS final rule with comment period on the CMS Web site at <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

Additionally, for CY 2011, we proposed to expand the list of services to which the higher equipment utilization rate assumption applies to include all other diagnostic imaging services that utilize similar expensive CT and MRI scanners. The additional 24 CPT codes (listed in Table 4 of the CY 2011 PFS proposed rule (75 FR 40055)) to which we proposed to apply the 75 percent equipment utilization rate assumption also have expensive diagnostic imaging equipment (priced at over \$1 million) included in their PE inputs. These services are predominantly diagnostic computed tomographic angiography (CTA) and magnetic resonance angiography (MRA) procedures that include similar expensive CT and MRI scanners in their direct PE inputs. We indicated in the CY 2010 PFS final rule with comment period (74 FR 61754) that we were persuaded by PPIS data on angiography that the extrapolation of MRI and CT data (and their higher equipment utilization rate) may be inappropriate. However, this reference was limited to those procedures that include an angiography room in the direct PE inputs, such as CPT code 93510 (Left heart catheterization, retrograde, from

the brachial artery, axillary artery or femoral artery; percutaneous). In contrast, CTA and MRA procedures include a CT room or MRI room, respectively, in the direct PE inputs, and the PPIS data confirm that a higher assumed utilization rate than 50 percent would be appropriate. The PPIS angiography room data that reflected a 56 percent equipment utilization rate would not specifically apply to CTA and MRA procedures. Thus, on further review, we believe it is appropriate to include CTA and MRA procedures in the list of procedures for which we assume a 75 percent equipment utilization rate, and we proposed to do so beginning in CY 2011.

Consistent with section 1848(c)(2)(B)(v)(III) of the Act (as amended by section 3135 of the ACA), the reduced expenditures attributable to this change in the utilization rate assumption applicable to CY 2011 shall not be taken into account when applying the budget neutrality limitation on annual adjustments described in section 1848(c)(2)(B)(ii)(II) of the Act.

As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), CY 2011 is the second year of the 4-year transition to the PE RVUs calculated using the PPIS data. We note that the reductions in the PE RVUs for expensive diagnostic imaging equipment attributable to the change to an equipment utilization rate assumption of 75 percent for CY 2011 are not subject to the transition.

Comment: Several commenters urged CMS not to finalize the proposed expansion of the list of procedures to which the 75 percent equipment utilization rate assumption would apply, pending further evaluation of equipment utilization data. While noting the statutory requirement of section 1848(b)(4)(C) of the Act (as added by section 3135(a) of the ACA), the commenters believe that CMS is not required to add additional services to the policy for CY 2011. Other commenters, including MedPAC, supported the proposed increase in the equipment utilization rate assumption from 50 percent to 75 percent for the 24 additional services that use diagnostic imaging equipment priced at over \$1 million.

Response: No commenters presented a rationale for not including the proposed 24 additional services to the 75 percent equipment utilization rate assumption, when the proposed additions use the same diagnostic CT or MRI imaging equipment as the current codes to which the policy applies. We note that the 90 percent equipment utilization rate assumption that we finalized in the CY 2010 PFS final rule with comment period (74 FR 61755) applies to CT and MRI scanners when used as diagnostic imaging equipment, one of these two pieces of equipment is listed as a direct PE input for the proposed MRA and CTA services, and no commenters recommended that we remove the CT or MRI equipment inputs from the additional codes. Therefore, we continue to believe that it is appropriate to apply the 75 percent equipment utilization rate assumption beginning in CY 2011 to MRA and CTA procedures, as we proposed.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to include CTA and MRA procedures in the 75 percent equipment utilization rate assumption policy because they include expensive CT and MRI scanners that cost more than \$1 million as direct PE inputs for these diagnostic imaging procedures. We are modifying our proposal, however, and will not include CPT code 77079 (Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)) because, upon further analysis for this final rule with comment period, we noted that the procedure does not include a CT room in its direct PE inputs.

For CY 2011, we are also adding to the 75 percent equipment utilization rate assumption policy three new CY 2011 CPT codes for diagnostic imaging procedures that include a CT room in their direct PE inputs, specifically CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material); 74177 (Computed tomography, abdomen and pelvis; with contrast material); and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with

contrast material(s) and further sections in one or both body regions). As new codes for CY 2011, the work, PE, and malpractice RVUs for these CPT codes that are displayed in Addendum C to this final rule with comment period are interim final values that are open to comment. Similarly, the assignment of the 75 percent equipment utilization rate assumption to these CPT codes, which contributes to the development of their PE RVUs, is being made on an interim final basis. We refer readers to section V.C. of this final rule with comment period for further discussion of the establishment of interim final RVUs for CY 2011 new and revised codes.

As a result of the CY 2011 changes, the 75 percent equipment utilization rate assumption will be applied to all diagnostic imaging procedures with nationally established rates under the PFS in CY 2011 and which include a CT or MRI scanner in their direct PE, consistent with the statutory requirement of section 1848(b)(4)(C) of the Act (as added by section 3135(a) of the ACA).

Consistent with section 1848(c)(2)(B)(v)(III) of the Act (as amended by section 3135 of the ACA), the reduced expenditures attributable to the change in the utilization rate assumption applicable to CY 2011 (from the CY 2011 transitional rate for the 90 percent equipment utilization rate assumption for expensive diagnostic imaging equipment costing over \$1 million (CT and MRI scanners) that would have applied under the final policy established in the CY 2010 PFS final rule with comment period to the 75 percent rate required under section 1848(b)(4)(C) of the Act) shall not be taken into account when applying the budget neutrality limitation on annual adjustments described in section 1848(c)(2)(B)(ii)(II) of the Act.

Table 3 below lists the codes to which the 75 percent equipment utilization rate assumption applies for CY 2011. The codes subject to this policy are also posted under the downloads for the CY 2011 PFS final rule with comment period on the CMS Web site at <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

TABLE 3—FINAL CPT CODES SUBJECT TO 75 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION IN CY 2011

CPT code	Short descriptor
70336	Mri, temporomandibular joint(s).
70450	Ct head/brain w/o dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70480	Ct orbit/ear/fossa w/o dye.

TABLE 3—FINAL CPT CODES SUBJECT TO 75 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION IN CY 2011—
Continued

CPT code	Short descriptor
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
70486	Ct maxillofacial w/o dye.
70487	Ct maxillofacial w/dye.
70488	Ct maxillofacial w/o & w/dye.
70490	Ct soft tissue neck w/o dye.
70491	Ct soft tissue neck w/dye.
70492	Ct soft tissue neck w/o & w/dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
70540	Mri orbit/face/neck w/o dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbit/face/neck w/o & w/dye.
70544	Mri angiography head w/o dye.
70545	Mri angiography head w/dye.
70546	Mri angiography head w/o & w/dye.
70547	Mri angiography neck w/o dye.
70548	Mri angiography neck w/dye.
70549	Mri angiography neck w/o & w/dye.
70551	Mri brain w/o dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
70554	Fmri brain by tech.
71250	Ct thorax w/o dye.
71260	Ct thorax w/dye.
71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.
71550	Mri chest w/o dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
71555	Mri angio chest w/or w/o dye.
72125	CT neck spine w/o dye.
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/dye.
72128	Ct chest spine w/o dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/dye.
72131	Ct lumbar spine w/o dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/dye.
72141	Mri neck spine w/o dye.
72142	Mri neck spine w/dye.
72146	Mri chest spine w/o dye.
72147	Mri chest spine w/dye.
72148	Mri lumbar spine w/o dye.
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72159	Mri angio spine w/o & w/dye.
72191	Ct angiography, pelv w/o & w/dye.
72192	Ct pelvis w/o dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
72195	Mri pelvis w/o dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
72198	Mri angio pelvis w/or w/o dye.
73200	Ct upper extremity w/o dye.
73201	Ct upper extremity w/dye.
73202	Ct upper extremity w/o & w/dye.
73206	Ct angio upper extr w/o & w/dye
73218	Mri upper extr w/o dye.
73219	Mri upper extr w/dye.
73220	Mri upper extremity w/o & w/dye.
73221	Mri joint upper extr w/o dye.
73222	Mri joint upper extr w/dye.
73223	Mri joint upper extr w/o & w/dye.
73225	Mri angio upr extr w/o & w/dye.
73700	Ct lower extremity w/o dye.
73701	Ct lower extremity w/dye.

TABLE 3—FINAL CPT CODES SUBJECT TO 75 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION IN CY 2011—Continued

CPT code	Short descriptor
73702	Ct lower extremity w/o & w/dye.
73706	Ct angio lower extr w/o & w/dye.
73718	Mri lower extremity w/o dye.
73719	Mri lower extremity w/dye.
73720	Mri lower extr w/& w/o dye.
73721	Mri joint of lwr extre w/o dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint of lwr extr w/o & w/dye.
73725	Mri angio lower extr w or w/o dye.
74150	Ct abdomen w/o dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/dye.
74175	Ct angio abdom w/o & w/dye.
74176	Ct abd & pelvis w/o contrast.
74177	Ct abdomen & pelvis w/contrast.
74178	Ct abd & pelv 1+ section/regns.
74181	Mri abdomen w/o dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o and w/dye.
74185	Mri angio, abdom w/or w/o dye.
74261	Ct colonography, w/o dye.
74262	Ct colonography, w/dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
75561	Cardiac mri for morph w/dye.
75563	Cardiac mri w/stress img & dye.
75565	Card mri vel flw map add-on.
75571	Ct hrt w/o dye w/ca test.
75572	Ct hrt w/3d image.
75573	Ct hrt w/3d image, congen.
75574	Ct angio hrt w/3d image.
75635	Ct angio abdominal arteries.
76380	CAT scan follow up study.
77058	Mri, one breast.
77059	Mri, both breasts.
77078	Ct bone density, axial.
77084	Magnetic image, bone marrow.

b. HCPCS Code-Specific PE Issues

In this section, we discuss other specific CY 2011 proposals and changes related to direct PE inputs. The changes that follow were proposed in the CY 2011 PFS proposed rule and included in the proposed CY 2011 direct PE database, which is available on the CMS Web site under the downloads for the CY 2011 PFS proposed rule at <http://www.cms.gov/PhysicianFeeSched/>. The final direct PE database for CY 2011 is available under the downloads for the CY 2011 PFS final rule with comment period at the same location.

(1) Biohazard Bags

We identified 22 codes for which the supply item “biohazard bag” (SM004) is currently considered a direct PE input. The item is already properly accounted for in the indirect PE because it is not attributable to an individual patient service. Therefore, we proposed to remove the biohazard bag from the CY 2011 direct PE database and noted that the changes in direct PE inputs for the

associated services were reflected in the proposed CY 2011 direct PE database.

We did not receive any public comments on our proposal to remove biohazard bags as a supply input. Therefore, we are finalizing our CY 2011 proposal to remove the supply item as a direct PE input for the associated services. This change is reflected in the final CY 2011 direct PE database.

(2) PE Inputs for Professional Component (PC) Only and Technical Component (TC) Only Codes Summing to Global Only Codes

In the case of certain diagnostic tests, different but related CPT codes are used to describe global, professional, and technical components of a service. These codes are unlike the majority of other diagnostic test CPT codes where modifiers may be used in billing a single CPT code in order to differentiate professional and technical components. When different but related CPT codes are used to report the components of these services, the different CPT codes are referred to as “global only,”

“professional component (PC) only,” and “technical component (TC) only” codes. Medicare payment systems are programmed to ensure that the PE RVUs for global only codes equal the sum of the PE RVUs for the PC and TC only codes. However, it came to our attention that the direct PE inputs for certain global only codes do not reflect the appropriate summation of their related TC only and PC only component code PE inputs as they appear in the direct PE database. While the PFS payment calculations have been programmed to apply the correct PE RVUs for the global only code based on a summation of component code PE RVUs, the direct PE database has reflected incorrect inputs that are overridden by the payment system. Therefore, we proposed to correct the direct PE inputs for the global only codes so that the inputs reflect the appropriate summing of the PE inputs for the associated PC only and TC only codes. The proposed CY 2011 direct PE database included PE

corrections to the 14 CPT codes listed in Table 4.

TABLE 4—GROUPS OF RELATED CPT CODES WITH PROPOSED CHANGES TO PE INPUTS SO THAT INPUTS FOR PROFESSIONAL COMPONENT (PC) ONLY AND TECHNICAL COMPONENT (TC) ONLY CODES SUM TO GLOBAL ONLY CODES

CPT Code	Long descriptor
93224	Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage, with visual superimposition scanning; includes recording, scanning analysis with report, physician review and interpretation.
93225	Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage, with visual superimposition scanning; recording (includes connection, recording, disconnection).
93226	Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage, with visual superimposition scanning; scanning analysis with report.
93230	Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage without superimposition scanning utilizing a device capable of producing a full miniaturized printout; including recording, microprocessor-based analysis with report, physician review and interpretation.
93231	Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage without superimposition scanning utilizing a device capable of producing a full miniaturized printout; recording (includes connection, recording, and disconnection).
93232	Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage without superimposition scanning utilizing a device capable of producing a full miniaturized printout; microprocessor-based analysis with report.
93268	Wearable patient activated electrocardiographic rhythm derived event recording with presymptom memory loop, 24-hour attended monitoring, per 30 day period of time; includes transmission, physician review and interpretation.
93270	Wearable patient activated electrocardiographic rhythm derived event recording with presymptom memory loop, 24-hour attended monitoring, per 30 day period of time; recording (includes connection, recording, and disconnection).
93271	Wearable patient activated electrocardiographic rhythm derived event recording with presymptom memory loop, 24-hour attended monitoring, per 30 day period of time; monitoring, receipt of transmissions, and analysis.
93720	Plethysmography, total body; with interpretation and report.
93721	Plethysmography, total body; tracing only, without interpretation and report.
93784	Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report.
93786	Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only.
93788	Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report.

Comment: A number of commenters expressed support for CMS' proposal to ensure that the direct PE inputs for certain global only codes reflect the appropriate summation of their related TC only and PC only component code PE inputs as they appear in the direct PE database. One commenter questioned why the prior clinical labor time for the global only codes in the PE database did not match the direct PE inputs that must have been used in CY 2010 to generate the PE RVUs, given that the PE RVUs for the global only codes were the sum of the PE RVUs for the component codes.

Response: We appreciate the commenters' support for the proposal, and we are finalizing our correction of the direct PE inputs for the global only codes so that the inputs reflect the appropriate summing of the PE inputs for the associated PC only and TC only codes. In response to the commenter who questioned why prior clinical labor time for the global only codes in the PE database did not match the direct PE inputs that must have been used to generate the PE RVUs for payment, we note that Medicare payment systems are programmed to ensure that the PE RVUs for global only codes equal the sum of

the PE RVUs for the PC and TC only codes. Therefore, rather than relying upon the direct PE inputs for the global only codes to determine the PE RVUs, which would have not resulted in values that equaled the summation of the component code PE RVUs, our PFS system was programmed so that the PE RVUs for the global only codes were set as the sum of the PE RVUs for the component codes. We expect the corrections to the inputs as incorporated in the direct PE database to alleviate any confusion caused by the prior inclusion of inputs associated with the global only codes that were not actually used to generate the PE RVUs.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to correct the direct PE inputs for the global only codes so that the inputs reflect the appropriate summing of the PE inputs for the associated PC only and TC only codes. The final CY 2011 direct PE database includes PE corrections to the 14 CPT codes listed in Table 4.

(3) Equipment Time Inputs for Certain Diagnostic Tests

In the CY 2011 PFS proposed rule (75 FR 40056), we stated that we had recently identified equipment time PE inputs that we believed were incorrect for four CPT codes associated with certain diagnostic tests (each is displayed in Table 4):

- CPT code 93225 is the TC only code that includes the connection, recording, and disconnection of the holter monitor (CMS Equipment Code EQ127) used in 24-hour continuous electrocardiographic rhythm derived monitoring. The CY 2010 equipment time input for the holter monitor is 42 minutes, which parallels the intra-service clinical labor input time for the CPT code. However, we believed that the equipment time should reflect the 24 hours of continuous monitoring in which the device is used exclusively by the patient. Therefore, we proposed to change the monitor equipment time for CPT code 93225 to 1440 minutes, the number of minutes in 24 hours.

- CPT code 93226 is the TC only code that includes the scanning analysis with report. We believed that the number of minutes the monitor (CMS Equipment

Code EQ127) is used in this service should parallel the intra-service clinical labor input time of 52 minutes during which the monitor is in use, instead of the CY 2010 equipment time of 1440 minutes, because this code does not represent 24 hours of device use. Therefore, we proposed to change the monitor equipment time for CPT code 93226 to 52 minutes.

- CPT 93224 is the global only code that includes the connection, recording, and disconnection of the monitor (CMS Equipment Code EQ127) and the scanning analysis with report, as well as the physician review and interpretation. We proposed direct PE inputs for CPT code 93224 to include 1492 total minutes of monitor time (which represents the total monitor time we proposed for CPT codes 93225 and 93226).

- CPT code 93788 is the TC only code that describes the scanning analysis with report for ambulatory blood pressure monitoring. We believed that the equipment time input for the blood pressure monitor should parallel the 10 minutes of clinical labor input for the CPT code since that is the time during which the monitor is in use. In CY 2010, the equipment time input for the monitor is 1440 minutes, which is appropriate only for CPT code 93786, the code that describes the 24 hours of ambulatory blood pressure monitoring recording. Therefore, we proposed to correct the equipment time input for the ambulatory blood pressure monitor in CPT code 93788 to 10 minutes.

- CPT code 93784 is the global only code that includes the recording, the scanning analysis with report, and the physician interpretation and report for ambulatory blood pressure monitoring. We proposed to establish the direct PE inputs for CPT code 93784 to include 1450 total minutes of time for the ambulatory blood pressure monitor (which represents the proposed total amount of monitor time included in CPT codes 93786 and 93788).

The proposed CY 2011 direct PE database reflected these changes.

Comment: Several commenters pointed out that the prior assignment of the 1440 minutes of holter monitor equipment time to CPT code 93226 stemmed from discussions between CMS and provider groups that resulted in PE policies initially implemented in CY 2007 (72 FR 18910). The commenters recommended that CMS retain the 1440 minutes of holter monitor equipment for CPT code 93226, consistent with current policy, rather than reassign the 1440 minutes of holter monitor equipment time as proposed to CPT code 93226.

Response: We agree with the commenters that it would be most appropriate to maintain our established policy for the equipment times associated with CPT codes 93225 and 93226, based upon further description of the direct practice expenses experienced by the current providers that typically furnish these services to Medicare beneficiaries. Therefore, we are not adopting the equipment time changes that we proposed for CPT codes 93225 and 93226. However, we are revising the direct PE inputs for CPT code 93224, a global only code, to include the total equipment time for the holter monitor that is incorporated in component codes CPT codes 93225 and 93226, as discussed in section II.A.3.b.(2) of this final rule with comment period. The PE inputs for CPT code 93224 did not previously correctly reflect the summation of the direct PE inputs for the component codes.

Comment: One commenter supported the proposed changes to the direct PE inputs for CPT codes 93784 through 93788. However, the commenter was confused about why 1440 minutes of equipment time were assigned to CPT code 93786, which the commenter stated is used only for the technical component of scanning the data rather than recording the data.

Response: As we stated in our proposal, we believe that the direct PE inputs for CPT code 93786 are currently correct because the code describes the recording of the data. We believe that the commenter may have inadvertently referred to CPT code 93786 instead of CPT code 93788, which is the technical component code that describes the scanning rather than the recording of the data. We proposed to remove the 1440 minutes associated with the scanning analysis from the inputs for CPT code 93788, not CPT code 93786.

After consideration of the public comments we received, we are finalizing our CY 2011 proposals to change the ambulatory blood pressure monitor equipment times included as direct PE inputs for CPT codes 938784 and 93788, while maintaining the current equipment time direct PE input for CPT code 93786. However, we are not finalizing our proposals to change the holter monitor equipment times included as direct PE inputs for CPT codes 93225 and 93226, but instead will maintain the inputs for CPT codes 93225 and 93226 as they were for CY 2010. We are also revising the direct PE inputs for CPT code 93224 to include the total equipment time for the holter monitor that is incorporated in CPT codes 93225 and 93226. The equipment

times in the final CY 2011 direct PE database reflect these decisions.

(4) Cobalt-57 Flood Source

Stakeholders requested that CMS reevaluate the useful life of the Cobalt-57 flood source (CMS Equipment Code ER001), given their estimate of approximately 271 days for the source's half-life. The CY 2010 useful life input in the CY 2010 direct PE database for the Cobalt-57 flood source is 5 years. Using publicly available catalogs, we found that the Cobalt-57 flood source is marketed with a useful life of 2 years. Therefore, we proposed to change the useful life input from the current 5 years to 2 years. The Cobalt-57 flood source was included with the revised useful life input for 96 HCPCS codes in the proposed CY 2011 direct PE database.

Comment: One commenter supported the proposal to change the useful life input from 5 years to 2 years for the Cobalt-57 flood source.

Response: We appreciate the commenter's support for our proposal.

After consideration of the public comment we received, we are finalizing our CY 2011 proposal to change the useful life input in the direct PE database for the Cobalt-57 flood source from 5 years to 2 years. This change is included in the final CY 2011 direct PE database.

(5) Venom Immunotherapy

One stakeholder provided updated price information for the venoms used for the five venom immunology CPT codes, specifically 95145 (Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom); 95146 (Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms); 95147 (Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms); 95148 (Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms); 95149 (Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms).

In the CY 2004 PFS final rule with comment period (68 FR 63206), we adopted a pricing methodology that utilizes the average price of a 1 milliliter

dose of venom and adds that price per dose as direct PE inputs for CPT codes 95145 and 95146. When a patient requires three stinging insect venoms, as for CPT code 95147, the price input for a 3-vespid mix is used. This 3-vespid mix price is also used to value CPT codes 95148 (four venoms) and 96149 (five venoms), with the single venom price added once to CPT code 97148 and twice to CPT code 97149.

As requested by the stakeholder, we updated the price inputs for the 1-milliliter dose of venom to \$16.67 and for the 3-vespid mix to \$30.22 in the proposed CY 2011 direct PE database.

Comment: One commenter supported the proposal to update the price inputs for the venoms used for venom immunotherapy.

Response: We appreciate the information provided by stakeholders regarding the price inputs for venom immunotherapy supplies, consistent

with our interest in utilizing accurate market prices as the direct PE inputs for these items.

After consideration of the public comment we received, we are finalizing our CY 2011 proposals to update the price inputs for the 1-milliliter dose of venom to \$16.67 and for the 3-vespid mix to \$30.22 in the CY 2011 direct PE database. These changes are included in the final CY 2011 direct PE database.

(6) Equipment Redundancy

Stakeholders recently brought to our attention that the ECG, 3-channel (with SpO₂, NIBP, temp, resp) (CMS Equipment Code EQ011) incorporates all of the functionality of the pulse oximeter with printer (CMS Equipment Code EQ211). Therefore, in HCPCS codes where CMS Equipment Code EQ011 is present, CMS Equipment Code EQ211 is redundant. On this basis, we proposed to remove the pulse oximeter

with printer (CMS Equipment Code EQ211) as an input for the 118 codes that also contain the ECG, 3-channel (with SpO₂, NIBP, temp, resp) (CMS Equipment Code EQ011). We made these adjustments in the proposed CY 2011 direct PE database.

We received no public comments regarding this proposal to address the pulse oximeter equipment redundancy. Therefore we are finalizing our CY 2011 proposal without modification. We have made these adjustments in the final CY 2011 direct PE database.

(7) Equipment Duplication

We recently identified a number of CPT codes with duplicate equipment inputs in the PE database. We proposed to remove the duplicate equipment items and modified the proposed CY 2011 direct PE database accordingly as detailed in Table 5.

TABLE 5—CPT CODES WITH PROPOSED REMOVAL OF DUPLICATE EQUIPMENT ITEMS IN THE DIRECT PE DATABASE

CPT Code		CMS equipment code for duplicate equipment	Description of equipment
19302	P-mastectomy w/1n removal	EF014 ED005	light, surgical. camera, digital system, 12 megapixel (medical grade).
19361	Breast reconstr w/lat flap	EF031 EQ168	table, power. light, exam.
44157	Colectomy w/ileoanal anast	EF031 EQ168	table, power. light, exam.
44158	Colectomy w/neo-rectum pouch	EF031 EQ168	table, power. light, exam.
56440	Surgery for vulva lesion	EF031 EQ170	table, power. light, fiberoptic headlight w-source.
57296	Revise vag graft, open abd	EF031 EQ170	table, power. light, fiberoptic headlight w-source.
58263	Vag hyst w/t/o & vag repair	EF031	table, power.
59610	Vbac delivery	EF031	table, power.
67228	Treatment of retinal lesion	EL005 EQ230	lane, exam (oph). slit lamp (Haag-Streit), dedicated to laser use.
76813	Ob us nuchal meas, 1 gest	ED024	film processor, dry, laser.
77371	Srs, multisource	EQ211 ED018 EL011	pulse oximeter w-printer. computer workstation, cardiac cath monitoring. room, angiography.
93540	Injection, cardiac cath	EQ011 EQ032 EQ088 EQ211	ECG, 3-channel (with SpO ₂ , NIBP, temp, resp). IV infusion pump. contrast media warmer. pulse oximeter w-printer.
93542	Injection for heart x-rays	ED018 EL011 EQ011 EQ032 EQ088 EQ211	computer workstation, cardiac cath monitoring. room, angiography. ECG, 3-channel (with SpO ₂ , NIBP, temp, resp). IV infusion pump. contrast media warmer. pulse oximeter w-printer.

Comment: One commenter pointed out that the equipment duplication issue for CPT codes 93540 and 93542 is irrelevant because these codes would no longer be reported for Medicare in CY 2011. The commenter stated that the

codes are being replaced by a new set of diagnostic cardiac catheterization CPT codes.

Response: We agree with the commenter's assessment that our proposal for these codes is not relevant

for CY 2011 because these codes are being deleted.

Comment: One commenter reviewed the duplicate inputs and offered a correction regarding CPT code 19302 (Mastectomy, partial (eg, lumpectomy,

tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy). The commenter pointed out that one of the line-items erroneously duplicated (light, surgical, EF014) for that code should have originally been applied to CPT code 19304 (Mastectomy, subcutaneous).

Response: We appreciate the commenter bringing this error to our attention and we agree with the commenter's assessment.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to remove the duplicate equipment items from the CY 2011 direct PE database as

detailed in Table 5, with modification to transfer the duplicate surgical light input from CPT code 19302 to CPT code 19304. These changes are reflected in the final CY 2011 direct PE database.

(8) Establishing Overall Direct PE Supply Price Inputs Based on Unit Prices and Quantities

In the CY 2011 PFS proposed rule (75 FR 40057), we stated that we had identified minor errors in total price inputs for a number of supply items due to mathematical mistakes in multiplying the item unit price and the quantity used in particular CPT codes for the associated services. We proposed to

modify the direct PE database to appropriately include the overall supply price input for a supply item as the product of the unit price and the quantity of the supply item used in the CPT code. Most of the overall supply price input changes were small, and we adjusted the proposed CY 2011 direct PE database accordingly. The CPT and Level II HCPCS codes and associated supplies for nonfacility and facility settings that were subject to these corrections are displayed in Tables 6 and 7, respectively.

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Table 6: Overall Supply Price Calculation Corrections for Nonfacility Settings

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
11952	Therapy for contour defects	SC029	needle, 18-27g
11954	Therapy for contour defects	SC029	needle, 18-27g
15820	Revision of lower eyelid	SA082	pack, ophthalmology visit (w-dilation)
15821	Revision of lower eyelid	SA082	pack, ophthalmology visit (w-dilation)
15822	Revision of upper eyelid	SA082	pack, ophthalmology visit (w-dilation)
17311	Mohs, 1 stage, h/n/hf/g	SG078	tape, surgical occlusive 1in (Blenderm)
17312	Mohs addl stage	SG078	tape, surgical occlusive 1in (Blenderm)
17313	Mohs, 1 stage, t/a/l	SG078	tape, surgical occlusive 1in (Blenderm)
17314	Mohs, addl stage, t/a/l	SG078	tape, surgical occlusive 1in (Blenderm)
21011	Exc face les sc < 2 cm	SH046	lidocaine 1% w-epi inj (Xylocaine w-epi)
21013	Exc face tum deep < 2 cm	SH046	lidocaine 1% w-epi inj (Xylocaine w-epi)
21073	Mnpj of tmj w/anesth	SG079	tape, surgical paper 1in (Micropore)
21076	Prepare face/oral prosthesis	SL047	dental stone powder
21081	Prepare face/oral prosthesis	SK024	film, dental
21310	Treatment of nosc fracture	SB034	mask, surgical, with face shield
23075	Exc shoulder les sc < 3 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
		SH021	bupivacaine 0.25% inj (Marcaine)
24075	Exc arm/elbow les sc < 3 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
		SH021	bupivacaine 0.25% inj (Marcaine)
25075	Exc forearm les sc < 3 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
		SH021	bupivacaine 0.25% inj (Marcaine)
26115	Exc hand les sc < 1.5 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
		SH021	bupivacaine 0.25% inj (Marcaine)
27327	Exc thigh/knee les sc < 3 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
27618	Exc leg/ankle tum < 3 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
28039	Exc foot/toe tum sc > 1.5 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
28043	Exc foot/toe tum sc < 1.5 cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
28045	Exc foot/toe tum deep < 1.5cm	SG056	gauze, sterile 4in x 4in (10 pack uou)
28306	Incision of metatarsal	SA048	pack, minimum multi-specialty visit
28307	Incision of metatarsal	SA048	pack, minimum multi-specialty visit
28310	Revision of big toe	SA048	pack, minimum multi-specialty visit
28312	Revision of toe	SA048	pack, minimum multi-specialty visit
28313	Repair deformity of toe	SA048	pack, minimum multi-specialty visit
28315	Removal of sesamoid bone	SA048	pack, minimum multi-specialty visit
28340	Resect enlarged toe tissue	SA048	pack, minimum multi-specialty visit
28344	Repair extra toe(s)	SA048	pack, minimum multi-specialty visit
28345	Repair webbed toe(s)	SA048	pack, minimum multi-specialty visit
28496	Treat big toe fracture	SA048	pack, minimum multi-specialty visit
28755	Fusion of big toe joint	SA048	pack, minimum multi-specialty visit
28820	Amputation of toe	SA048	pack, minimum multi-specialty visit
28890	High energy eswt, plantar f	SC051	syringe 10-12ml
29870	Knee arthroscopy, dx	SG079	tape, surgical paper 1in (Micropore)
32553	Ins mark thor for rt perq	SB034	mask, surgical, with face shield
36475	Endovenous rf, 1st vein	SC074	iv pressure infusor bag
36592	Collect blood from picc	SG050	gauze, non-sterile 2in x 2in
41530	Tongue base vol reduction	SD009	canister, suction
41805	Removal foreign body, gum	SD134	tubing, suction, non-latex (6ft) with Yankaur tip (1)

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
41806	Removal foreign body,jawbone	SD134	tubing, suction, non-latex (6ft) with Yankauer tip (1)
42107	Excision lesion, mouth roof	SD009	canister, suction
46505	Chemodeneration anal musc	SD009	canister, suction
49411	Ins mark abd/pcf for rt perq	SB034	mask, surgical, with face shield
49440	Place gastrostomy tube perc	SK089	x-ray developer solution
49441	Place duod/jej tube perc	SK089	x-ray developer solution
49442	Place cecostomy tube perc	SK089	x-ray developer solution
49446	Change g-tube to g-j perc	SK089	x-ray developer solution
49450	Replace g/c tube perc	SK089	x-ray developer solution
49451	Replace duod/jej tube perc	SK089	x-ray developer solution
49452	Replace g-j tube perc	SK089	x-ray developer solution
49460	Fix g/colon tube w/device	SK089	x-ray developer solution
49465	Fluoro exam of g/colon tube	SK089	x-ray developer solution
50382	Change ureter stent, percut	SB034	mask, surgical, with face shield
50384	Remove ureter stent, percut	SB034	mask, surgical, with face shield
50385	Change stent via transureth	SB034	mask, surgical, with face shield
50386	Remove stent via transureth	SB034	mask, surgical, with face shield
50387	Change ext/int ureter stent	SB034	mask, surgical, with face shield
50389	Remove renal tube w/fluoro	SB034	mask, surgical, with face shield
51100	Drain bladder by needle	SH047	lidocaine 1%-2% inj (Xylocaine)
51101	Drain bladder by trocar/cath	SH047	lidocaine 1%-2% inj (Xylocaine)
51727	Cystometrogram w/up	SC051	syringe 10-12ml
51728	Cystometrogram w/vp	SC051	syringe 10-12ml
51729	Cystometrogram w/vp&up	SC051	syringe 10-12ml
52649	Prostate laser enucleation	SA048	pack, minimum multi-specialty visit
53855	Insert prost urethral stent	SB024	gloves, sterile
59300	Episiotomy or vaginal repair	SG062	packing, gauze plain 0.25-0.50in (5 yd uou)
59812	Treatment of miscarriage	SA052	pack, post-op incision care (staple)
64490	Inj paravert f jnt c/t 1 lev	SK025	film, dry, radiographic, 8in x 10in
64493	Inj paravert f jnt l/s 1 lev	SH021	bupivacaine 0.25% inj (Marcaine)
		SK025	film, dry, radiographic, 8in x 10in
65272	Repair of eye wound	SA082	pack, ophthalmology visit (w-dilation)
65286	Repair of eye wound	SA082	pack, ophthalmology visit (w-dilation)
66250	Follow-up surgery of eye	SA082	pack, ophthalmology visit (w-dilation)
67031	Laser surgery, eye strands	SA082	pack, ophthalmology visit (w-dilation)
67105	Repair detached retina	SA082	pack, ophthalmology visit (w-dilation)
67110	Repair detached retina	SA082	pack, ophthalmology visit (w-dilation)
67120	Remove eye implant material	SA082	pack, ophthalmology visit (w-dilation)
67228	Treatment of retinal lesion	SA082	pack, ophthalmology visit (w-dilation)
67901	Repair eyelid defect	SA048	pack, minimum multi-specialty visit
75571	Ct hrt w/o dye w/ca test	SJ019	electrode adhesive disk
75572	Ct hrt w/3d image	SJ019	electrode adhesive disk
75573	Ct hrt w/3d image, congen	SJ019	electrode adhesive disk
75574	Ct angio hrt w/3d image	SJ019	electrode adhesive disk
75960	Transcath iv stent rs&i	SK034	film, x-ray 14in x 17in
76821	Middle cerebral artery echo	SM013	disinfectant, surface (Envirocide, Sanizide)
77371	Srs, multisource	SG079	tape, surgical paper 1in (Micropore)
77372	Srs, linear based	SG079	tape, surgical paper 1in (Micropore)
77373	Sbrt delivery	SG079	tape, surgical paper 1in (Micropore)
78452	Ht muscle image spect, mult	SC051	syringe 10-12ml

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
		SK092	x-ray fixer solution
78454	Ht musc image, planar, mult	SK092	x-ray fixer solution
88125	Forensic cytopathology	SL026	clearing agent (Histo-clear)
88355	Analysis, skeletal muscle	SK073	skin marking ink (tattoo)
		SL061	embedding paraffin
		SL078	histology freezing spray (Freeze-It)
		SL201	stain, eosin
88356	Analysis, nerve	SB023	gloves, non-sterile, nitrile
		SK073	skin marking ink (tattoo)
		SL061	embedding paraffin
		SL078	histology freezing spray (Freeze-It)
		SL108	Pipette
88365	Insitu hybridization (fish)	SL201	stain, eosin
		SF004	blade, microtome
		SL179	1.0N NaOH
		SL183	slide, organosilane coated
		SL189	ethanol, 100%
		SL190	ethanol, 70%
88367	Insitu hybridization, auto	SL194	Hemo-De
		SM016	eye shield, splash protection
		SC057	syringe 5-6ml
		SF004	blade, microtome
		SL030	cover slip, glass
		SL085	label for microscope slides
		SL178	0.2N HCL
		SL179	1.0N NaOH
		SL181	pipette tips, sterile
		SL183	slide, organosilane coated
		SL189	ethanol, 100%
		SL190	ethanol, 70%
		SL191	ethanol, 85%
		SL194	Hemo-De
88368	Insitu hybridization, manual	SM016	eye shield, splash protection
		SF004	blade, microtome
		SL179	1.0N NaOH
		SL183	slide, organosilane coated
		SL189	ethanol, 100%
		SL190	ethanol, 70%
88385	Eval molecu probes, 51-250	SL194	Hemo-De
		SM016	eye shield, splash protection
		SL207	air, filtered, compressed
		SL218	DNA, Versagene, blood kit
88386	Eval molecu probes, 251-500	SL220	ethanol, 200%
		SL225	gas, nitogen, ultra-high purity (compressed), grade 5.0
		SL227	gas, nitogen, ultra-high purity (compressed), grade 5.0

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
90470	Immune admin H1N1 im/nasal	SB036	paper, exam table
91065	Breath hydrogen test	(blank)	Sivrite-4
91132	Electrogastrography	SD062	electrode, surface
91133	Electrogastrography w/test	SD062	electrode, surface
92550	Tympanometry & reflex thresh	SK059	paper, recording (per sheet)
92597	Oral speech device eval	SB022	gloves, non-sterile
92610	Evaluate swallowing function	SB022	gloves, non-sterile
92626	Eval aud rehab status	SK008	audiology scoring forms
92627	Eval aud status rehab add-on	SK008	audiology scoring forms
92640	Aud brainstem implt programg	SK068	Razor
95004	Percut allergy skin tests	SC023	multi-tine device
95024	Id allergy test, drug/bug	SA048	pack, minimum multi-specialty visit
		SG050	gauze, non-sterile 2in x 2in
95027	Id allergy titrate-airborne	SA048	pack, minimum multi-specialty visit
		SC052	syringe 1ml
95044	Allergy patch tests	SK087	water, distilled
95052	Photo patch test	SK087	water, distilled
95148	Antigen therapy services	SH009	antigen, venom
95805	Multiple sleep latency test	SK094	x-ray marking pencil
96040	Genetic counseling, 30 min	SK062	patient education booklet
96102	Psycho testing by technician	SK057	paper, laser printing (each sheet)
		SC018	iv infusion set
96360	Hydration iv infusion, init	SC051	syringe 10-12ml
		SG050	gauze, non-sterile 2in x 2in
		SC018	iv infusion set
96365	Ther/proph/diag iv inf, init	SC051	syringe 10-12ml
		SG050	gauze, non-sterile 2in x 2in
		SB022	gloves, non-sterile
96366	Ther/proph/diag iv inf addon	SB022	gloves, non-sterile
96367	Tx/proph/dg addl seq iv inf	SB022	gloves, non-sterile
96369	Sc ther infusion, up to 1 hr	SC013	infusion pump cassette-reservoir
96371	Sc ther infusion, reset pump	SC013	infusion pump cassette-reservoir
96372	Ther/proph/diag inj, sc/im	SB022	gloves, non-sterile
		SB022	gloves, non-sterile
		SC051	syringe 10-12ml
96374	Ther/proph/diag inj, iv push	SG050	gauze, non-sterile 2in x 2in
		SB022	gloves, non-sterile
		SC051	syringe 10-12ml
96375	Tx/pro/dx inj new drug addon	SC051	syringe 10-12ml
		SG050	gauze, non-sterile 2in x 2in
96401	Chemo, anti-neopl, sq/im	SC051	syringe 10-12ml
		SG050	gauze, non-sterile 2in x 2in
96402	Chemo hormon antineopl sq/im	SC051	syringe 10-12ml
		SG050	gauze, non-sterile 2in x 2in
96409	Chemo, iv push, sngl drug	SC018	iv infusion set
		SC051	syringe 10-12ml
96411	Chemo, iv push, addl drug	SC018	iv infusion set
		SC051	syringe 10-12ml
96413	Chemo, iv infusion, 1 hr	SC018	iv infusion set
		SC051	syringe 10-12ml
96417	Chemo iv infus each addl seq	SC018	iv infusion set
		SC018	iv infusion set
96445	Chemotherapy, intracavitary	SC018	iv infusion set
		SH069	sodium chloride 0.9% irrigation (500-1000ml uou)

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
96542	Chemotherapy injection	SC018	iv infusion set
99366	Team conf w/pat by hc pro	SK062	patient education booklet
G0270	MNT subs tx for change dx	SK057	paper, laser printing (each sheet)
		SK062	patient education booklet
G0271	Group MNT 2 or more 30 mins	SK057	paper, laser printing (each sheet)

Table 7: Overall Supply Price Calculation Corrections for Facility Settings

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
15738	Muscle-skin graft, leg	SG017	bandage, Kling, non-sterile 2in
15820	Revision of lower eyelid	SA082	pack, ophthalmology visit (w-dilation)
15821	Revision of lower eyelid	SA082	pack, ophthalmology visit (w-dilation)
15822	Revision of upper eyelid	SA082	pack, ophthalmology visit (w-dilation)
19303	Mast, simple, complete	SB006	drape, non-sterile, sheet 40in x 60in
20900	Removal of bone for graft	SA054	pack, post-op incision care (suture)
21011	Exc face les sc < 2 cm	SA048	pack, minimum multi-specialty visit
21013	Exc face tum deep < 2 cm	SA048	pack, minimum multi-specialty visit
21193	Reconst lwr jaw w/o graft	SJ061	tongue depressor
21194	Reconst lwr jaw w/graft	SJ061	tongue depressor
21240	Reconstruction of jaw joint	SJ061	tongue depressor
21366	Treat cheek bone fracture	SJ061	tongue depressor
21435	Treat craniofacial fracture	SJ061	tongue depressor
21555	Exc neck les sc < 3 cm	SA048	pack, minimum multi-specialty visit
21930	Exc back les sc < 3 cm	SA048	pack, minimum multi-specialty visit
22902	Exc abd les sc < 3 cm	SA048	pack, minimum multi-specialty visit
23075	Exc shoulder les sc < 3 cm	SA048	pack, minimum multi-specialty visit
24075	Exc arm/elbow les sc < 3 cm	SA048	pack, minimum multi-specialty visit
25075	Exc forearm les sc < 3 cm	SA048	pack, minimum multi-specialty visit
26115	Exc hand les sc < 1.5 cm	SA048	pack, minimum multi-specialty visit
27047	Exc hip/pelvis les sc < 3 cm	SA048	pack, minimum multi-specialty visit
27327	Exc thigh/knee les sc < 3 cm	SA048	pack, minimum multi-specialty visit
27618	Exc leg/ankle tum < 3 cm	SA048	pack, minimum multi-specialty visit
28307	Incision of metatarsal	SA048	pack, minimum multi-specialty visit
28340	Resect enlarged toe tissue	SA048	pack, minimum multi-specialty visit
28345	Repair webbed toe(s)	SA048	pack, minimum multi-specialty visit
28820	Amputation of toe	SA048	pack, minimum multi-specialty visit
33516	Cabg, vein, six or more	SA052	pack, post-op incision care (staple)
34510	Transposition of vein valve	SA054	pack, post-op incision care (suture)
35013	Repair artery rupture, arm	SA048	pack, minimum multi-specialty visit
41150	Tongue, mouth, jaw surgery	SA048	pack, minimum multi-specialty visit
41153	Tongue, mouth, neck surgery	SA048	pack, minimum multi-specialty visit
41155	Tongue, jaw, & neck surgery	SA048	pack, minimum multi-specialty visit
41805	Removal foreign body, gum	SD134	tubing, suction, non-latex (6ft) with Yankauer tip (1)

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
41806	Removal foreign body, jawbone	SD134	tubing, suction, non-latex (6ft) with Yankauer tip (1)
42160	Treatment mouth roof lesion	SD122	suction tip, Yankauer
51925	Hysterectomy/bladder repair	SB006	drape, non-sterile, sheet 40in x 60in
56620	Partial removal of vulva	SA048	pack, minimum multi-specialty visit
57284	Repair paravag defect, open	SA051	pack, pelvic exam
		SB006	drape, non-sterile, sheet 40in x 60in
57285	Repair paravag defect, vag	SA051	pack, pelvic exam
		SB006	drape, non-sterile, sheet 40in x 60in
57423	Repair paravag defect, lap	SA051	pack, pelvic exam
		SB006	drape, non-sterile, sheet 40in x 60in
58660	Laparoscopy, lysis	SB006	drape, non-sterile, sheet 40in x 60in
58662	Laparoscopy, excise lesions	SJ046	silver nitrate applicator
58670	Laparoscopy, tubal cautery	SJ046	silver nitrate applicator
58940	Removal of ovary(s)	SA052	pack, post-op incision care (staple)
58952	Resect ovarian malignancy	SB006	drape, non-sterile, sheet 40in x 60in
64632	N block inj, common digit	SA048	pack, minimum multi-specialty visit
65112	Remove eye/revise socket	SA050	pack, ophthalmology visit (no dilation)
65114	Remove eye/revise socket	SA050	pack, ophthalmology visit (no dilation)
65235	Remove foreign body from eye	SA082	pack, ophthalmology visit (w-dilation)
65265	Remove foreign body from eye	SA082	pack, ophthalmology visit (w-dilation)
65272	Repair of eye wound	SA082	pack, ophthalmology visit (w-dilation)
65273	Repair of eye wound	SA082	pack, ophthalmology visit (w-dilation)
65280	Repair of eye wound	SA082	pack, ophthalmology visit (w-dilation)
65285	Repair of eye wound	SA082	pack, ophthalmology visit (w-dilation)
65286	Repair of eye wound	SA082	pack, ophthalmology visit (w-dilation)
65290	Repair of eye socket wound	SA082	pack, ophthalmology visit (w-dilation)
65770	Revise cornea with implant	SA050	pack, ophthalmology visit (no dilation)
65850	Incision of eye	SA082	pack, ophthalmology visit (w-dilation)
65865	Incise inner eye adhesions	SA082	pack, ophthalmology visit (w-dilation)
65870	Incise inner eye adhesions	SA082	pack, ophthalmology visit (w-dilation)
66180	Implant eye shunt	SA082	pack, ophthalmology visit (w-dilation)
66185	Revise eye shunt	SA082	pack, ophthalmology visit (w-dilation)
66220	Repair eye lesion	SA082	pack, ophthalmology visit (w-dilation)
66250	Follow-up surgery of eye	SA082	pack, ophthalmology visit (w-dilation)
66500	Incision of iris	SA082	pack, ophthalmology visit (w-dilation)
66600	Remove iris and lesion	SA082	pack, ophthalmology visit (w-dilation)
66605	Removal of iris	SA082	pack, ophthalmology visit (w-dilation)
66625	Removal of iris	SA082	pack, ophthalmology visit (w-dilation)
66630	Removal of iris	SA082	pack, ophthalmology visit (w-dilation)
66635	Removal of iris	SA082	pack, ophthalmology visit (w-dilation)
66682	Repair iris & ciliary body	SA082	pack, ophthalmology visit (w-dilation)
66820	Incision, secondary cataract	SA082	pack, ophthalmology visit (w-dilation)
66850	Removal of lens material	SA082	pack, ophthalmology visit (w-dilation)
66852	Removal of lens material	SA082	pack, ophthalmology visit (w-dilation)
66930	Extraction of lens	SA082	pack, ophthalmology visit (w-dilation)
66940	Extraction of lens	SA082	pack, ophthalmology visit (w-dilation)
66983	Cataract surg w/iol, 1 stage	SA082	pack, ophthalmology visit (w-dilation)
67015	Release of eye fluid	SA082	pack, ophthalmology visit (w-dilation)
67031	Laser surgery, eye strands	SA082	pack, ophthalmology visit (w-dilation)

CPT/ HCPCS Code	Short Descriptor	CMS Supply Code with Overall Price Corrections	Description of Supply
67036	Removal of inner eye fluid	SA082	pack, ophthalmology visit (w-dilation)
67040	Laser treatment of retina	SA082	pack, ophthalmology visit (w-dilation)
67105	Repair detached retina	SA082	pack, ophthalmology visit (w-dilation)
67107	Repair detached retina	SA082	pack, ophthalmology visit (w-dilation)
67110	Repair detached retina	SA082	pack, ophthalmology visit (w-dilation)
67115	Release encircling material	SA082	pack, ophthalmology visit (w-dilation)
67120	Remove eye implant material	SA082	pack, ophthalmology visit (w-dilation)
67228	Treatment of retinal lesion	SA082	pack, ophthalmology visit (w-dilation)
67400	Explore/biopsy eye socket	SA082	pack, ophthalmology visit (w-dilation)
67412	Explore/treat eye socket	SA082	pack, ophthalmology visit (w-dilation)
67440	Explore/drain eye socket	SA082	pack, ophthalmology visit (w-dilation)
67908	Repair eyelid defect	SG008	applicator, cotton-tipped, non-sterile 6in
88356	Analysis, nerve	SL108	Pipette

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Comment: Several commenters agreed that the overall supply price inputs should be equal to the product of the supply price and the quantity associated with each code. Some commenters pointed out that for many of the supply items displayed in Tables 6 and 7, the overall supply prices remained incorrect in the proposed CY 2011 direct PE database. The commenters speculated that an underlying programming error may have led to incorrect calculations.

Response: In constructing the proposed CY 2011 direct PE database posted on the CMS web site, we inadvertently retained a display column of data that reflected our previous calculation error, despite our correct calculation of the values for PFS ratesetting purposes. We have corrected the underlying process error that led to the incorrect display. We have modified the direct PE database for the CY 2011 PFS final rule with comment period to appropriately display the overall supply price input for a supply item as the product of the unit price and the quantity of the supply item used in the CPT code.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to modify the direct PE database to include the overall supply price input for a supply item as the product of the unit price and the quantity of the supply item used in the CPT code. We have modified the display column within the publicly available database to reflect the proper calculation. These changes are reflected in the final CY 2011 direct PE database.

c. AMA RUC Recommendations in CY 2010 for Changes to Direct PE Inputs

In a March 2010 letter, the AMA RUC made specific PE recommendations that we considered in the CY 2011 PFS proposed rule (75 FR 40062 through 40063). The proposed changes that follow were included in the proposed CY 2011 direct PE database, which is available on the CMS Web site under the downloads for the CY 2011 PFS proposed rule at <http://www.cms.gov/PhysicianFeeSched/>. The final direct PE database for CY 2011 is available under the downloads for the CY 2011 PFS final rule with comment period at the same location.

(1) Electrogastrography and Esophageal Function Test

We proposed to accept the AMA RUC recommendations for the CY 2011 PE inputs for the following CPT codes: 91132 (Electrogastrography, diagnostic, transcutaneous); 91133 (Electrogastrography, diagnostic, transcutaneous; with provocative testing); 91038 (Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation; prolonged (greater than 1 hour, up to 24 hours)). For CPT code 91038, we assumed a useful life of 5 years for the equipment item "ZEPHR impedance/pH reflux monitoring system with data recorder, software, monitor, workstation and cart," based on its entry in the AHA's publication, "Estimated Useful Lives of Depreciable Hospital Assets," which we use as a standard reference. The proposed CY 2011 direct PE database was changed accordingly.

(2) 64-Slice CT Scanner and Software

The AMA RUC submitted an updated recommendation regarding the correct pricing of the 64-slice CT scanner and its accompanying software. Based on the documentation accompanying the recommendation, we accepted this recommendation and proposed to update the price input for the 64-slice scanner and software. This affected the following four CPT codes that use either the scanner, the software, or both: 75571 (computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium); 75572 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)); 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)); and 75574 (Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image post processing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structure, if performed)). The proposed CY 2011 direct PE database was modified accordingly.

(3) Breath Hydrogen Test

The AMA RUC provided recommendations regarding the PE inputs for CPT code 91065 (breath

hydrogen test (e.g., for detection of lactase deficiency, fructose intolerance, bacterial overgrowth, or oro-cecal gastrointestinal transit). We accepted the recommendations with two modifications. We folded the two pieces of equipment listed as "quinGas Table-Top Support Stand, 3 Tank" and "Drying Tube, Patient Sample" into the "BreathTrackerDigital SC Instrument" and summed their inputs into one equipment line-item, since these equipment items are used together specifically for the service in question. We increased the useful life input of the "BreathTrackerDigital SC Instrument" from 7 to 8 years based on our use of the American Hospital Association (AHA)'s publication entitled, "Estimated Useful Lives of Depreciable Hospital Assets" as a standard reference. Additionally, because the AMA RUC did not include equipment times in their recommendations for this CPT code, we used 53 minutes as the total time for all equipment items based on the total intra-service period for the clinical labor, consistent with our general policy for establishing equipment times. These modifications were reflected in the proposed CY 2011 direct PE database.

(4) Radiographic Fluoroscopic Room

A recent AMA RUC review of services that include the radiographic fluoroscopic room (CMS Equipment Code EL014) as a direct PE input revealed that the use of the item is no longer typical for certain services in which it is specified within the current direct cost inputs. The AMA RUC recommended to CMS that the radiographic fluoroscopic room be deleted from CPT codes 64420 (Injection, anesthetic agent; intercostal nerve, single); 64421 (Injection, anesthetic agent; intercostal nerves, multiple, regional block); and 64620 (Destruction by neurolytic agent, intercostal nerve). We accepted these recommendations and, therefore, these changes were included in the proposed CY 2011 direct PE database.

Comment: Several commenters generally expressed support for our acceptance of these AMA RUC-recommended direct PE inputs with the stated refinements. The AMA RUC expressed appreciation for CMS' acceptance of the committee's recommendations.

Response: We appreciate the assistance of stakeholders in our efforts to utilize the most accurate direct PE inputs for PFS services. We also appreciate the judicious work of the AMA RUC in providing these recommendations in time for us to

respond to them and include our proposals in the CY 2011 proposed rule.

Comment: One commenter expressed concern about these recommendations on the basis of the flawed professional composition of the AMA RUC. The commenter stated that without fair representation by all specialties, including nonphysician practitioners who may bill Part B directly under the PFS, CMS' reliance on the AMA RUC as representing the professional views and knowledge of all healthcare specialties for purposes of establishing the direct PE inputs for services paid under the PFS is deeply flawed.

Response: As we have stated previously (69 FR 66243), because the AMA RUC is an independent committee, we are not in a position to set the requirements for AMA RUC membership. Concerned stakeholders should communicate directly with the AMA RUC regarding its professional composition. We note that we alone are responsible for all decisions about the direct PE inputs for purposes of PFS payment so, while the AMA RUC provides us with recommendations for new and revised CPT codes in the context of what we believe is its broad expertise, we ultimately remain responsible for determining the direct PE inputs for all new or revised services.

After consideration of the public comments we received, we are finalizing our CY 2011 proposals to accept the AMA RUC recommendations, with certain changes described above, regarding the direct PE inputs for electrogastrography and esophageal function tests, the 64-slice CT scanner and software, the breath hydrogen test, and certain procedures that no longer require a radiographic fluoroscopic room. These decisions are reflected in the final CY 2011 direct PE database.

(5) Cystometrogram

The AMA RUC recently identified a rank order anomaly regarding CPT code 51726 (Complex cystometrogram (i.e., calibrated electronic equipment)). Currently, this procedure has higher PE RVUs, despite being less resource-intensive than the three CPT codes for which it serves as the base: 51727 (Complex cystometrogram (i.e., calibrated electronic equipment); with urethral pressure profile studies (i.e., urethral closure pressure profile), any technique); 51728 (Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (that is, bladder voiding pressure), any technique); and 51729 (Complex cystometrogram (i.e., calibrated electronic equipment); with

voiding pressure studies (that is, bladder voiding pressure) and urethral pressure profile studies (that is, urethral closure pressure profile), any technique).

Since the AMA RUC's general view is that CPT codes with a 0-day global period do not have pre-service time associated with the code, the AMA RUC recommended removing the nonfacility pre-service clinical labor time from the PE inputs for 51726. Additionally, the AMA RUC recommended that the nonfacility clinical intra-service staff time for CPT code 51276 be reduced from the 118 minutes of intra-service clinical labor time currently assigned to the code to 85 minutes of intra-service clinical labor time. These changes would resolve the rank order anomaly and bring the PE inputs for CPT code 51726 into alignment with the other three codes. Finally, and for the reasons stated above, the AMA RUC recommended that CMS remove the 23 minutes of pre-service nonfacility clinical labor time from CPT code 51725 (Simple cystometrogram (CMG) (for example, spinal manometer)). We agreed with the AMA RUC recommendations, proposed to accept these recommendations for CY 2011 and, therefore, changed the direct PE inputs for CPT codes 51725 and 51726 in the nonfacility setting in the proposed CY 2011 direct PE database.

Comment: Some commenters argued that the rank order anomaly resulted from clinical labor inputs that were too low in the more complex codes, rather than too high in the base codes. These commenters stated that the AMA RUC and CMS had addressed the wrong "end" of the rank order anomaly in making the changes to the clinical labor minutes assigned to CPT codes 51725 and 51726. Several commenters on the CY 2010 PFS final rule with comment period, where new CY 2011 CPT code 51727, 51728, and 51729 were assigned interim direct PE inputs, also argued that CPT codes 51727, 51728, and 51729 should have additional clinical labor inputs, including a greater number of minutes during the intra-service period and minutes during the pre-service period.

Response: We have reviewed the direct PE inputs for all five CPT codes in this series and continue to agree with the AMA RUC's recommendations regarding changes for CY 2011. Specifically, we believe the pre-service nonfacility clinical labor time for the 0-day global period CPT codes 51725 and 51726 should be removed and the intra-service clinical labor time for CPT code 51726 should also be reduced, consistent with the usual treatment of

other 0-day global codes. We believe the AMA RUC provided recommendations to us regarding the direct PE inputs for these four cystometrogram services that accurately reflect the costs of the resources (that is, the clinical labor, equipment, and supplies) typically required to furnish these services to Medicare beneficiaries.

Comment: Several commenters requested that CMS change the supply inputs included in the direct PE database for the complex cystometrogram services. For example, the commenters requested that single dual sensor catheters replace the single sensor catheters currently included as direct PE inputs for these codes. The commenters stated that both the catheters and their price inputs are outdated. In other cases, the commenters explained that certain supplies in the database were not those typically used by certain physician specialties in performing the services.

Response: We rely on our review of recommendations received from the AMA RUC in order to make changes to the clinical labor, supply, and equipment inputs for CPT codes within the direct PE database. We have no reason to believe that the supplies used in the complex cystometrogram procedures described by CPT codes 51727, 51728, and 51729 are outdated because these were new codes for CY 2010 and the AMA RUC recently addressed their direct PE inputs when initially recommending values for the services. We believe the AMA RUC's extensive expertise and broad perspective generally allows it to accurately identify the direct PE inputs for new and revised CPT codes. We encourage stakeholders who believe that enhancements in technology or changes in medical practice have resulted in changes in the supplies or equipment typically used in furnishing a particular service to address these concerns with the AMA RUC.

As we discuss further in section II.A.3.e. of this final rule with comment period with respect to our proposal regarding updating supply and equipment price inputs, we welcome public requests for updates to supply price and equipment price and useful life inputs associated with existing codes through the process we are adopting beginning in CY 2011.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to accept the recommendations of the AMA RUC regarding the revised direct PE inputs for CPT codes 51725 and 52726. The final direct PE inputs are

included in the final CY 2011 direct PE database.

d. Referral of Existing CPT Codes for AMA RUC Review

As part of our review of high cost supplies, we conducted a clinical review of the procedures associated with high cost supplies to confirm that those supplies currently are used in the typical case described by the CPT codes. While we confirmed that most high cost supplies could be used in the procedures for which they are currently direct PE inputs, we noted that one of the high cost supplies, fiducial screws (CMS Supply Code SD073) with a current price of \$558, is included as a direct PE input for two CPT codes, specifically 77301 (Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications) and 77011 (Computed tomography guidance for stereotactic localization). The documentation used in the current pricing of the supply item describes a kit that includes instructions, skull screws, a drill bit, and a collar for the TALON® System manufactured by Best nomos. Best nomos' literature describes the insertion of the screws into the patient's skull to ensure accurate set-up. When CPT codes 77301 and 77011 were established in CY 2002 and CY 2003, respectively, we accepted the AMA RUC recommendations to include fiducial screws in the PE for these services. Upon further review, while we understand why this supply may still be considered a typical PE input for CPT code 77011, we do not now believe that fiducial screws, as described in the Best nomos literature, would typically be used in CPT code 77301, where the most common clinical scenario would be treatment of prostate cancer.

Therefore, in order to ensure that CPT codes 77301 and 77011 are appropriately valued for CY 2011 through the inclusion or exclusion of fiducial screws in their PE, in the CY 2011 PFS proposed rule (75 FR 40063), we asked the AMA RUC to review these CPT codes with respect to the inclusion of fiducial screws in their PE. We requested that the AMA RUC make recommendations to us regarding whether this supply should be included in the PE or removed from the PE for CPT codes 77301 and 77011 in a timeframe that would allow us to adopt interim values for these codes for CY 2011, should the AMA RUC recommend a change. Were the AMA RUC to continue to recommend the inclusion of fiducial screws in the PE for CPT code 77301 and/or 77011 for CY 2011, we

requested that the AMA RUC provide us with a detailed rationale for the inclusion of this specialized supply in the PE for the typical case reported under the relevant CPT code. We also requested that the AMA RUC furnish updated pricing information for the screws if they were to continue to recommend the screws as a PE input for one or both of these CPT codes in CY 2011.

Comment: The AMA RUC recommended that CMS remove the fiducial screws as a direct PE input from both CPT codes 77011 and 77301. Several commenters also agreed that the fiducial screws would not typically be used with CPT code 77301.

Additionally, multiple commenters pointed out that the fiducial screws may now be reported using HCPCS supply code A4648 (Tissue marker, implantable, any type, each) when the markers are implanted.

Response: We appreciate the responsiveness of the AMA RUC to our request and the interest of the other commenters in this issue.

After consideration of the public comments we received and the AMA RUC recommendation following publication of the CY 2011 PFS proposed rule, for CY 2011, we are accepting the AMA RUC's recommendation and removing fiducial screws from the direct PE database as inputs for CPT codes 77011 and 77301. Because the direct PE inputs for these codes are being revised on an interim final basis for CY 2011, the changes are subject to public comment on this final rule with comment period.

e. Updating Equipment and Supply Price Inputs for Existing Codes

Historically, we have periodically received requests to change the PE price inputs for supplies and equipment in the PE database. In the past, we have considered these requests on an *ad hoc* basis and updated the price inputs as part of quarterly or annual updates if we believed them to be appropriate. In the CY 2011 PFS proposed rule (75 FR 49963), we proposed to establish a regular and more transparent process for considering public requests for changes to PE database price inputs for supplies and equipment used in existing codes.

We proposed to act on public requests to update equipment and supply price inputs annually through rulemaking by following a regular and consistent process as discussed in the following paragraphs. We proposed to use the annual PFS proposed rule released in the summer and the final rule with comment period released on or about

November 1 each year as the vehicle for making these changes.

We would accept requests for updating the price inputs for supplies and equipment on an ongoing basis; requests must be received no later than December 31 of each calendar year to be considered for inclusion in the next proposed rule. In that next proposed rule, we would present our review of submitted requests to update price inputs for specific equipment or supplies and our proposals for the subsequent calendar year. We would then finalize changes in the final rule with comment period for the upcoming calendar year. Our review of the issues and consideration of public comments may result in the following outcomes that would be presented in the final rule with comment period:

- Updating the equipment or supply price inputs, as requested.
- Updating the equipment or supply price inputs, with modifications.
- Rejecting the new price inputs.
- Declining to act on the request pending a recommendation from the AMA RUC.

To facilitate our review and preparation of issues for the proposed rule, at a minimum, we would expect that requesters would provide the following information:

- Name and contact information for the requestor.
- The name of the item exactly as it appears in the direct PE database under downloads for the most recent PFS final rule with comment period, available on the CMS Web site at <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

In order to best evaluate the requests in the context of our goal of utilizing accurate market prices for these items as direct PE inputs, we also would expect requestors to provide multiple invoices from different suppliers/manufacturers. In some cases, multiple sources may not be available, whereupon a detailed explanation should be provided to support the request. When furnishing invoices, requestors should take into consideration the following parameters:

- ++ May be either print or electronic but should be on supplier and/or manufacturer stationery (for example, letterhead, billing statement, etc.)
- ++ Should be for the typical, common, and customary version of the supply or equipment that is used to furnish the services.
- ++ Price should be net of typical rebates and/or any discounts available, including information regarding the magnitude and rationale for such rebates or discounts.

++ If multiple items are presented on the same invoice, relevant item(s) should be clearly identified.

We solicited public comments on this process, including the information that requestors should furnish to facilitate our full analysis in preparation for the next calendar year's rulemaking cycle.

Comment: Several commenters supported establishing a regular and more transparent process for considering public requests for changes to the direct PE price inputs for supplies and equipment used in existing codes. However, other commenters were concerned that the process might prevent CMS from making timely corrections to the database that are brought to the attention of the agency by specialty societies or other stakeholders. These commenters suggested creating an expedited process whereby mistakes could be corrected.

Response: We appreciate the broad support for the proposal. We believe that this process, though regular, would not limit our ability to correct technical errors that are discovered by the agency or brought to our attention by stakeholders. On these occasions, we would continue to correct errors and issue correction notices to final rules when appropriate. The regular process for updating supply and equipment prices is intended to reflect significant changes in the market prices of supplies and equipment that are used in the direct PE database. It would not substitute for the timely correction of technical errors.

Comment: Some commenters were concerned that the proposed process would necessitate a 12- to 24-month delay between CMS' acknowledgement of a price update and the resulting change in PE RVU calculations. The commenters pointed out that the current ad hoc process has historically resulted in a fairly timely response from the agency in most circumstances and were concerned that the formalization of the process might result in unnecessary delays. One commenter suggested creating a process for quarterly updates to the supply and equipment price inputs.

Response: We understand that some commenters are concerned about the timelines for price updates. However, we believe that the value of the transparency of the proposed process outweighs its potential for slowing the previous ad hoc process. Additionally, it is important to acknowledge that in most previous cases, price input updates would not have been immediately effective since such updates have always required CMS' review, concurrence, and processing

through the rate setting methodology prior to any change in Medicare payment rates. Additionally, many stakeholders already provide public comments to CMS regarding specific issues addressed in our annual rate setting for the PFS through the notice and comment rulemaking process.

Therefore, we believe that the annual process offers both an economic use of stakeholders' resources, as well as the best opportunity for broad public input into proposed price changes. These are qualities any accelerated alternative, such as quarterly updates, would lack.

We believe that an annual update process most effectively promotes both timeliness and transparency, while also allowing for public comment and input regarding our proposals before the adoption of pricing changes that could have a significant effect on payment for services under the PFS.

Comment: Some commenters asserted that it may be more difficult to obtain invoices for some supplies that are not frequently used and there should be acceptable alternative sources of information, including price lists or other information from the manufacturer. One commenter suggested that in the case of items that are not used in high volumes in physicians' office, volume or other discounts are unlikely for physicians' practices.

Response: Even though the direct PE inputs should reflect the resource costs required for typical cases, we understand that there may be circumstances in which updated invoices or invoices that reflect volume or other discounts may be difficult to obtain. As stated in our proposal, we will consider a detailed written explanation in support of requests submitted without the documentation usually required.

Comment: One commenter urged that the updating of supply and equipment prices be only for "like" items and not for "newer technology" items. The commenter requested that CMS refer the initial review of new supply and equipment inputs to the AMA RUC Practice Expense Subcommittee for review and recommendation back to CMS. Other commenters made specific requests for additions, deletions, or substitutions of supply and equipment items associated with particular codes.

Response: We appreciate the opportunity to clarify that this regular and consistent process would only apply to the price inputs for supply and equipment items. As part of our review of equipment price inputs, we will also consider updates to the useful life of equipment insofar as that information is

supported by similar documentation. However, we will continue to encourage stakeholders who believe that there should be additions, deletions, or substitutions of direct PE inputs associated with particular codes to address these concerns through the AMA RUC, including when a stakeholder believes that enhanced technology has replaced older technology in the typical case of a particular service. We believe the AMA RUC recommendations are an efficient and effective mechanism to inform our review of changes to the clinical labor, supply, and equipment inputs within the direct PE database.

Comment: One commenter was concerned about the potential for CMS to reject the requested price input outright and suggested that CMS be required to explain its rejection of the request for an updated price input.

Response: We appreciate the concerns of the commenter and consider this perspective as providing additional support for instituting such a regular and transparent process. As we stated in the CY 2011 proposed rule (75 FR 40063), we would present our review of submitted requests to update price inputs for specific equipment or supplies and our proposals for the subsequent calendar year in the annual proposed rule. This process would provide CMS an annual opportunity to explain our review and decisions regarding public requests for changes in direct PE price inputs.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to act on public requests to update equipment and supply price inputs annually through rulemaking by following a regular and consistent process as discussed in the preceding paragraphs. We will use the annual PFS proposed rule released in the summer and the final rule with comment period released on or about November 1 each year as the vehicle for making these changes. In order to make the most effective use of the rulemaking process and be responsive to the concerns of stakeholders that we consider the most recent evidence available, we ask that requests for updates to supply price inputs or equipment price or useful life inputs be submitted as comments to the PFS final rule with comment period each year, subject to the deadline for public comments applicable to that rule. Alternatively, stakeholders may submit requests to CMS on an ongoing basis throughout a given calendar year to CMS *PE_Price_Input_Update@cms.hhs.gov*. Requests received by the end of a calendar year will be

considered in rulemaking during the following year. For example, requests received by December 31, 2010 will be considered in conjunction with the CY 2012 PFS rulemaking cycle. We refer readers to the description earlier in this section of the minimum information we are requesting that stakeholders provide in order to facilitate our review and preparation of issues for the proposed rule.

In the CY 2012 PFS proposed rule, scheduled to be released in the summer of CY 2011, we will present a review of any timely requests we receive to update supply price inputs or equipment price or useful life inputs. After reviewing the issues and responding to the public comments, we will finalize our decision as one of the outcomes listed below for each request in the final rule with comment period for CY 2012.

- Updating the equipment or supply price inputs, as requested.
- Updating the equipment or supply price inputs, with modifications.
- Rejecting the new price inputs.
- Declining to act on the request pending a recommendation from the AMA RUC.

f. Other Issues

We received other public comments on matters related to direct PE inputs that were not the subject of proposals in the CY 2011 PFS proposed rule. We thank the commenters for sharing their views and suggestions. Because we did not make any proposals regarding these matters, we do not generally summarize or respond to such comments in this final rule with comment period. However, we are summarizing and responding to several of the public comments in order to reiterate or clarify certain information.

Comment: Several commenters stated that the clinical labor minutes for CPT code 37210 (Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure) are inconsistent with recommendations forwarded to CMS by the AMA RUC for CY 2007 and accepted by CMS in the CY 2007 PFS final rule with comment period (71 FR 69643). The commenters indicated that 10 minutes of clinical labor time were erroneously not attributed to this CPT code in the proposed CY 2011 direct PE database.

Response: We agree with the commenters' assessment and appreciate being informed of the error. The 10 minutes of clinical labor time missing from the direct PE inputs for CPT code 37210 have been incorporated and this change is reflected in the final CY 2011 direct PE database.

Comment: Several commenters expressed concerns regarding the current direct PE inputs for various services. One commenter submitted extensive information regarding a perceived disparity between the equipment inputs for echocardiography services and those for other ultrasound services. Another commenter requested that CMS ask the AMA RUC to establish nonfacility RVUs for the placement or insertion of high dose rate brachytherapy catheters/applicators because it is common practice, especially in gynecology, for physicians to perform such procedures in their offices or in freestanding clinics. One commenter stated that the proposed PE RVUs do not provide sufficient payment to cover the cost of prothrombin time (PT)/international normalized ratio (INR) home monitoring services and recommended that CMS alter the direct PE inputs for those services. Another commenter requested that CMS alter direct PE inputs for holter monitoring based on changes to the language in CPT code descriptors from the current "24 hours" to "up to 48 hours," even when the AMA RUC did not recommend such changes.

Response: We did not propose CY 2011 changes to the direct PE inputs for any of those services referenced by the commenters and, therefore, their direct PE inputs have already been finalized in a prior year's PFS rulemaking. As we have previously stated in this section, we encourage stakeholders who believe a change is required in the direct PE inputs associated with a particular service in the typical case that is furnished in the facility or nonfacility setting to address these concerns with the AMA RUC with respect to codes that have been reviewed by the AMA RUC. The direct PE inputs for existing services paid under the PFS have all been adopted through rulemaking that has allowed for public notice and comment, so their current direct PE inputs are final unless we would make a proposal to change them in a future year. In most cases, we like to receive and review recommendations from the AMA RUC for new and revised codes or other codes for which another review has been conducted in order to assist us in determining whether we should make changes to the clinical labor, supply, and equipment inputs within the direct

PE database and, if so, what revisions should be made.

Additionally, throughout the year we meet with parties who want to share their views on topics of interest to them. These discussions may provide us with information regarding changes in medical practice and afford opportunities for the public to bring to our attention issues they believe we should consider for future rulemaking. Thus, we encourage stakeholders to contact us at any time if there are topics related to the direct PE inputs for physicians' services that they would like to discuss.

B. Malpractice Relative Value Units (RVUs)

1. Background

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: Work, PE, and malpractice. From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 4505(f) of the BBA required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. Therefore, initial implementation of resource-based malpractice RVUs occurred in 2000.

The statute also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. The first review and update of resource-based malpractice RVUs was addressed in the CY 2005 PFS final rule with comment period (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). In the CY 2010 PFS final rule with comment period, we implemented the second review and update of malpractice RVUs. For a discussion of the second review and update of malpractice RVUs see the CY 2010 PFS proposed rule (74 FR 33537) and final rule with comment period (74 FR 61758).

2. Malpractice RVUs for New and Revised Services Effective Before the Next 5-Year Review

Currently, malpractice RVUs for new and revised codes effective before the next 5-Year Review (for example, effective CY 2011 through CY 2014) are determined by a direct crosswalk to a similar "source" code or a modified crosswalk to account for differences in

work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust the malpractice RVUs for the new/revised code to reflect the difference in work RVUs between the source code and the AMA RUC's recommended work value (or the work value we are applying as an interim final value under the PFS) for the new code. For example, if the interim final work RVUs for the new/revised code are 10 percent higher than the work RVUs for the source code, the malpractice RVUs for the new/revised code would be increased by 10 percent over the source code RVUs. This approach presumes the same risk factor for the new/revised code and source code but uses the work RVUs for the new/revised code to adjust for risk-of-service. The assigned malpractice RVUs for new/revised codes effective between updates remain in place until the next 5-Year Review.

For CY 2011, we explained that we will continue our current approach for determining malpractice RVUs for new/revised codes that become effective before the next 5-Year Review and update. Under this approach we crosswalk the new/revised code to the RVUs of a similar source code and adjust for differences in work (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source code and the new/revised code. Additionally, we stated that we would publish a list of new/revised codes and the analytic crosswalk(s) used for determining their malpractice RVUs in the CY 2011 final rule with comment period, which we have not previously done. We also explained that the CY 2011 malpractice RVUs for new/revised codes would be implemented as interim final values in the CY 2011 PFS final rule with comment period, where they would be subject to public comment, and finalized in the CY 2012 PFS final rule with comment period.

Comment: Several commenters supported the continuation of our current approach to determining malpractice RVUs for new/revised codes that become effective before the next 5-Year Review and update. The commenters stated that publication of the new/revised codes and the analytic crosswalk(s) used for determining their malpractice RVUs in the final rule is a move toward greater transparency. A few commenters requested that CMS provide the rationale used for selecting crosswalks for new/revised codes and subject the rationale to public comment.

Response: For purposes of determining malpractice RVUs for the CY 2011 new/revised codes, we

accepted all source code recommendations submitted by the AMA RUC. We understand that the AMA RUC-recommended source codes for new/revised codes were based on the expected similar specialty mix of practitioners furnishing the source code and the new/revised code. In other words, the medical specialties furnishing a source code were expected to be similar to the specialty mix furnishing the new/revised code. In adopting all of the AMA RUC's source code recommendations for CY 2011, we agree with its assessment of these similarities in each new/revised code case. If we were to disagree with the AMA RUC's malpractice source code recommendations in a future year for any new/revised codes, we would provide the rationale for both our difference of opinion and the alternative source code we select for purposes of establishing the interim final malpractice RVUs.

After consideration of the public comments we received, we are continuing our current approach of assigning the interim final malpractice RVUs for new/revised codes based on the methodology described earlier in this section. We adjusted the malpractice RVUs of the CY 2011 new/revised codes for differences in work RVUs (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source code and the new/revised code to reflect the specific risk-of-service for the new/revised code. The source code crosswalks for the CY 2011 new/revised codes are being adopted on an interim final basis and are subject to public comment on this CY 2011 final rule with comment period, as are the CY 2011 malpractice RVUs of the new/revised codes that are listed in Addendum C to this final rule with comment period. The malpractice RVUs for the CY 2011 new/revised codes will be finalized in the CY 2012 PFS final rule with comment period, where we will also respond to the public comments received on the values that are included in this CY 2011 final rule with comment period.

Table 8 lists the CY 2011 new/revised codes and their respective source codes for determining the interim final CY 2011 malpractice RVUs. We are also posting this crosswalk on the CMS Web site under the downloads for the CY 2011 PFS final rule with comment period at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

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Table 8: Source Codes for CY 2011 New/Revised Codes Used to Set the Malpractice RVUs

CY 2011 New/ Revised CPT Code	CY 2011 New/Revised CPT Code Short Descriptor	CPT Code Crosswalk for Malpractice RVUs
11042	Deb subq tissue 20 sq cm/<	11042
11043	Deb musc/fascia 20 sq cm/<	11043
11044	Deb bone 20 sq cm/<	11044
11045	Deb subq tissue add-on	15003
11046	Deb musc/fascia add-on	15361
11047	Deb bone add-on	15361
11900	Injection into skin lesions	11900
11901	Added skin lesions injection	11901
12001	Repair superficial wound(s)	12001
12002	Repair superficial wound(s)	12002
12004	Repair superficial wound(s)	12004
12005	Repair superficial wound(s)	12005
12006	Repair superficial wound(s)	12006
12007	Repair superficial wound(s)	12007
12011	Repair superficial wound(s)	12011
12013	Repair superficial wound(s)	12013
12014	Repair superficial wound(s)	12014
12015	Repair superficial wound(s)	12015
12016	Repair superficial wound(s)	12016
12017	Repair superficial wound(s)	12017
12018	Repair superficial wound(s)	12018
15823	Revision of upper eyelid	15823
19357	Breast reconstruction	19357
22551	Neck spine fuse&remove addl	22856
22552	Addl neck spine fusion	22614
23430	Repair biceps tendon	23430
29540	Strapping of ankle and/or ft	29540
29550	Strapping of toes	29550
29914	Hip arthro w/femoroplasty	29866
29915	Hip arthro acetabuloplasty	29806
29916	Hip arthro w/labral repair	29806
30901	Control of nosebleed	30901
31295	Sinus endo w/balloon dil	31525
31296	Sinus endo w/balloon dil	31535
31297	Sinus endo w/balloon dil	31240
31634	Bronch w/balloon occlusion	31629
33620	Apply r&l pulm art bands	33660
33621	Transthor cath for stent	33320
33622	Redo compl cardiac anomaly	33783
36410	Non-routine bl draw > 3 yrs	36410
37220	Iliac revasc	35473
37221	Iliac revasc w/stent	37205
37222	Iliac revasc add-on	35473
37223	Iliac revasc w/stent add-on	37206
37224	Fem/popl revas w/tla	35474
37225	Fem/popl revas w/ather	35493
37226	Fem/popl revasc w/stent	37205

CY 2011 New/ Revised CPT Code	CY 2011 New/Revised CPT Code Short Descriptor	CPT Code Crosswalk for Malpractice RVUs
37227	Fem/popl revasc stint & ather	35493
37228	Tib/per revasc w/tla	35470
37229	Tib/per revasc w/ather	35495
37230	Tib/per revasc w/stent	37205
37231	Tib/per revasc stint & ather	37205
37232	Tib/per revasc add-on	35470
37233	Tibper revasc w/ather add-on	35495
37234	Revasc opn/prq tib/pero stint	37206
37235	Tib/per revasc stint & ather	37206
38900	Io map of sent lymph node	19126
43283	Lap esoph lengthening	44121
43327	Esoph fundoplasty lap	43280
43328	Esoph fundoplasty thor	33660
43332	Transab esoph hiat hern rpr	43281
43333	Transab esoph hiat hern rpr	43282
43334	Transthor diaphrag hern rpr	43281
43335	Transthor diaphrag hern rpr	43282
43336	Thorabd diaphr hern repair	43112
43337	Thorabd diaphr hern repair	43112
43338	Esoph lengthening	32602
43753	Tx gastro intub w/asp	99281
43754	Dx gastr intub w/asp spec	91037
43755	Dx gastr intub w/asp specs	91037
43756	Dx duod intub w/asp spec	89100
43757	Dx duod intub w/asp specs	89100
47490	Incision of gallbladder	49442
49327	Lap ins device for rt	49435
49412	Ins device for rt guide open	15171
49418	Insert tun ip cath perc	36558
49421	Ins tun ip cath for dial opn	49421
51736	Urine flow measurement	51736
51741	Electro-uroflowmetry first	51741
52281	Cystoscopy and treatment	52281
52332	Cystoscopy and treatment	52332
53860	Transurethral rf treatment	57522
55866	Laparo radical prostatectomy	55866
57155	Insert uteri tandems/ovoids	57155
57156	Ins vag brachytx device	57155
59400	Obstetrical care	59400
59409	Obstetrical care	59409
59410	Obstetrical care	59410
59412	Antepartum manipulation	59412
59414	Deliver placenta	59414
59425	Antepartum care only	59425
59426	Antepartum care only	59426
59430	Care after delivery	59430
59510	Cesarean delivery	59510
59514	Cesarean delivery only	59514
59515	Cesarean delivery	59515
59610	Vbac delivery	59610
59612	Vbac delivery only	59612

CY 2011 New/ Revised CPT Code	CY 2011 New/Revised CPT Code Short Descriptor	CPT Code Crosswalk for Malpractice RVUs
59614	Vbac care after delivery	59614
59618	Attempted vbac delivery	59618
59620	Attempted vbac delivery only	59620
59622	Attempted vbac after care	59622
61781	Scan proc cranial intra	61797
61782	Scan proc cranial extra	63086
61783	Scan proc spinal	61797
61885	Insrt/redo neurostim 1 array	61885
64415	N block inj brachial plexus	64415
64445	N block inj sciatic sng	64445
64447	N block inj fem single	64447
64479	Inj foramen epidural c/t	64479
64480	Inj foramen epidural add-on	64480
64483	Inj foramen epidural l/s	64483
64484	Inj foramen epidural add-on	64484
64566	Neuroeltrd stim post tibial	51736
64568	Inc for vagus n elect impl	63664
64569	Revise/repl vagus n eltrd	63047
64570	Remove vagus n eltrd	61535
64611	Chemodenerv saliv glands	64653
65778	Cover eye w/membrane	65430
65779	Cover eye w/membrane stent	65600
66174	Trnslum dil eye canal	67121
66175	Trnslum dil eye canal w/stnt	67570
66761	Revision of iris	66761
67028	Injection eye drug	67028
69801	Incise inner ear	69801
71250	Ct thorax w/o dye	71250
72125	Ct neck spine w/o dye	72125
72128	Ct chest spine w/o dye	72128
72131	Ct lumbar spine w/o dye	72131
73080	X-ray exam of elbow	73080
73200	Ct upper extremity w/o dye	73200
73510	X-ray exam of hip	73510
73610	X-ray exam of ankle	73610
73630	X-ray exam of foot	73630
73700	Ct lower extremity w/o dye	73700
74176	Ct angio abd & pelvis	74150
74177	Ct angio abd&pelv w/contrast	74160
74178	Ct angio abd & pelv 1+ regns	74170
76881	Us xtr non-vasc complete	76885
76882	Us xtr non-vasc lmtd	73630
77427	Radiation tx management x5	77427
88120	Cytp urine 3-5 probes ea spec	88365
88121	Cytp urine 3-5 probes cmptr	88365
88172	Cytp dx eval fna 1st ea site	88172
88177	Cytp c/v auto thin lyr addl	88172
88300	Surgical path gross	88300
88302	Tissue exam by pathologist	88302
88304	Tissue exam by pathologist	88304
88305	Tissue exam by pathologist	88305

CY 2011 New/ Revised CPT Code	CY 2011 New/Revised CPT Code Short Descriptor	CPT Code Crosswalk for Malpractice RVUs
88307	Tissue exam by pathologist	88307
88363	Xm archive tissue molec anal	85396
90460	Imadm any route 1st vac/tox	90471
90461	Imadm any route addl vac/tox	90472
90870	Electroconvulsive therapy	90870
90935	Hemodialysis one evaluation	90935
90937	Hemodialysis repeated eval	90937
90945	Dialysis one evaluation	90945
90947	Dialysis repeated eval	90947
91010	Esophagus motility study	91010
91013	Esophgl motil w/stim/perfus	91010
91117	Colon motility 6 hr study	43235
92081	Visual field examination(s)	92081
92082	Visual field examination(s)	92082
92132	Cmptr ophth dx img ant segmt	92020
92133	Cmptr ophth img optic nerve	92083
92134	Cptr ophth dx img post segmt	92083
92228	Remote retinal imaging mgmt	92250
92285	Eye photography	92285
92504	Ear microscopy examination	92504
92507	Speech/hearing therapy	92507
92508	Speech/hearing therapy	92508
92606	Non-speech device service	92606
92607	Ex for speech device rx 1hr	92607
92608	Ex for speech device rx addl	92608
92609	Use of speech device service	92609
93040	Rhythm ecg with report	93040
93042	Rhythm ecg report	93042
93224	Ecg monit/reprt up to 48 hrs	93224
93227	Ecg monit/reprt up to 48 hrs	93227
93268	Ecg record/review	93268
93272	Ecg/review interpret only	93272
93451	Right hrt cath	33210
93452	Left hrt cath w/ventriclgrphy	33967
93453	R&l hrt cath w/ventriclgrphy	33213
93454	Coronary artery angio s&i	33967
93455	Coronary art/grft angio s&i	93619
93456	R hrt coronary artery angio	33216
93457	R hrt art/grft angio	33240
93458	L hrt artery/ventricle angio	33213
93459	L hrt art/grft angio	33240
93460	R&l hrt art/ventricle angio	33240
93461	R&l hrt art/ventricle angio	33208
93462	L hrt cath trnsptl puncture	33210
93463	Drug admin & hemodynamic meas	36140
93464	Exercise w/hemodynamic meas	36140
93563	Inject congenital card cath	93975
93564	Inject hrt congntl art/grft	93975
93565	Inject l ventr/atrial angio	93975
93566	Inject r ventr/atrial angio	93975
93567	Inject suprnlv aortography	93975

CY 2011 New/ Revised CPT Code	CY 2011 New/Revised CPT Code Short Descriptor	CPT Code Crosswalk for Malpractice RVUs
93568	Inject pulm art hrt cath	93975
93652	Ablate heart dysrhythm focus	93652
93922	Upr/l xtremity art 2 levels	93922
93923	Upr/lxtr art stdy 3+ lvls	93923
93924	Lwr xtr vasc stdy bilat	93924
95800	Slp stdy unattended	95819
95801	Slp stdy unatnd w/anal	95819
95803	Actigraphy testing	95819
95805	Multiple sleep latency test	95805
95806	Sleep study unatt&resp efft	95806
95807	Sleep study attended	95807
95808	Polysomnography 1-3	95808
95810	Polysomnography 4 or more	95810
95811	Polysomnography w/cpap	95811
95950	Ambulatory eeg monitoring	95950
95953	Eeg monitoring/computer	95953
95956	Eeg monitor technol attended	95956
96105	Assessment of aphasia	96125
96446	Chemotx admn prtl cavity	96413
97597	Rmvl devital tis 20 cm/<	97597
97598	Rmvl devital tis addl 20 cm<	97598
99224	Subsequent observation care	99231
99225	Subsequent observation care	99232
99226	Subsequent observation care	99233

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3. Revised Malpractice RVUs for Selected Disc Arthroplasty Services

As discussed in the CY 2010 PFS proposed rule (74 FR 33539), we assign malpractice RVUs to each service based upon a weighted average of the risk factors of all specialties that furnish the service. For the CY 2010 review of malpractice RVUs, we used CY 2008 Medicare payment data on allowed services to establish the frequency of a service by specialty. CPT code 22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical) had zero allowed services for CY 2008. Therefore, our contractor initially set the level of services to 1, and assigned a risk factor according to the average risk factor for all services that do not explicitly have a separate technical or professional component. We proposed to adopt our contractor's initial malpractice RVUs for CPT code 22856 in the CY 2010 proposed rule. Application of the average physician risk factor would have resulted in a significant decrease in malpractice RVUs for CPT code 22856 in CY 2010.

Several commenters on the CY 2010 PFS proposed rule expressed concern regarding the proposed malpractice RVUs for CPT code 22856, which represented a proposed reduction of more than 77 percent. The commenters stated that this service is predominantly furnished by neurosurgeons and orthopedic surgeons. Given the high risk factors associated with these specialty types and the changes in malpractice RVUs for comparable services, the commenters stated that a reduction in the malpractice RVUs of this magnitude for CPT code 22856 could not be correct.

After consideration of the public comments, for CY 2010, we set the risk factor for CPT code 22856 as the weighted average risk factor of six comparable procedures mentioned by the commenters: CPT code 22554 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2); CPT code 22558 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar); CPT code 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other

than for decompression), single interspace, lumbar); CPT code 22845 (Anterior instrumentation; 2 to 3 vertebral segments (list separately in addition to code for primary procedure)); CPT code 63075 (Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophylectomy; cervical, single interspace); and CPT code 20931 (Allograft for spine surgery only; structural (list separately in addition to code for primary procedure)). The weighted average risk factor for these services is 8.4.

Since publication of the CY 2010 PFS final rule with comment period, stakeholders have mentioned that we made significant changes to the malpractice RVUs for CPT code 22856 in CY 2010. The commenters also brought to our attention that other services are clinically similar to CPT code 22856 and have similar work RVUs and, therefore, some stakeholders believe these services should all have similar malpractice RVUs. Services mentioned by the stakeholders that are clinically similar to CPT code 22856 include CPT code 22857; CPT code 22861 (Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace;

cervical); CPT code 22862 (Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, lumbar); CPT code 22864 (Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical); and CPT code 22865 (Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar).

After further review of this issue, for CY 2011 we proposed to apply the same risk factor used for CPT code 22856 to certain other services within this family of services (CPT codes 22857 through 22865) for which there were no allowed services in CY 2008. CPT codes 22861 and 22864 had zero allowed services in CY 2008 and our contractor initially set their malpractice RVUs in the same way as it did for CPT code 22856. Therefore, for CY 2011 we proposed to assign the weighted average risk factor used for CPT code 22856 (that is, the weighted average of the risk factors for CPT codes 20931, 22554, 22558, 22845, 22857, and 63075) to CPT codes 22861 and 22864. However, CPT codes 22857, 22862, and 22865 are low volume services (allowed services under 100). Our policy for low volume services is to apply the risk factor of the dominant specialty as indicated by our claims data. Thus, for CY 2011 we proposed to continue to apply our policy for low volume services to CPT codes 22857, 22862, and 22865.

Comment: A few commenters expressed support for the proposed changes in malpractice RVUs for disc arthroplasty services that are similar to CPT code 22856. One commenter urged CMS to finalize the proposal in the CY 2011 PFS final rule.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to apply the same risk factor used for CPT code 22856 to CPT codes 22861 and 22864 for purposes of setting the malpractice RVUs for these codes prior to the next 5-Year Review of malpractice RVUs.

C. Potentially Misvalued Services Under the Physician Fee Schedule

1. Valuing Services Under the PFS

As discussed in section I. of this final rule with comment period, in order to value services under the PFS, section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: The work, practice expense (PE), and malpractice components. Section 1848(c)(1)(A) of

the Act defines the work component to include "the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service." Additionally, the statute provides that the work component shall include activities that occur before and after direct patient contact. Furthermore, the statute specifies that with respect to surgical procedures, the valuation of the work component for the code would reflect a "global" concept in which pre-operative and post-operative physicians' services related to the procedure would also be included.

In addition, section 1848(c)(2)(C)(i) of the Act specifies that "the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service." As discussed in detail in sections I.A.2. and I.A.3. of this final rule with comment period, the statute also defines the PE and malpractice components and provides specific guidance in the calculation of the RVUs for each of these components. Section 1848(c)(1)(B) of the Act defines the PE component as "the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses."

Section 1848(c)(2)(C)(ii) of the Act specifies that the "Secretary shall determine a number of practice expense relative value units for the services for years beginning with 1999 based on the relative practice expense resources involved in furnishing the service." Furthermore, section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Finally, on March 23, 2010, the ACA was enacted, further requiring the Secretary to periodically review and identify potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being potentially misvalued. Section 3134(a) of the ACA added a new section 1848(c)(2)(K) of the Act which requires the Secretary to periodically identify potentially misvalued services using certain criteria, and to review and make appropriate adjustments to the relative values for those services. Section 3134(a) of the ACA also added a new section 1848(c)(2)(L) of the Act which requires the Secretary to develop a validation process to validate the RVUs of potentially misvalued codes under

the PFS and make appropriate adjustments.

As discussed in section I.A.1. of this final rule with comment period, we establish physician work RVUs for new and revised codes based on our review of recommendations received from the AMA RUC. The AMA RUC also provides recommendations to CMS on the values for codes that have been identified as potentially misvalued. To respond to concerns expressed by MedPAC, the Congress, and other stakeholders regarding accurate valuation of services under the PFS, the AMA RUC created the Five-Year Review Identification Workgroup in 2006. In addition to providing recommendations to CMS for work RVUs, the AMA RUC's Practice Expense Subcommittee reviews direct PE (clinical labor, medical supplies, and medical equipment) for individual services and examines the many broad methodological issues relating to the development of PE RVUs.

In accordance with section 1848(c) of the Act, we determine appropriate adjustments to the RVUs, taking into account the recommendations provided by the AMA RUC and MedPAC, and publish the explanation for the basis of these adjustments in the PFS proposed and final rules. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available, in addition to taking into account the results of consultations with organizations representing physicians.

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services Under the PFS

a. Background

In its March 2006 Report to Congress, MedPAC noted that "misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services." In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time for a number of reasons: "For example, when a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are required to perform it. Over time, skill, and stress involved may decline as physicians become more familiar with the service and more efficient at providing it. The amount of physician work needed to furnish an existing service may decrease when new technologies are incorporated. Services

can also become overvalued when practice expenses decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently, reducing its cost per use. Likewise, services can become undervalued when physician work increases or practice expenses rise." In the ensuing years since MedPAC's 2006 report, additional groups of potentially misvalued services have been identified by Congress, CMS, MedPAC, the AMA RUC, and other stakeholders.

In recent years CMS and the AMA RUC have taken increasingly significant steps to address potentially misvalued codes. As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made the initial recommendations, "CMS and the AMA RUC have taken several steps to improve the review process." Most recently, section 1848(c)(2)(K)(ii) of the Act (as added by section 3134 of the ACA) directed the Secretary to specifically examine potentially misvalued services in seven categories as follows:

- (1) Codes and families of codes for which there has been the fastest growth.
- (2) Codes or families of codes that have experienced substantial changes in practice expenses.
- (3) Codes that are recently established for new technologies or services.
- (4) Multiple codes that are frequently billed in conjunction with furnishing a single service.
- (5) Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- (6) Codes which have not been subject to review since the implementation of the RBRVS (the so-called "Harvard-valued codes").
- (7) Other codes determined to be appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act (as added by section 3134 of the ACA) also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition; the Secretary may conduct surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the review and appropriate adjustment of potentially misvalued services. This section authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Finally, section 1848(c)(2)(K)(iii)(V) of the Act (as added by section 3134 of the ACA) specifies

that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

Over the last several years, CMS, in conjunction with the AMA RUC, has identified and reviewed numerous potentially misvalued codes in all seven of the categories specified in section 1848(c)(2)(K)(ii) (as added by section 3134 of the ACA), and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years, consistent with the new legislative mandate on this issue. In the current process, the AMA RUC reviews potentially misvalued codes that are identified either by CMS or through its own processes and recommends revised work RVUs and/or direct PE inputs for those codes to CMS. CMS then assesses the recommended revised work RVUs and/or direct PE inputs and, in accordance with section 1848(c) of the Act, we determine if the recommendations constitute appropriate adjustments to the RVUs under the PFS. Since CY 2009, CMS and the AMA RUC have identified over 700 potentially misvalued codes.

For example, in regard to the first category (codes and families of codes for which there has been the fastest growth), for CY 2009 CMS identified over 100 potentially misvalued codes for which an analysis of the utilization data showed an annual growth in allowed services of 10 percent (or more) for 3 consecutive years (73 FR 38586). Each of these codes had allowed charges of \$1 million or more in CY 2007. We published this list in the CY 2009 PFS proposed rule (73 FR 38586 through 38589) and requested that the AMA RUC immediately begin a review of the codes on this list. Meanwhile, in parallel with CMS' efforts, the AMA RUC also initiated processes to identify and review potentially misvalued codes on an ongoing basis using certain screens, including screens for "CMS fastest growing procedures" and "high volume growth." Both of these AMA RUC screens are applicable to the first category of potentially misvalued codes specified in the ACA. We plan to continue to analyze Medicare claims data over future years to identify additional services that exhibit rapid growth and high Medicare expenditures for referral to the AMA RUC for review as potentially misvalued codes.

Pertaining to the second category specified in section 1848(c)(2)(K)(ii) of the Act (as added by section 3134 of the ACA) (codes or families of codes that have experienced substantial changes in practice expenses), in CY 2009 we requested that the AMA RUC continue its review of direct PE inputs, focusing particularly on high-volume codes where the PE payments are increasing significantly under the transition to the new PE methodology (73 FR 38589). The AMA RUC has responded by sending CMS recommendations for revised direct PE inputs for codes identified for PE review on an ongoing basis.

Additionally in CY 2009, we began an initiative to review and update the prices for high-cost supplies in order to ensure the accuracy and completeness of the direct PE inputs. We discuss our most recent efforts in refining the process to update the prices of high-cost supplies in section II.C.5. of this final rule with comment period.

For the third category of potentially misvalued codes identified in section 1848(c)(2)(K)(ii) (as added by section 3134 of the ACA) (codes that are recently established for new technologies or services), the AMA RUC routinely identifies such codes through a screen based on 3 years of Medicare claims data, and sends CMS recommendations for revised work RVUs and/or direct PE inputs for these codes on an ongoing basis. The AMA RUC may determine that a code for a new service requires reevaluation or does not require reevaluation, or it may conclude, on a case-by-case basis, that more than 3 years of claims data are necessary before the code can be reviewed. In that case, it would determine the appropriate future timeframe for review.

We also note that in its June 2008 Report to Congress entitled "Reforming the Health Care System" and in the context of a discussion about primary care, MedPAC acknowledges, " * * * Efficiency can improve more easily for other types of services, such as procedures, with advances in technology, technique, and other factors. Ideally, when such efficiency gains are achieved, the fee schedule's relative value units (RVUs) for the affected services should decline accordingly, while budget neutrality would raise the RVUs for the fee schedule's primary care services." (page 27). Section II.C.5. of this final rule with comment period includes a discussion regarding periodic updates to the costs of high-cost supplies. This discussion is highly relevant to new technology services, where growth in volume of a

service as it diffuses into clinical practice may lead to a decrease in the cost of expensive supplies. We also expect that other efficiencies in physician work and PE may be achieved after an initial period of relative inefficiency that reflects the "learning curve." We plan to pay particular attention to the work values and direct PE inputs for these new services and the AMA RUC's periodic review process to ensure that any efficiencies are captured under the PFS over time, recognizing that the appropriate timing for revaluing these services needs to be considered on a case-by-case basis depending on the growth rate in service volume.

We have also addressed the fourth category (multiple codes that are frequently billed in conjunction with furnishing a single service) in rulemaking prior to the enactment of the ACA. As discussed in the CY 2009 PFS proposed rule (73 FR 38586), we have a longstanding policy of reducing payment for multiple surgical procedures performed on the same patient, by the same physician, on the same day. Over the ensuing years, the multiple procedure payment reduction (MPPR) policy has been extended to a number of nuclear diagnostic and diagnostic imaging procedures. We continue our work to recognize efficiencies in this area with a new CY 2011 policy to expand the MPPR policy to additional combinations of imaging services and to therapy services for CY 2011 as described in section II.C.4. of this final rule with comment period.

We note the AMA RUC has also established a screen to identify services performed by the same physician on the same date of service 95 percent of the time or more. Over the past 2 years, the CPT Editorial Panel has established new bundled codes to describe a comprehensive service for certain combinations of these existing services that are commonly furnished together, and the AMA RUC has recommended work values and direct PE inputs to CMS for these comprehensive service codes that recognize the associated efficiencies. We look forward to working with the AMA RUC in this joint effort to examine codes commonly reported together and more appropriately value common combinations services.

We address the fifth category of potentially misvalued codes (codes with low relative values, particularly those that are often billed multiple times for a single treatment) in section II.C.3.b. of this final rule with comment period. That is, we have provided a list of services with low work RVUs that are commonly reported with multiple units in a single encounter and requested that

the AMA RUC review these codes that we have identified as potentially misvalued.

The sixth category (codes which have not been subject to review since the implementation of the RBRVS (the so-called "Harvard-valued codes")) also continues to be addressed by CMS and the AMA RUC on an ongoing basis. As we noted in the CY 2009 PFS proposed rule (73 FR 38589), there were at that time approximately 2,900 codes, representing \$5 billion in annual spending, that were originally valued using Harvard data and had not subsequently been evaluated by the AMA RUC. Consequently, in CY 2009, we requested that the AMA RUC engage in an ongoing effort to review the remaining Harvard-valued codes, focusing first on the high-volume, low-intensity codes (73 FR 38589). In response to our request, the AMA RUC initially conducted an analysis of Harvard-valued services with utilization above 10,000 services per year, which resulted in a list of 296 distinct services (73 FR 69883). The AMA RUC, in its public comment on the CY 2009 proposed rule, stated that it believes it would be effective to limit any review to these 296 services and also noted that of the 296 services identified, 23 had already been identified by another screen and were in the process of being reviewed (73 FR 69883). To date, the AMA RUC has reviewed and submitted to CMS recommendations for revised work RVUs and/or direct PE inputs for a number of Harvard-valued codes, prioritizing those codes with utilization of over 1 million services. The AMA RUC and CMS intend to continue our ongoing assessment of Harvard-valued codes, next targeting codes with utilization of over 100,000 services.

Finally, the seventh category of potentially misvalued codes in section 1848(c)(2)(K)(iii) (as added by section 3134 of the ACA) is all other codes determined to be appropriate by the Secretary. In this category, CMS has previously proposed policies and requested that the AMA RUC review codes for which there have been shifts in the site-of-service (site-of-service anomalies), as well as codes that qualify as "23-hour stay" outpatient services. The policies for valuation of both the site-of-service anomaly codes and the "23-hour stay" codes are developed further in sections II.C.3.d. and e., respectively, of this final rule with comment period. For CY 2011, we have also identified codes with low work RVUs but that are high volume based on claims data as another category of potentially misvalued codes and referred these codes to the AMA RUC

for review, as discussed in section II.C.3.b. of this final rule with comment period. In addition, for CY 2011 we have newly targeted key codes that the AMA RUC uses as reference services for valuing other services, termed "multispecialty points of comparison" services, and referred these to the AMA RUC for review as potentially misvalued codes as described in section II.C.3.a. of this final rule with comment period. Finally, we note the AMA RUC has also established screens to identify potentially misvalued codes in additional categories, including codes with a high intra-service work per unit of time (IWPUT) and codes representing services that had been surveyed by one specialty, but are now performed by a different specialty. We will continue to review AMA RUC recommendations for revised work RVUs and/or direct PE inputs for codes that fall into these categories.

As a result of the combined efforts of CMS and the AMA RUC to address potentially misvalued codes, for CY 2009 the AMA RUC recommended revised work values and/or PE inputs for 204 misvalued services (73 FR 69883). For CY 2010, an additional 113 codes were identified as misvalued and the AMA RUC provided new recommendations for revised work RVUs and/or PE inputs to CMS as discussed in the CY 2010 PFS final rule with comment period (74 FR 61778). Upon review of the AMA RUC-recommended work RVUs, CMS accepted the majority of the values as appropriate adjustments to the RVUs under the PFS, in accordance with section 1848(c) of the Act. However, for a number of codes, mainly the site-of-service anomaly codes, we indicated that although we would accept the AMA RUC valuations for these codes on an interim basis through CY 2010, we had ongoing concerns about the methodology used by the AMA RUC to review these services (73 FR 69883 and 74 FR 61776 through 61778, respectively). In the CY 2010 PFS final rule with comment period, we requested that the AMA RUC reexamine the site-of-service anomaly codes and use the building block methodology to revalue the services (74 FR 61777). In that same rule, we also stated that we would continue to examine these codes and consider whether it would be appropriate to propose additional changes in future rulemaking. We discuss our CY 2011 proposals with respect to these codes in section II.C.3.d. of this final rule with comment period.

c. Validating RVUs of Potentially Misvalued Codes

In addition to identifying and reviewing potentially misvalued codes, section 1848(c)(2)(L) (as added by section 3134 of the ACA) specifies that the Secretary shall establish a formal process to validate relative value units under the PFS. The validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed to validate a sampling of the work RVUs of codes identified through any of the seven categories of potentially misvalued codes specified by section 1848(c)(2)(K)(i)¹ of the Act (as added by section 3134 of the ACA). Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services. Currently, while CMS does assess the AMA RUC-recommended work RVUs to determine if the recommendations constitute appropriate adjustments to the RVUs under the PFS, we intend to establish a more extensive validation process of RVUs in the future in accordance with the requirements of section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA). Therefore, in the CY 2011 PFS proposed rule (75 FR 40068), we solicited public comments on possible approaches and methodologies that we should consider for a validation process. We were interested in public comments regarding approaches, including the use of time and motion studies, to validate estimates of physician time and intensity that are factored into the work RVUs for services with rapid growth in Medicare expenditures, one of the categories that the statute specifically directs CMS to examine. We indicated that we plan to discuss the validation process in a future PFS rule once we have considered the matter further in conjunction with any public comments and other input from stakeholders that we receive.

Comment: Some commenters were skeptical that there could be viable alternative methods to the existing AMA RUC code review process for validating physician time and intensity that would preserve the appropriate relativity of specific physician's services under the

current payment system. These commenters generally urged CMS to rely solely on the AMA RUC to provide valuations for services under the PFS. A number of commenters expressed the belief that since CMS has reviewed the AMA RUC recommendations for codes and generally accepted these valuations in the past, these actions constitute a "CMS validation process." The commenters asserted that this current "CMS validation process" more than meets the requirement of section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA).

In addition, a number of commenters opposed the approach of using time and motion studies to validate estimates of physician time and intensity, stating that properly conducted time and motion studies are extraordinarily expensive and, given the thousands of codes paid under the PFS, it would be unlikely that all codes could be studied. The commenters generally opposed applying different methodologies to valuing different services under the PFS and supported using a consistent methodology for all codes. Some commenters observed that it would be extremely difficult for CMS to establish a process by which to validate a sample of work RVUs under the PFS because of the relative nature of the system. Specifically, one commenter noted that the "advantages of a relative system are considerable—they allow scaling based on available funds and make it far easier for a payer such as Medicare to set rates for multiple services with a single adjustment to the conversion factor. However, one disadvantage of a relative system is that it cannot be externally validated unless all components are included in the validation. Services cannot be examined for absolute accuracy, only for relative precision. If we identify some component of the calculation used to generate the RVU that is incorrect, it is impossible to know whether this is a systemic error or an issue with an individual code. If it is a systemic error, then it does not invalidate the relative value system, which merely must operate on an even playing field." That is, many commenters believe that as long as appropriate relativity is maintained in the work RVUs for services valued under the PFS, the specific methodology for valuing services is less important. Accordingly, many commenters expressed support for the AMA RUC's use of "magnitude estimation" to develop the recommended value for a service and urged CMS to accept the AMA RUC's recommendations as the most informed and best estimation of

the true value of physician work for a service.

In contrast, some commenters declared that "the flaws inherent in the RUC system are the lack of accountability and transparency." These commenters believe that the AMA RUC's composition as a professional panel puts cognitive services at a disadvantage and suggested that "the composition of the RUC needs to be modified to more accurately reflect the desired workforce composition. At present primary care specialties are under-represented which we [the commenters] believe contributes to the overvaluation of procedural codes and undervaluation of cognitive codes." Similarly, other commenters noted that while certified registered nurse anesthetists (CRNAs) furnished approximately 32 million anesthesia services in the United States annually and can bill Medicare directly for their services, "the AMA RUC excludes CRNAs from directly participating in its deliberations because CRNAs are not physicians." These commenters noted that "without fair representation by all specialties that bill Part B directly, CMS' reliance on the AMA-RUC as representing the professional views and knowledge of all healthcare specialties is deeply flawed." The commenters also advised that "while the RUC relies on persuasion and brokering deals, RVUs need to be validated empirically." In general, these commenters believe that since section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA) expressly specifies that CMS has the authority to conduct surveys and studies and collect data, CMS should develop a process that uses empirical evidence as the basis for validation of work RVUs.

Response: We agree with the commenters that the work before us to develop a formal validation process as specified by section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA) will be a challenging but worthwhile effort to ensure accurate valuation of physician work under the PFS. While we have reviewed AMA RUC recommendations for codes and frequently accepted these valuations in the past, we disagree with the commenters' assertion that these actions constitute a formal CMS validation process as envisioned by section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA). Section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA) clearly specifies a new requirement that "the Secretary shall establish a process to validate relative value units under the fee schedule." While we solicited

comments on the possibility of using time and motion studies to support a future validation process, we understand that these studies would require significant resources and we remain open to suggestions for other approaches to developing a validation process.

In response to the commenters who raised the issue of the AMA RUC's most commonly used approach for valuing codes, referred to as "magnitude estimation," we note that the AMA RUC does not rely on a single consistent methodology to value codes. Based on our historical and current review of the AMA RUC recommendation summaries which accompany the work RVU recommendations for each code newly valued or revalued by the AMA RUC each year, we have noticed that the AMA RUC appears to use a variety of methodologies in its valuation process. For some codes, the AMA RUC uses magnitude estimation in conjunction with survey data from surveys conducted by the specialty societies to support the values. For other codes, the AMA RUC uses magnitude estimation to override the results of the survey data, recommending to CMS a value that is not based on survey data, but rather, justified in terms of its appropriate relativity within the system to other similar services. The AMA RUC may also elect to use a crosswalk approach in valuing a code by applying a work value from a currently valued code to the code under review based on the clinical similarity of the procedures or explicit considerations of pre-, intra-, and post-service time. In some instances, we note that the AMA RUC has asserted that it uses the building block methodology to value the code, a methodology we have historically supported (74 FR 61777). Since the AMA RUC uses a variety of methodologies for valuing codes, not just magnitude estimation supported by survey data, or our recommended methodology of valuation based on building blocks, we foresee that validation of the work RVUs will be complex, perhaps requiring an initial study of the all the possible valuation methodologies currently being employed by the AMA RUC so that we can better understand how relativity between services under the PFS has developed and been maintained over the years.

As we have stated previously (69 FR 66243), because the AMA RUC is an independent committee, we are not in a position to set the requirements for AMA RUC membership regarding primary care specialties or other types of practitioners. Concerned stakeholders

should communicate directly with the AMA RUC regarding its professional composition. We note that we alone are responsible for all decisions about establishing the RVUs for purposes of PFS payment so, while the AMA RUC provides us with recommendations regarding the work and direct PE inputs for new and revised CPT codes in the context of its broad expertise, we determine the interim final RVUs for all new or revised services. Additionally, the interim RVUs are subject to public comment and we respond to those comments in a final rule when we adopt the final RVUs for the new and revised CPT codes. We believe that the formal validation process will further complement the ongoing work of the AMA RUC to provide recommendations to us regarding the valuation of PFS services.

Comment: While a number of commenters strongly opposed CMS' plans to develop a formal validation process, many other commenters expressed support for the development and establishment of a system-wide validation process of the work RVUs under the PFS. The commenters commended CMS for seeking new approaches to validation, as well as being open to suggestions from the public on this process. A number of commenters submitted technical advice and offered their time and expertise as resources for CMS to draw upon in any examination of possible approaches to developing a formal validation process.

Furthermore, MedPAC advised that a formal validation process should include validating the fee schedule's estimates of physician time. MedPAC noted that "Contract research for CMS and the Assistant Secretary for Planning and Evaluation has shown that some of the time estimates are likely too high. In addition, the Government Accountability Office has found that the fee schedule does not adequately account for efficiencies occurring when a physician furnishes multiple services for the same patient on the same day." Finally, MedPAC suggested that CMS should consider alternative approaches, "such as collecting data on a recurring basis from a cohort of practices and other facilities where physicians and nonphysician clinical practitioners work."

Some commenters noted that "involving RUC experts, those who are most intimately acquainted with and possess the deepest level of expertise and experience makes the most sense" and stated that these individuals "are also those best equipped to provide insights and guidance to help shape an independent validation system." A

number of commenters asked CMS to confirm that stakeholders would be given the opportunity to comment on any specific proposals for a validation process that CMS plans to implement.

Response: We thank the many commenters who generously offered to help and provided technical suggestions, including the use of statistical modeling and possible sources of data that we should consider in developing a validation process. We will review MedPAC's suggestions to examine physician time in the formal validation process. We will also consider the commenters' recommendation that we include the AMA RUC and other professional groups who also have a stake in ensuring appropriate payment for practitioners' services. As we stated previously, we intend to establish a more extensive validation process of RVUs in the future in accordance with the requirements of section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA). We note that MedPAC, in providing comments to the CY 2011 PFS proposed rule, "strongly supports efforts to improve the accuracy of the fee schedule's RVUs." We plan to discuss the validation process in more detail in a future PFS rule once we have considered the matter further in conjunction with the public comments that we have received in response to our solicitation in the CY 2011 proposed rule as well as other input from stakeholders. Moreover, we note that any proposals we would make on the formal validation process would be subject to public comment, and we would consider those comments before finalizing any policies.

3. CY 2011 Identification and Review of Potentially Misvalued Services

In this section, we discuss codes that may be potentially misvalued according to five different criteria:

- Codes on the multi-specialty points of comparison list;
- Codes with low work RVUs commonly billed in multiple units per single encounter;
- Codes with high volume and low work RVUs;
- Codes with site-of-service anomalies; and
- Codes that qualify as "23-hour stay" outpatient services.

a. Codes on the Multispecialty Points of Comparison List

The AMA RUC uses a scale referred to as the multispecialty points of comparison (MPC) to evaluate the reasonableness of a specialty society's recommended RVU value for a service.

The MPC list contains reference codes of established comparison services that are used in the valuation of new codes. The current MPC list consists of 316 codes which the AMA RUC may use to compare and contrast the relativity of codes under review to existing relative values. Since the AMA RUC may use the values on the MPC list as a basis for relativity when determining the values for new, revised, and newly reviewed codes (including potentially misvalued codes), it is essential that the services on the MPC list be appropriately valued since any codes misvalued on the MPC list could contribute to the misvaluation of other codes under review. While we believe that the entire MPC list should be assessed to ensure that services are paid appropriately under the PFS, we prioritized the review of the MPC list, ranking the codes by allowed service units and charges based on CY 2009 claims data. We proposed to refer the codes in Table 9 to the AMA RUC for review in CY 2011.

TABLE 9—CODES ON THE MPC LIST REFERRED FOR AMA RUC REVIEW

CPT code	Short descriptor
66984	Cataract surg w/ol, 1 stage.
97110	Therapeutic exercises.
43239	Upper GI endoscopy, biopsy.
20610	Drain/inject, joint/bursa.
78815	Pet image w/ct, skull-thigh.
45385	Lesion removal colonoscopy.
45380	Colonoscopy and biopsy.
11721	Debride nail, 6 or more.
17000	Destruct premalg lesion.
92980	Insert intracoronary stent.
74160	Ct abdomen w/dye.
71020	Chest x-ray.
11100	Biopsy, skin lesion.
66821	After cataract laser surgery.
52000	Cystoscopy.
92083	Visual field examination(s).
73721	Mri jnt-of lwr extre w/o dye.
93010	Electrocardiogram report.
77334	Radiation treatment aid(s).
92250	Eye exam with photos.
95810	Polysomnography, 4 or more.
77003	Fluoroguide for spine inject.
11056	Trim skin lesions, 2 to 4.
76700	Us exam, abdom, complete.
77290	Set radiation therapy field.
77300	Radiation therapy dose plan.
43235	Uppr gi endoscopy, diagnosis.
71275	Ct angiography, chest.
95900	Motor nerve conduction test.
31231	Nasal endoscopy, dx.
95165	Antigen therapy services.
94060	Evaluation of wheezing.
31575	Diagnostic laryngoscopy.

Comment: While some commenters agreed with CMS that the entire MPC list should be assessed to ensure that services are paid appropriately under the PFS, and supported the proposal that the AMA RUC review the services

listed in Table 9, a number of other commenters expressed surprise that CMS seemed to be suggesting that any code on the MPC list could be classified as potentially misvalued. Many commenters noted that the MPC list of codes is considered the “gold standard” within the PFS and it is used to help judge the appropriate relativity of procedures across specialties. A number of commenters assured CMS that the codes on the MPC list have been thoroughly vetted and, therefore, these commenters took issue with CMS for implying that the codes could somehow be considered potentially misvalued. Specifically, one commenter noted, “[t]he assumption of the specialties, the RUC and CMS has been that these services are appropriately valued and well established.” Another commenter expressed the concern as follows: “[c]hallenging the rank order of the MPC list essentially negates 20 years of RUC work. Obtaining new data to validate the old data inevitably leads to the problem of what should be done if the data yield different results. Is there any reason to believe that a newer survey is a more accurate survey, or that the data analysis and subsequent opinion of the current or future RUCs will be more valid than that of previous RUCs? Admittedly data collection methods have become more refined in the past 20 years, but that neither means nor implies that relativity amongst physician services has changed.” Some commenters reminded CMS that the AMA RUC is already planning to review some codes on the MPC list in the coming year, while other commenters noted that some of the codes on the MPC list have been reviewed by the AMA RUC within the past 6 years. Some commenters did not believe that some of the well-established services on the MPC list would need another review and that the resources required to re-review such services could be better used elsewhere. Furthermore, some commenters believe that if a code has been surveyed as part of the potentially misvalued services initiative during the last 5 years and it is identified again using a different screen, that it need not be resurveyed again.

Finally, several commenters noted that while reviewing all the codes on the MPC list would “be a substantial undertaking for the RUC, properly valuing these services will help restore equity in the physician payment system.” The commenters further suggested that CMS should specify to the AMA RUC what it considers good survey methodology, including the use of peer review and time studies.

Response: We note that the vast majority of commenters, whether they supported or opposed our proposal, acknowledged the significant and central role that the MPC list plays in the valuation of services under the PFS. Because it is currently the “gold standard” to which other codes, across specialties, are compared, we agree with the commenters who suggested that codes on this list should be vetted, though we disagree that we should assume this has been done or occurs automatically and systematically. We also acknowledge that the AMA RUC recently has reviewed some of the codes and is planning to review more codes on the MPC list. Our proposal suggested prioritizing the review of the codes by ranking them according to utilization which, in our view, would potentially provide the most immediate benefit to the system.

If a code on the MPC list has not been reviewed recently—certainly more recently than 6 years ago—we believe that the code is vulnerable to being potentially misvalued and that the misvaluation of an MPC code could disproportionately affect the correct valuation of other related services under the PFS. Given the rapid changes in medical practice, we have no reason to believe that the relativity of the MPC codes would not have changed over the past 20 years and we would expect that more recent survey data would more accurately reflect the physician work in current medical practice. If the codes are resurveyed and newer more accurate data are available, we would support using the most recent available data to value physician work under the PFS, which is consistent with our general policy to use the most current data whenever possible and practicable to update the PFS.

Given the evolving review process of the AMA RUC over the past several years, CMS’ strong interest in ensuring current and appropriate physician work values for PFS services, and the increased emphasis on revaluing established services that are potentially misvalued, we are requesting that the AMA RUC provide a current and comprehensive recommendation on the appropriate physician work value, including describing and affirming the methodology for the recommended work value, for all of the codes listed in Table 9. To the extent the AMA RUC chooses to limit its work in reexamining MPC codes that have recently been evaluated, consistent with our usual practice, we will consider the context in which we evaluate the AMA RUC’s recommendation for the value of the code.

Although valuation is ultimately our responsibility, the AMA RUC and CMS remain partners in ensuring the appropriate valuation of physician work for services under the PFS and we believe our proposal serves to enhance this process. Accordingly, after consideration of the public comments we received, we are finalizing our CY 2011 proposal and we look forward to receiving the AMA RUC's recommendations for the codes listed in Table 9.

b. Codes With Low Work RVUs Commonly Billed in Multiple Units Per Single Encounter

Consistent with section 1848(c)(2)(K)(ii) of the Act (as added by section 3134 of the ACA) which identifies categories of potentially misvalued codes for our review, we believe services with low work RVUs that are commonly billed with multiple units in a single encounter are an additional appropriate category for identifying potentially misvalued codes. An example of a high multiple/low work RVU service is CPT code 95004 (Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests). For purposes of compiling a list of the high multiple/low work RVU services, we defined a high multiple service as one that is commonly performed in multiples of 5 or more per day. Then, we selected from high multiple services with work RVUs of less than or equal to 0.5 RVUs. We note that in selecting 5 per day as the minimum threshold for the number of common services performed in a multiple service encounter, we intended to establish a meaningful threshold which, in conjunction with the threshold for work RVUs of 0.5 RVUs or less, would produce a reasonable number of services for the RUC to review that have substantial total work RVUs for the comprehensive service furnished during a single treatment. That is, as a general example, with a work RVU threshold of 0.5 RVUs and a multiple threshold of 5 per day, the total work RVUs for a typical treatment would equate to 2.5 RVUs, which is approximately comparable to a high level office visit, an interpretation of a complex imaging procedure, or a minor surgical procedure.

In the CY 2011 PFS proposed rule (75 FR 40069), we requested that the AMA RUC review the codes in Table 10.

TABLE 10—CODES WITH LOW WORK RVUS THAT ARE COMMONLY BILLED IN MULTIPLE UNITS REFERRED FOR AMA RUC REVIEW

CPT code	Short descriptor
95904	Sense nerve conduction test.
17003	Destruct premalg les, 2–14.
95004	Percut allergy skin tests.
11101	Biopsy, skin add-on.
95024	Id allergy test, drug/bug.
76000	Fluoroscope examination.
95144	Antigen therapy services.
95010	Percut allergy titrate test.
88300	Surgical path, gross.
95027	Id allergy titrate—airborne.
95015	Id allergy titrate—drug/bug.
95148	Antigen therapy services.

c. Codes With High Volume and Low Work RVUs

We believe that codes that have low work RVUs but are high volume based on claims data are another category of potentially misvalued codes. Although these codes have low work RVUs (less than or equal to 0.25 RVUs), the high utilization of these codes represents significant expenditures under the PFS such that their appropriate valuation is especially important. Table 11 contains a list of such codes and we requested that the AMA RUC review these codes in the CY 2011 PFS proposed rule (75 FR 40069).

TABLE 11: CODES WITH LOW WORK RVUS THAT ARE HIGH VOLUME REFERRED FOR AMA RUC REVIEW

CPT code	Short descriptor
71010	Chest x-ray.
73510	X-ray exam of hip.
97035	Ultrasound therapy.
88313	Special stains group 2.
73630	X-ray exam of foot.
72100	X-ray exam of lower spine.
73030	X-ray exam of shoulder.
73562	X-ray exam of knee, 3.
73560	X-ray exam of knee, 1 or 2.
94010	Breathing capacity test.
77052	Comp screen mammogram add-on.
88304	Tissue exam by pathologist.
73564	X-ray exam, knee, 4 or more.
72170	X-ray exam of pelvis.
74000	X-ray exam of abdomen.
73610	X-ray exam of ankle.
11719	Trim nail(s).
73620	X-ray exam of foot.
92567	Tympanometry.
73110	X-ray exam of wrist.
73130	X-ray exam of hand.
93701	Bioimpedance, cv analysis.
72040	X-ray exam of neck spine.
92543	Caloric vestibular test.

Comment: A number of commenters agreed with CMS' proposal for the AMA RUC to review codes with low work

RVUs that are commonly billed with multiple units, and codes with high volume and low work RVUs. Other commenters did not support these proposals based on a belief that just because a code has low work RVUs, the conclusion should not necessarily be drawn that the code is potentially misvalued.

Response: While we do not believe that low work RVUs automatically indicate that the code is misvalued, we believe that some codes in this category may be vulnerable to being potentially misvalued because they have not been subject to review recently, there are particular challenges associated with establishing appropriate low work RVUs for services, and these services would not likely be subject to AMA RUC revaluation without CMS' recommendation. Accordingly, after consideration of the public comments we received, we are finalizing our CY 2011 proposal and we look forward to receiving the AMA RUC's recommendation for the codes listed in Tables 10 and 11.

d. Codes With Site-of-Service-Anomalies

In previous years, we requested that the AMA RUC review codes that, according to the Medicare claims database, have experienced a change in the typical site of service since the original valuation of the code. For example, we have found services that originally were furnished in the inpatient setting but for which current claims data show the typical case has shifted to being furnished outside the inpatient setting. Since the procedures were typically performed in the inpatient setting when the codes were originally valued, the work RVUs for these codes would have been valued to include the inpatient physician work furnished, as well as to reflect the intensive care and follow-up normally associated with an inpatient procedure. If the typical case for the procedure has shifted from the inpatient setting to an outpatient or physician's office setting, it is reasonable to expect that there have been changes in medical practice, and that such changes would represent a decrease in physician time or intensity or both. The AMA RUC reviewed and recommended to CMS revised work RVUs for 29 codes for CY 2009 and 11 codes for CY 2010 that were identified as having site-of-service anomalies.

In the CY 2010 PFS proposed and final rules with comment period (74 FR 33556 and 74 FR 61777, respectively), we encouraged the AMA RUC to utilize the building block methodology when revaluing services with site-of-service

anomalies. Specifically, where the AMA RUC has determined in its review that changes in the inclusion of inpatient hospital days, office visits, and hospital discharge day management services (that is, the "building blocks" of the code) are warranted in the revaluation of the code, we asked the AMA RUC to adjust the site-of-service anomaly code for the work RVUs associated with those changes.

Additionally, we suggested that in cases where the AMA RUC has adjusted the pre-service, intra-service and post-service times of the code under review, the AMA RUC should also make associated work RVU adjustments to account for those changes. However, we remained concerned that in the AMA RUC's recommendations of the work RVUs for the CYs 2009 and 2010 site-of-service anomaly codes, the AMA RUC may have determined that eliminating or reallocating pre-service and post-service times, hospital days, office visits, and hospital discharge day management services was appropriate to reflect the typical case that is now occurring in a different setting, but the work RVUs associated with those changes may not have been systematically extracted or reallocated from the total work RVU value for the service.

In the CYs 2009 and 2010 PFS final rules with comment period (73 FR 69883 and 74 FR 61776 through 61778, respectively), we indicated that although we would accept the AMA RUC valuations for these site-of-service anomaly codes on an interim basis through CY 2010, we had ongoing concerns about the methodology used by the AMA RUC to review these services. We requested that the AMA RUC reexamine the site-of-service anomaly codes and use the building block methodology to revalue the services (74 FR 61777). We also stated that we would continue to examine these codes and consider whether it would be appropriate to propose additional changes in future rulemaking.

Accordingly, in preparation for CY 2011 rulemaking, we conducted a comprehensive analysis of the codes that the AMA RUC reviewed for CYs 2009 and 2010 due to site-of-service anomaly concerns. We systematically applied the reverse building block methodology to the 29 codes from CY 2009 and 11 codes from CY 2010 as follows:

- First, we obtained the original work RVU value assigned to the code (this is the "starting value") and made a list of the building block services with RVUs that were originally associated with the code (that is, before the AMA RUC reviewed the code for site-of-service anomalies).
- Next, we examined the AMA RUC-recommended changes to the building blocks of the code.
- We then deducted the RVUs associated with the AMA RUC's recommended eliminations from the code's starting RVU value.

Generally, the AMA RUC eliminated inpatient hospital visit building blocks from the value of the code since the site-of-service for the code has shifted from the inpatient setting to another setting. We noted in some cases, the AMA RUC left an inpatient hospital visit in the valuation of the code. We believe this is inconsistent with the change in the site-of-service to non-inpatient settings. Accordingly, we adhered to the methodology and deducted the RVUs associated with all inpatient hospital visits from the starting value. In cases where the AMA RUC recommended adding or substituting outpatient visits, we also added or substituted the RVUs associated with those changes to the starting value. If the AMA RUC recommended changes to the pre-, intra-, or post-service times, we calculated the incremental change in RVUs associated with that time and either added or deducted that RVU amount from the starting value. We noted that the RVU values associated with the incremental time change were calculated using the intensity associated with the particular pre-, intra-, or post-

period. For the intensity of the intra-service period, we utilized the original IWP/PUT associated with the code. The AMA RUC generally recommended allowing only half of a hospital discharge day management service for the site-of-service anomaly codes. That is, CPT code 99238 (Hospital discharge day management; 30 minutes or less) has a work RVU value of 1.28; therefore, half the value associated with CPT code 99238 is 0.64. Accordingly, if a code had one CPT code 99238 listed as part of the original valuation, we deducted 0.64 RVUs from the starting value.

We standardized the methodology so that each of the site-of-service anomaly codes had half of a hospital discharge day management service value accounted in the valuation. Finally, we noted that while we eliminated the RVUs associated with all inpatient hospital visits built into the code's starting value, because the typical case no longer occurs in the inpatient setting, we allowed for the possibility that in some cases, some part of the work which had been furnished in the inpatient setting may continue to be furnished even in the outpatient setting. Therefore, to be conservative in our deductions of work RVUs associated with the inpatient hospital codes from the starting values, we allowed the intra-time of any inpatient hospital visits included in the original valuation to migrate to the post-service period of the code. Accordingly, while we deducted the full RVUs of an inpatient hospital visit from the starting value, we added the intra-service time of the inpatient hospital visit to the post-service time of the code and accounted for the incremental change in RVUs. The following description provides an example of our methodology.

CPT code 21025 (Excision of bone (e.g., for osteomyelitis or bone abscess); mandible) has a starting value of 11.07 RVUs. Table 12 shows the building blocks that are included in the original valuation of the code.

TABLE 12

Pre-service time	Median intra-service time	Immediate post-service time	99231	99232	99238	99211	99212	99213	Original IWP/PUT
75 min	120 min ..	43 min	1 visit	1 visit	1 visit	2 visits	2 visits	2 visits	0.0145
			(0.76 RVUs)	(1.39 RVUs)	(1.28 RVUs)	(0.36 RVUs)	(0.96 RVUs)	(1.94 RVUs)	

The AMA RUC removed two inpatient hospital visits and reduced the outpatient visits from 6 to 4 visits. Table

13 shows the building blocks that were recommended for CY 2009 by the AMA

RUC after its review of the code for site-of-service anomalies.

TABLE 13

Pre-service time	Median intra-service time	Immediate post-service time	99231	99232	99238	99211	99212	99213	Original IWPUP
85 min	90 min ...	30 min					2 visits	2 visits	0.0530

Next we calculated the RVUs associated with the changes to the building blocks recommended by the AMA RUC. We note that the immediate post-service value of 0.38 RVUs (Table 14) includes 30 minutes of intra-service time from inpatient hospital CPT code

99231 (Level 1 subsequent hospital care, per day). Also, the median intra-service value of 0.44 RVUs (Table 14) was determined using the starting IWPUP value of 0.0145. Additionally, our methodology accounted for a half of a hospital discharge day management

service (CPT code 99238) for the site-of-service anomaly code. Table 14 shows the RVU changes to the building blocks that were calculated based on the methodology discussed above.

TABLE 14

Pre-service time	Median intra-service time	Immediate post-service time	99231	99232	99238	99211	99212	99213
0.22 RVUs	-0.44 RVUs ..	0.38 RVUs	-0.76 RVUs	-1.39 RVUs	-0.64 RVUs	-0.36 RVUs	

In the final step, the RVUs associated with the changes to the building blocks recommended by the AMA RUC (Table 14) were deducted from or added to the starting value of 11.07 RVUs, which resulted in the CY 2011 reverse building

block value of 8.08 RVUs (11.07 + 0.22 - 0.44 + 0.38 - 0.76 - 1.39 - 0.64 - 0.36 = 8.08).

The methodology discussed above was applied to each of the site-of-service anomaly codes from CYs 2009 and 2010

and the results are summarized in Tables 15 and 16.

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TABLE 15: CY 2009 Site-of-Service Anomaly Codes¹

CPT Code	Short Descriptor	CY 2008 RVUs ("Starting Value")	RUC Recommended Value for CY 2009	CY 2011 Reverse Building Block Value
21025	Excision of bone, lower jaw	11.07	9.87	8.09
23415	Release of shoulder ligament	10.09	9.07	10.63
25116	Remove wrist/forearm lesion	7.38	7.38	7.21
42440	Excise submaxillary gland	7.05	7.05	6.52
52341	Cysto w/ureter stricture tx	6.11	5.35	5.62
52342	Cysto w/up stricture tx	6.61	5.85	6.20
52343	Cysto w/renal stricture tx	7.31	6.55	5.90
52344	Cysto/uretero, stricture tx	7.81	7.05	5.58
52345	Cysto/uretero w/up stricture	8.31	7.55	5.76
52346	Cystouretero w/renal strict	9.34	8.58	6.05
52400	Cystouretero w/congen repr	10.06	8.66	7.00
52500	Revision of bladder neck	9.39	7.99	8.72
52640	Relieve bladder contracture	6.89	4.73	5.01
53445	Insert uro/ves nck sphincter	15.21	15.21	11.72
54410	Remove/replace penis prosth	16.48	15.00	14.00
54530	Removal of testis	9.31	8.35	8.88
57287	Revise/remove sling repair	11.49	10.97	10.20
62263	Epidural lysis mult sessions	6.41	6.41	6.99
62350	Implant spinal canal cath	8.04	6.00	0.41
62355	Remove spinal canal catheter	6.60	4.35	-0.43
62360	Insert spine infusion device	3.68	4.28	-3.14
62361	Implant spine infusion pump	6.59	5.60	-0.92
62362	Implant spine infusion pump	8.58	6.05	-0.51
62365	Remove spine infusion device	6.57	4.60	-0.35
63650	Implant neuroelectrodes	7.57	7.15	4.25
63685	Insrt/redo spine n generator	7.87	6.00	4.80
64708	Revise arm/leg nerve	6.22	6.22	6.17
64831	Repair of digit nerve	10.23	9.00	8.87
65285	Repair of eye wound	14.43	14.43	13.52

¹We note that in this table, we have not adjusted the RVUs for these codes for the RVU changes to the evaluation and management codes that resulted from the CY 2010 elimination of the consultation codes (74 FR 61775). However, we note that we may, if appropriate, adjust the RVUs for services with global periods to account for relevant changes in the RVUs for evaluation and management services as necessary.

TABLE 16: CY 2010 Site-of-Service Anomaly Codes²

CPT Code	Short Descriptor	CY 2009 RVUs ("Starting Value")	RUC Recommended Value for CY 2010	CY 2011 Reverse Building Block Value
28120	Part removal of ankle/heel	5.64	8.08	6.03
28122	Partial removal of foot bone	7.56	7.56	6.79
28725	Fusion of foot bones	11.97	11.97	12.41
28730	Fusion of foot bones	12.21	12.21	10.06
36825	Artery-vein autograft	10.00	15	13.12
42415	Excise parotid gland/lesion	17.99	17.99	15.17
42420	Excise parotid gland/lesion	20.87	20.87	17.80
49507	Prp i/hern init block >5 yr	9.97	9.97	9.37
49521	Rerepair ing hernia, blocked	12.36	12.36	11.59
49587	Rpr umbil hern, block > 5 yr	7.96	7.96	7.19
61885	Insrt/redo neurostim 1 array	7.37	7.57	3.22

²We note that in this table, we have not adjusted the RVUs for these codes for the RVU changes to the evaluation and management codes that resulted from the CY 2010 elimination of the consultation codes (74 FR 61775). However, we note that we may, if appropriate, adjust the RVUs for services with global periods to account for relevant changes in the RVUs for evaluation and management services as necessary.

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For most codes in Tables 15 and 16, the CY 2011 reverse building block methodology produced a value that was somewhat lower than the AMA RUC-recommended value. While our results suggested that the majority of the codes with site-of-service anomalies continue to be overvalued under the AMA RUC's most recent recommendations, we also found that the methodology may produce a result that is considerably reduced or, in several cases, a negative value. We understand that in previous years, stakeholders have expressed confusion as to why the application of a building block methodology would produce negative values. We believe in some cases, the starting value, that is, the original work RVU, may have been misvalued using building block inputs that were not consistent with the service, although the overall work value of the code may have been consistent with the values for other similar services. Moreover, a number of these services are the Harvard-valued codes, for which the RVUs were established many years ago based on historical inputs that may no longer be appropriate for the code. An attempt to extract the RVUs associated with these inappropriate inputs through the reverse building block methodology could produce aberrant results. Furthermore, in some cases, we noticed that the original IWPUR of the code was negative even before the code was reviewed by the AMA RUC for a site-of-service anomaly. A negative value for

the IWPUR is counterintuitive to the IWPUR concept, indicating that the code was originally misvalued at the building block level. At a minimum, we believe that in cases where the reverse building block methodology produced aberrant results, and where clinical review indicated a need for further analysis, the codes should be referred back to the AMA RUC for review and new valuation should be performed based on the building block methodology.

We noted the application of the reverse building block methodology is an objective way to account for changes in the resources resulting from the change in the site-of-service in which the typical service is furnished. However, because relative values under the PFS are "relative," that is, where work relative value units for a code are established relative to work relative value units for other codes, the recommended methodology of valuing services based on input building blocks is best applied within the context of the AMA RUC discussion. For example, we recognize that the AMA RUC looks at families of codes and may assign RVUs based on a particular code ranking within the family. This method of valuing services preserves relativity within the relative value scale for that code family. However, we have stated that we believe the relative value scale requires each service to be valued based on the resources used in furnishing the service as specified in section 1848(c)(1)(A) of the Act, which defines

the physician work component to include "the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service." Furthermore, section 1848(c)(2)(C)(i) of the Act specifies that "the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service." Read together, these two sections of the statute support our intention to rely on the building block methodology to determine appropriate work RVUs for codes.

We noted that we continue to rely on the extensive expertise provided by the AMA RUC to recommend appropriate input building blocks for codes. Additionally, the AMA RUC's unique infrastructure and broad perspective permits the valuation of a code within the context of relativity to the entire relative value system. Therefore, we believe that the recommended methodology of valuing services based on input building blocks is best applied within the context of the AMA RUC discussion.

Accordingly, in the CY 2011 PFS proposed rule (75 FR 40072), we requested that the AMA RUC review the CPT codes displayed in Tables 15 and 16. In addition, where the application of the CY 2011 reverse building block methodology produced an aberrant result that is clearly not a reflection of physician work for the service, we requested that the AMA RUC review the

input building blocks and recommend an appropriate RVU value that is both consistent with the building blocks of the code and appropriate relative to the values for other codes in the family. For other codes where the application of the CY 2011 reverse building block methodology produced a result that is consistent with the physician work for the service, we encouraged the AMA RUC to confirm the values and recommend these work values for CY 2011. In this way, we hoped to receive new AMA RUC recommendations for all of the codes in Tables 15 and 16 for CY 2011. Furthermore, we indicated that if the recommendations that we received from the AMA RUC were not consistent with the building block methodology and not appropriate relative to the values of other services, and the application of the CY 2011 reverse building block methodology produced a result that CMS medical advisors believe is consistent with the work for the service, we proposed to adopt the CY 2011 reverse building block methodology values that are listed in Tables 15 and 16 for CY 2011. In cases where the reverse building block methodology produced a negative work value, we suggested that the AMA RUC review and revise the building blocks of the code so that a new valuation could be determined based on the building block methodology. For such codes, if the revised recommendations that we hoped to receive from the AMA RUC were still not consistent with the building block methodology upon revision, because we could not pay for these services based on negative work RVUs, we proposed to modify the AMA RUC-recommended values for these codes as CMS determined to be clinically appropriate and adopt the CMS-modified RVUs on an interim final basis for CY 2011.

In their future work, we urged the AMA RUC to use the building block methodology when valuing services or provide CMS with extensive rationale for cases where the AMA RUC believes the building block methodology is inappropriate for a specific code. Since section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA) specifies that the Secretary shall establish a process to validate work RVUs of potentially misvalued codes under the PFS, as we have discussed earlier in this section, we believe codes that are valued using the building block methodology would be more likely to meet the standards of a systematic RVU validation process that could be developed in accordance with the requirements of the statute.

Comment: While several commenters supported CMS' recommendation to use the reverse building block methodology to value physician work for codes identified as having site-of-service anomalies, the majority of commenters strongly opposed the reverse building block methodology, expressing concern that the methodology produced very low or negative work RVUs for a number of the codes listed in Tables 14 and 15. Several letter writing campaigns by groups of providers and beneficiaries affected by some of the codes listed in Tables 14 and 15 produced scores of comments expressing confusion and alarm that CMS appeared to be on the verge of finalizing negative work RVUs. Some commenters noted that the values calculated by the application of the reverse building block methodology would result in rank order anomalies across the PFS.

Many commenters reiterated CMS' observation that some of the codes were originally Harvard-valued, for which the RVUs were established many years ago based on historical inputs that may no longer be appropriate for the code, and an attempt to extract the RVUs associated with these inappropriate inputs through the reverse building block methodology would produce aberrant (that is, very low or negative) results. Some commenters disagreed with CMS' statement that if the typical case for the procedure has shifted from the inpatient setting to an outpatient or physician's office setting, it would be reasonable to expect that there have been changes in medical practice, and that such changes would represent a decrease in physician time, or intensity, or both. These commenters believe that that this assumption is fundamentally wrong and that the reverse actually may be true. One commenter noted, "When a procedure migrates from the inpatient to the outpatient setting, the physician work and practice expense actually increase. The result is more office visits, more utilization of office staff, more consumption of office supplies, and no decrease in legal liability to the physician (and in some instances increased legal liability as functions formerly performed by hospital staff are now done by physician office staff)."

A number of commenters asserted that any mathematical or computational methodology used to value physician work is simply absurd. Many commenters stated their preference for the AMA RUC's established valuation process which the commenters believe is based on specialty society survey data. Other commenters asserted that the AMA RUC's use of magnitude estimation is the only methodology that

makes sense in assigning physician work values to individual services because the PFS is a relative system and maintaining appropriate relativity between the services is paramount in valuing physician work.

Response: We acknowledge that commenters overwhelmingly objected to the proposed reverse building block methodology because, in some cases, it produced very low or negative physician work values. While we explained in the proposed rule (75 FR 40071 through 40072) the possible reasons why negative values could be generated in the application of the reverse building block methodology, the commenters generally disregarded this explanation and summarily dismissed the methodology as invalid based on the reasoning that negative work values are absurd. Responding to the commenters who were concerned that CMS was preparing to implement negative work RVUs imminently, we assure the commenters that at no time was this a possibility, as we made clear in the CY 2011 PFS proposed rule (75 FR 40072) where we acknowledge that we could not pay for services based on negative work RVUs. As we stated in the proposed rule, in cases where the reverse building block methodology produced a negative work value, we suggested that the AMA RUC review and revise the building blocks of the code so that a new valuation could be determined based on the building block methodology. We further proposed that if we did not believe the AMA RUC recommended values were consistent with the building block methodology, we would modify the recommended values as we determined to be clinically appropriate and adopt the modified RVUs on an interim final basis for CY 2011.

The AMA RUC has not provided revised work recommendations to us for these codes for CY 2011. Therefore, in light of the strong public opposition to the reverse building block methodology and since we remain convinced that the values for the codes with site-of-service anomalies listed in Tables 14 and 15 continue to be misvalued based on our clinical review of the building blocks for those services as recommended previously by the AMA RUC, we believe that the most appropriate action is to continue to await the further AMA RUC review of these codes that we requested in the CY 2011 PFS proposed rule (75 FR 40072). However, after consideration of the public comments we received, we are modifying our CY 2011 proposal and we will not apply the reverse building block methodology to value any of these codes for CY 2011 as we proposed. We

are requesting that the AMA RUC reconsider its previously recommended values that have been applied on an interim basis in CYs 2009 and 2010, as applicable, and revise the work RVUs to better reflect the intensity of the services and the revised physician times and post-procedure visits included in the valuation of these codes. As we stated in the CY 2011 PFS proposed rule (75 FR 40072), we suggest that the AMA RUC review and revise the building blocks of the codes so that a new valuation can be determined based on the building block methodology. Until we receive the revised values from the AMA RUC for CY 2012 and can make a determination regarding them, we will continue to accept the existing AMA RUC-recommended work RVUs listed in Tables 14 and 15 on an interim basis for CY 2011. We would follow our usual method of reviewing the AMA RUC recommendations in the context of the associated valuation methodologies it used for CY 2012 and would either accept the recommendations for these codes or provide alternative work values that would be adopted on an interim final basis for CY 2012 and open to public comment on the CY 2012 PFS final rule with comment period.

e. Codes With "23-hour" Stays

In the CY 2010 PFS proposed rule (74 FR 33557), we requested that the AMA RUC review services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours. We stated in the proposed rule that we believed these to be primarily outpatient services and expressed concern that the value of evaluation and management (E/M) visits for inpatients was inappropriately included in the valuation of codes that qualify as "23-hour stay" outpatient services.

We received a number of comments in response to the discussion in the CY 2010 proposed rule. The AMA RUC stated that it already values stays of less than 23 hours appropriately by reducing the hospital discharge day management service (that is, CPT code 99238), from 1 day to a half day. The AMA RUC also explained that when the AMA RUC refers to 23-hour stay services in discussions at AMA RUC meetings, it is referring primarily to services that are reported in the Medicare claims database as typically outpatient services, but where the patient is kept overnight and, on occasion, even longer in the hospital. Because the AMA RUC believes the patient stays overnight in the hospital, it believes the inclusion of inpatient E/M visits to be appropriate in the valuation of this category of codes.

We believe that the 23-hour stay issue encompasses several scenarios. The typical patient is commonly in the hospital for less than 24 hours, which often means the patient may indeed stay overnight in the hospital. On occasion, the patient may stay longer than a single night in the hospital; however, in both cases, the patient is considered for Medicare purposes to be a hospital outpatient, not an inpatient, and our claims data support that the typical 23-hour stay service is billed as an outpatient service. Accordingly, we believe that the valuation of the codes that fall into the 23-hour stay category should not reflect work that is typically associated with an inpatient service. For example, inpatient E/M visit codes such as CPT codes 99231 (Level 1 subsequent hospital care, per day); 99232 (Level 2 subsequent hospital care, per day); and 99233 (Level 3 subsequent hospital care, per day), should not be included at the full value in the valuation of 23-hour stay services.

Currently, the valuation of 23-hour stay services is conducted in a nonuniform manner by the AMA RUC. The AMA RUC has indicated that it currently includes a half hospital discharge day management service and no hospital inpatient visits for outpatient services with expected hospital stays of 23 hours or less. In contrast, for those outpatient services where the AMA RUC believes that the recovery period could be longer than 23 hours, the AMA RUC stated in its comment on the CY 2010 PFS proposed rule that it currently includes a full hospital discharge day management service and one or more inpatient E/M visits in the code's value. However, we note the typical 23-hour stay service is billed as an outpatient service and so long as the typical case continues to be billed as an outpatient service, we believe the code should not incorporate physician work values for services that are typically associated with an inpatient service. In the CY 2010 PFS proposed rule and final rule with comment period (74 FR 33556 and 74 FR 61777, respectively), we stated that we believed the use of inpatient E/M visit codes for services rendered in the post-service period for outpatient 23-hour stay procedures would result in overpayment for pre- and post-service work that would not be furnished. Accordingly, we proposed in the CY 2010 proposed rule (74 FR 33556 through 33557) not to allow any additional inpatient E/M service to be billed for care furnished during the post-procedure period when care is furnished for an outpatient service

requiring less than a 24-hour hospital stay.

However, we find it is plausible that while the patient receiving the 23-hour stay service remains a hospital outpatient, the patient would typically be cared for by the physician furnishing the procedure during that post-procedure period. While we do not believe that post-procedure hospital "visits" would be at the inpatient level since the typical case is an outpatient who would be ready to be discharged from the hospital in 23 hours or less, we agree that the intra-service time of the inpatient hospital visit may be included in the valuation for the 23-hour stay code.

Accordingly, for CY 2011 we modified our proposed CY 2010 approach and suggested that in the future, when the AMA RUC reviews new and potentially misvalued codes that are identified as 23-hour stay services, the AMA RUC would apply the following methodology:

- Begin with the starting RVU value of the 23-hour stay code under review and decrease the hospital discharge day management service from one day to a half day.
 - Deduct the RVUs of inpatient hospital visits from the starting RVU value.
 - Reallocate the time associated with the intra-service portion of the inpatient hospital visits to the immediate post-service time of the 23-hour stay code under review.
- Example:* A 23-hour stay code is currently valued at 15 RVUs and has 1 hospital discharge day management service and 1 level 3 subsequent hospital care visit incorporated in this value.
- Applying step (1): $15 - 0.64^* = 14.36$
 - Applying step (2): $14.36 - 2^{**} = 12.36$
 - Applying step (3): $12.36 + (30 \text{ minutes} \times 0.0224)^{***} = 13.032 \text{ RVUs}$

* Value associated with 1/2 hospital discharge day management service.

** Value associated with an inpatient hospital visit, CPT code 99233.

*** Value associated with the reallocated intra-service time multiplied by the post-service intensity of the 23-hour stay code.

Finally, we note that since work relative value-units are established by the Secretary in the context of relativity to other codes in the system, the recommended methodology for the evaluation of 23-hour stay codes is best applied within the context of relativity. We appreciate that the AMA RUC has the ability to assess the 23-hour stay code after application of the recommended methodology to ensure

appropriate relativity of this code and other codes within the system. We strongly encourage the AMA RUC to apply the recommended methodology to ensure the consistent and appropriate valuation of the physician work for these services.

Comment: A number of commenters asserted that if a service is performed in the hospital and the patient stays overnight, the work of the physician is typically the same regardless of whether the hospital designates the patient receiving the services as an inpatient or outpatient. Other commenters supported CMS' position in that it is appropriate for physicians' services related to the post-procedure care of the patient to be recognized and the intra-service time of the inpatient hospital visit should be included in the valuation for the 23-hour stay code. Some commenters noted that recent issues associated with hospital observation care may also be impacting CPT observation care codes, and these commenters "request that any changes in the 23+ hour stay policy be deferred until after the RUC conducts its consideration of hospital observation services in February 2011."

Response: While some commenters advocated for a deferral on the issue of valuing 23-hour stay services, we note that a number of commenters supported CMS' proposed approach. As we stated in the CY 2010 PFS proposed rule (74 FR 33557) and affirmed in the CY 2011 PFS proposed rule (75 FR 40072), we believe these services, for a typical patient, would be considered for Medicare purposes to be hospital outpatient services, not inpatient services, and our claims data support that the typical 23-hour stay service is billed as an outpatient service. Furthermore, since the typical patient commonly remains in the hospital for less than 24 hours, even if the stay extends overnight, and discharge from the hospital is therefore imminent, we believe the acuity of the typical patient is less than that of a typical inpatient who is admitted to the hospital, resulting in less intensity for the physician work to care for the hospital outpatient immediately following a 23-hour stay procedure. Accordingly, we believe that the valuation of the codes that fall into the 23-hour stay category should not reflect physician work that is typically associated with an inpatient service. Furthermore, we do not believe that it would be more beneficial to suspend valuing 23-hour services in the manner we discussed in the proposed rule until after the AMA RUC's review of hospital observation care services. Even if the AMA RUC were to provide

future recommendations to us for valuing surgical procedures in which hospital observation care services were substituted for hospital inpatient care visits, we believe that we should treat the valuation of the physician time in the same manner as discussed previously, that is, by valuing the intra-service time of the hospital observation care service in the immediate post-service time of the 23-hour stay code being valued.

Accordingly, in light of the support from the commenters, we are finalizing our proposed approach to valuing 23-hour stay services by allowing the intra-service portion of the subsequent hospital care visits (or observation care visits in the future if the AMA RUC were to recommend them instead as building blocks for outpatient surgical services) furnished to outpatients in the hospital post-procedure to be allocated to the immediate post-service time of the procedure to account for the physician work in these cases. We encourage the AMA RUC to apply this methodology itself in the recommendations it provides to us for valuing 23-hour stay codes, in order to ensure the consistent and appropriate valuation of the physician work for these services.

4. Expanding the Multiple Procedure Payment Reduction (MPPR) Policy to Additional Nonsurgical Services

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same patient by the same physician on the same day, largely based on the presence of efficiencies in the practice expense (PE) and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with the same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future.

Consistent with recommendations of MedPAC in its March 2005 Report to Congress on Medicare Payment Policy, under the CY 2006 PFS, the MPPR policy was extended to the technical component (TC) of certain diagnostic imaging procedures performed on contiguous areas of the body in a single session (70 FR 70261). The reduction recognizes that, for the second and subsequent imaging procedures, there are some efficiencies in clinical labor,

supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent procedures and, because equipment time and indirect costs are allocated based on clinical labor time; those would also be reduced accordingly.

The imaging MPPR policy currently applies to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and ultrasound services within 11 families of codes based on imaging modality and body region. When we adopted the policy in CY 2007, we stated that we believed efficiencies were most likely to occur when contiguous body areas are the focus of the imaging because the patient and equipment have already been prepared for the second and subsequent procedures, potentially yielding resource savings in areas such as clerical time, technical preparation, and supplies (70 FR 45850). Therefore, the MPPR policy currently applies only to procedures involving contiguous body areas within a family of codes, not across families, and to those procedures that are furnished in a single session. Additionally, while the MPPR policy applies to TC-only services and to the TC of global services, it does not apply to professional component (PC) services.

Under the current imaging MPPR policy, full payment is made for the TC of the highest-paid procedure, and payment is reduced by 25 percent of the TC for each additional procedure when an MPPR scenario applies. We had originally planned to phase in the MPPR policy over a 2-year period, with a 25 percent reduction in CY 2006 and a 50 percent reduction in CY 2007 (70 FR 70263). However, the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) capped the PFS payment amount for most imaging procedures at the amount paid under the hospital outpatient prospective payment system (OPPS). In view of the DRA, we determined that it would be prudent to retain the MPPR at 25 percent while we continued to examine the appropriate payment levels (71 FR 69659). The DRA also exempted reduced expenditures attributable to the MPPR policy from the PFS budget neutrality provision. Most recently, effective July 1, 2010, section 3135(b) of the ACA increased the MPPR on the TC of imaging services under the policy established in the CY 2006 PFS final rule with comment period from 25 to 50 percent and exempted the reduced expenditures attributable to this further change from the PFS budget neutrality provision.

In the July 2009 GAO report entitled, "Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together," the GAO recommended that we take further steps to ensure that fees for services paid under the PFS reflect efficiencies that occur when services are furnished by the same physician on the same beneficiary on the same day. The GAO recommended the following: (1) Expanding the existing MPPR policy to the PC to reflect efficiencies in physician work for certain imaging services; and (2) expanding the MPPR to reflect PE efficiencies that occur when certain nonsurgical, nonimaging services are furnished together. The GAO also encouraged us to focus on service pairs that have the most impact on Medicare spending.

In the March 2010 report, MedPAC noted its concerns about mispricing of services under the PFS. MedPAC indicated that it would explore whether expanding the unit of payment through packaging or bundling would improve payment accuracy and encourage more efficient use of services.

In the CYs 2009 and 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy.

b. CY 2011 Expansion of the Imaging Technical Component MPPR Policy to Additional Combinations of Imaging Services

Over the past 2 years, the AMA RUC has examined several services billed 90 percent or more of the time together as part of the potentially misvalued service initiative and, in several cases, created one code to describe the complete service, with a value that reflects the expected efficiencies. Notwithstanding the bundling work of the RUC, there may be additional imaging and other diagnostic services that are furnished together less than 90 percent of the time where we could still expect efficiencies in the TC, and in some cases in the PC, resulting in potential overpayment for these services under current policy when furnished together.

Section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with

furnishing a single service, and review and make appropriate adjustments to their relative values. As a first step in applying this provision, we proposed a limited expansion of the current imaging MPPR policy for CY 2011. We will continue to review other possible expansions of the MPPR policy to the TC and/or PC of imaging procedures or other diagnostic tests for the future. Any further changes will be addressed in future rulemaking.

In a related policy for hospital outpatient payment of imaging services, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569), the OPPS adopted a policy to pay for two or more CT and CTA, MRI and MRA, or ultrasound procedures furnished in the same session through a single composite ambulatory payment classification (APC) group. These composite APC payments were based on the 11 families of codes subject to the MPPR under the PFS that were collapsed into 3 imaging families for the OPPS according to their modality—1 for ultrasound, 1 for CT and CTA, and 1 for MRI and MRA services.

At that time, we stated our belief that the contiguous body area concept that was incorporated in the PFS imaging families was not necessary for potential efficiencies to be achieved in an imaging session. We provided examples to illustrate that we would not expect second and subsequent imaging services of the same modality involving noncontiguous body areas to require duplicate facility resources (comparable to the TC under the PFS) for clinical labor activities such as greeting the patient, providing education and obtaining consent, retrieving prior exams, setting up an intravenous infusion, and preparing and cleaning the room, any more than second and subsequent imaging procedures of the same modality involving contiguous body areas. While we noted that multiple imaging claims under the OPPS are generally within the same imaging modality and involve contiguous body areas the vast majority of the time, we estimated that the collapsed 3 families, as opposed to the 11 PFS families, would add 12 percent additional claims to those eligible for a single composite APC payment under the OPPS based on the provision of 2 or more imaging services in a single session, allowing us to capture additional claims with efficiencies.

Taking into consideration the OPPS policy that was adopted in the CY 2009 OPPS/ASC final rule with comment period, for CY 2011 under the PFS, we proposed to apply the MPPR regardless

of family, that is, the policy would apply to multiple imaging services furnished within the same family of codes or across families. This proposal would simplify the current imaging MPPR policy in a way that is consistent with the standard PFS MPPR policy for surgical procedures that does not group procedures by body region. Therefore, the MPPR would apply to CT and CTA, MRI and MRA, and ultrasound procedures services furnished to the same patient in the same session, regardless of the imaging modality, and not limited to contiguous body areas.

Because of the different pieces of equipment used for CT/CTA, MRI/MRA, and ultrasound procedures, it would be unlikely that a single practitioner would furnish more than one imaging procedure involving 2 different modalities to one patient in a single session where the proposed MPPR policy would apply. On the other hand, while most multiple procedures furnished with a single modality in one session would involve procedures currently assigned to one of the 11 imaging families, it would not be uncommon for more than one imaging procedure of the same modality to be furnished across families and, like the scenario for hospital outpatient imaging services, we would expect efficiencies to occur in these cases. Therefore, we believe that an expansion of the current imaging MPPR policy to account for efficiencies in such situations would allow us to pay more appropriately for these multiple imaging procedure sessions, consistent with our ongoing efforts to address misvalued services.

The expansion of the imaging MPPR policy to include all of the current codes in a single family to which the standard 50 percent reduction for second and subsequent procedures would apply would reduce payment for 20 percent more services than the current MPPR policy under the PFS. Thus, in CY 2011, we would capture additional efficiencies and pay more appropriately in these cases. We note that section 1848(c)(2)(B)(v)(VI) (as added by section 3135(b) of the ACA) specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent in CY 2011 are excluded from the PFS budget neutrality adjustment. However, the reduced payment for code combinations that would newly be subject to the imaging MPPR policy under this proposal would be made in a budget neutral manner under the PFS, as these new combinations are not included under section 1848(b)(4)(D) (as added by section 3135(b) of the ACA), which addresses "single-session imaging to

consecutive body parts" under the established imaging MPPR policy.

We also proposed to add the CY 2010 codes displayed in Table 17 of the CY 2011 PFS proposed rule (75 FR 40075) to the list of imaging services subject to the MPPR policy in CY 2011. These four codes (CPT codes 75771 through 75774) were newly created for CY 2010 and are similar to codes currently in imaging family 2, titled CT and CTA (Chest/Thorax/Abdomen/Pelvis).

We further note that new CY 2010 CPT codes 74261 (Computed tomography (CT) colonography, diagnostic, including image postprocessing; without contrast material) and 74262 (Computed tomography (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed) were added to the CY 2010 MPPR policy through the July 2010 PFS quarterly update, with a retroactive effective date of January 1, 2010. These codes replaced CPT code 0067T (Computed tomographic (CT) colonography (that is, virtual colonoscopy); diagnostic) in CY 2010, which was on the list of procedures subject to the imaging MPPR policy prior to CY 2010.

As discussed earlier in this section, reduced expenditures attributable to the increase in the MPPR for multiple imaging procedures to consecutive body parts (that is, those previously designated in the same family of codes) are exempt from the budget neutrality provision of the PFS. However, the reduced expenditures attributable to the MPPR for combinations of multiple imaging procedures that we proposed for CY 2011 (the MPPR for multiple imaging procedures not involving consecutive body parts) would be subject to budget neutrality adjustment under the PFS. We note that this formulation for whether reduced expenditures are exempt from budget neutrality applies both to procedures currently subject to the imaging MPPR and to new codes that would be subject to the policy in CY 2011 and in future years. To the extent that imaging procedures described by the new codes are furnished in combination with other procedures that are subject to the imaging MPPR on consecutive body areas, the reduced expenditures attributable to the MPPR for these combinations would be exempt from the PFS budget neutrality adjustment.

Comment: With one exception, the commenters uniformly opposed the proposal to consolidate the imaging families for application of the imaging MPPR and urged CMS not to finalize the

proposal. The exception was MedPAC, which supported the policy as reasonable and consistent with the hospital OPSS policy on multiple imaging and the PFS MPPR policy for multiple surgical procedures, neither of which are limited to procedures involving contiguous body areas.

Many commenters pointed out that the AMA RUC has worked to resolve any duplication in the direct PE inputs for services commonly furnished together over the past few years. The commenters stated that new bundled services were implemented in CY 2010 and speculated that additional ones would be implemented in the future and, therefore, concluded that a general MPPR to adjust PFS payment when imaging services are commonly furnished together is not necessary. The commenters argued that any duplication in the PE should be resolved at the code pair level. The AMA RUC urged CMS to continue to work within the established processes and offered for its Practice Expense Subcommittee to review specific code pairs about which CMS was concerned regarding potential PE duplication and recommend a course of action that would be fair and consistent.

Response: The imaging MPPR is not intended to supersede the AMA RUC process that values services described by CPT codes. We encourage the AMA RUC to continue examining code pairs for PE duplication based upon the typical case and appropriately valuing new comprehensive codes for bundled services that are established by the CPT Editorial Panel. However, we believe that it is necessary to address the PE duplication immediately for imaging code pairs that have not been recently reviewed or bundled into single comprehensive codes. We note that as more code combinations are bundled into a single complete service reported by one CPT code, they would no longer be subject to the MPPR. For example, there are new CY 2011 codes to describe abdominal and pelvic CT scans furnished together, specifically CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material); 74177 (Computed tomography, abdomen and pelvis; with contrast material); and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with contrast material(s) and further sections in one or both body regions). We are accepting the AMA RUC recommendations for the direct PE inputs for these codes for CY 2011 and, therefore, their TCs are valued accordingly. Whereas prior to CY 2011, the 50 percent imaging MPPR would

have applied to the TC of the second service when an abdominal and pelvic CT were furnished in the same imaging session, this will no longer be the case in CY 2011. Instead, the TC payment for the comprehensive code will reflect the valuing of the specific services furnished in combination with one another. Thus, we believe our current and proposed MPPR formulations are consistent with the AMA RUC's work to review code pairs for potential PE duplication and to appropriately value comprehensive codes for a bundle of component services.

Comment: Numerous commenters opposed applying the MPPR to noncontiguous body area imaging services using the same modality and to combinations of imaging services involving different modalities. Many commenters indicated that there is no major duplication in clinical labor activities when two studies of noncontiguous body areas using a single imaging modality are furnished in the same session and even less duplication when imaging services are furnished in a separate session on the same day using different modalities. The commenters argued that the duplication in clinical labor activities that occurs in the pre- and post-operative periods for multiple surgical procedures does not apply to imaging services.

More specifically, several commenters observed that the minimal duplicate costs of a few minutes of technician time do not justify a 50 percent payment reduction in the TC for the second service. Some commenters also believe that the imaging MPPR creates an incentive for physicians to order separate procedures on different days, thereby discouraging efficiencies. In addition, the commenters contended that the imaging MPPR is detrimental to patient care, access, and convenience.

One commenter asserted that it is not appropriate to compare the OPSS composite ambulatory payment classification (APC) groups to office-based imaging as a justification for expanding the imaging MPPR under the PFS. The commenter cited an analysis of OPSS payment demonstrating that CMS pays hospitals for the second imaging study at nearly 100 percent of the amount paid for a single study, concluding that not until the third study would the payment be reduced from the sum of what would otherwise be paid under the OPSS if the studies were performed alone.

Another commenter agreed that the current PFS imaging families could be further collapsed to eliminate the contiguous body area concept but opposed applying the MPPR across

modalities. The commenter suggested establishing three families to parallel the modality-based APC groups used under the OPPS, that is, CT/CTA, MRI/MRA, and ultrasound. Another commenter noted that highly specialized clinics often treat complex conditions and perform multiple imaging services on noncontiguous body areas primarily for good patient care. As an example of a situation when complex imaging services are used to diagnose and treat significant medical conditions, the commenter indicated that a CT of the chest may be furnished, resulting in a diagnosis of lung cancer. In addition, the same commenter noted that appropriate treatment of the patient's neurological signs and symptoms also requires a CT of the head, because primary lung tumors account for 50 percent of all metastatic brain tumors. The commenter explained that these medically necessary combinations of imaging services are often performed in a single imaging session. Results of the initial imaging service, contended the commenter, could change the course of treatment for the patient and it would be prudent not to delay or complicate a patient's treatment plan. The commenter also pointed out that it is a convenience to the patient to have same day access for all imaging services.

Another commenter acknowledged that while some efficiencies are gained in certain situations and settings when multiple imaging services are furnished together, the expanded MPPR policy would not appropriately pay for the additional studies required for the majority of patients with significant medical conditions. The commenter explained that highly organized clinics treating these complex patients often structure patient encounters so that there are intervening consultations with multiple providers and additional tests in between imaging services.

Response: While most multiple procedures furnished with a single modality in 1 session would involve procedures currently assigned to 1 of the 11 imaging families, it would not be uncommon for more than 1 imaging procedure of the same modality to be furnished across families, and we would expect efficiencies to occur in these cases. As noted by MedPAC, the proposed PFS MPPR expansion to eliminate the concept of contiguous body areas as the basis for a payment reduction due to efficiencies is consistent with the established hospital OPPS policy on multiple imaging and the PFS MPPR policy for multiple surgical procedures, neither of which is limited to procedures involving

contiguous body areas. While we acknowledge that the OPPS composite imaging APCs utilize a different payment methodology than an MPPR to reflect the level of efficiencies when multiple imaging services are furnished together, consideration of the specific body areas imaged is not an aspect of the OPPS policy. The OPPS methodology continues to distinguish among services using different imaging modalities in part because of the statutory requirement that APCs be clinically homogenous. This same limitation would not apply to an MPPR. Despite the differences in their payment methodologies, both the OPPS and the PFS strive to recognize the efficiencies in the TCs when multiple imaging services are furnished together. We continue to believe that there are significant efficiencies in the TCs when multiple imaging procedures of the same modality are furnished on noncontiguous body areas in the same imaging a session, and believe that an expanded imaging MPPR under the PFS is an important policy refinement to pay more appropriately for the comprehensive imaging service under such circumstances.

Because most of the combinations of imaging services furnished in one session that are not now subject to the imaging MPPR occur within one modality, we believe it would be unnecessarily complex to continue separate families (even if fewer than 11) for different imaging modalities to address the limited circumstances when imaging services furnished with more than one modality are performed in a single imaging session. Even in these unusual cases, we would expect certain efficiencies in the TCs, such as the establishment of venous access only one time. Finally, the more general proposed policy would provide a streamlined basis for our further consideration of other possible expansions of an MPPR policy to the TC and/or PC of imaging procedures or other diagnostic tests in the future.

Consistent with our current expectations for provider ordering practices under the established imaging MPPR policy for single modality, contiguous body area imaging studies, under an expanded MPPR we would not expect providers to order multiple imaging procedures of different modalities or for noncontiguous body areas on different days or order different imaging sessions on the same day simply to garner increased payment unless it were medically reasonable and necessary that the studies be furnished on different days or in different sessions on the same day. However, where it is

medically necessary to have intervening consultations among multiple providers or other diagnostic tests furnished to a patient between imaging services on the same day to which the MPPR would otherwise apply, such cases would constitute separate imaging sessions and the MPPR would not apply.

Comment: Many commenters addressed CMS' assertion that because of the different pieces of equipment used for CT/CTA, MRI/MRA, and ultrasound procedures it would be unlikely that a single practitioner would furnish more than one imaging procedure involving two different modalities to one patient in a single session where the proposed MPPR policy would apply. While most commenters agreed with this statement, the commenters questioned why CMS would implement the proposal if this were the case. When procedures are furnished across modalities, the commenters believe them to be separate and distinct procedures with little or no overlap and argue that efficiencies cannot be achieved. The commenters asserted that CMS offered no data to support its expectation that efficiencies would occur when different imaging modalities are furnished at the same time. Many commenters requested a more rigorous analysis, validated evidence to support the proposed expansion, and an opportunity for stakeholders to comment on the analysis.

A number of the commenters agreed that specialized staff with different expertise and certification is often needed to furnish services within the different imaging modalities. When multiple imaging is necessary, the commenters explained that two appointments are created, and the patient is checked in twice, prepared and instructed twice, educated on each study independently, transported from one room to another, and furnished separate supplies such as contrast and IV tubing, following which the two rooms are cleaned.

Response: We agree with the majority of commenters that in most cases a practitioner would not furnish more than one imaging procedure involving two different modalities to one patient in a single session. While there may be some instances where the MPPR applies to two different modalities used in a single session, the MPPR would not apply in most cases because this clinical scenario is uncommon. In response to the commenters who questioned why we proposed to apply an MPPR across modalities, we believe that if, in the unusual case, more than one imaging service of different modalities were

furnished to a patient in a single session, there would be some efficiencies in the TC, such as greeting the patient only one time and setting up one intravenous line. We acknowledge that the application of a general MPPR policy to numerous imaging service combinations may result in an overestimate of the efficiencies in some cases and an underestimate in others, but this can be true for any service paid under the PFS, and we believe it is important to establish a general policy to pay appropriately for the TCs of combinations of imaging services upon which we may consider building in the future. We do not believe that it is administratively efficient or necessary for appropriate payment to maintain modality-specific imaging families given the uncommon occurrences of pairs of imaging services involving different modalities furnished by one practitioner on the same day to a single patient that we observe in our claims data.

Comment: Several commenters generally opposed the inclusion of nondiagnostic radiation oncology imaging procedures in any future expansion of the MPPR policy, given the clinical differences between radiation oncology and diagnostic imaging. In addition, one commenter noted that cardiologists commonly provide echocardiography services and peripheral vascular ultrasound tests. While both types of services use ultrasound technology that resembles the technology used in the ultrasound procedures currently subject to the imaging MPPR, the commenter reported that these services are furnished using a different machine and different staff who have different expertise so the imaging MPPR policy.

Response: We did not propose to expand the existing contiguous body area MPPR policy, which currently includes only nonobstetrical chest, abdominal, and pelvic ultrasound services, to include peripheral vascular ultrasound services or echocardiography services in CY 2011. While we explained in the CY 2011 PFS proposed rule (75 FR 40074) that we would continue to review other possible expansions of the MPPR policy to the TC and/or PC of imaging procedures or other diagnostic tests for the future, we have not proposed to do so at this time. Further changes to include services such as nondiagnostic radiation oncology imaging services or echocardiography or peripheral vascular ultrasound services would be addressed in future rulemaking.

Comment: A few commenters reported that it is often difficult for imaging providers to understand when

an encounter begins and ends and, therefore, urged CMS to better define a single session. They explained that it is not always easy to identify when the use of the -59 modifier (Distinct procedural services), denoting a separate session under the current imaging MPPR policy, is appropriate. This ambiguity leaves the responsibility for determining whether imaging services are furnished in a separate session to the judgment of the imaging technologist, leading to inconsistent determinations and, therefore, variable payment for the same services furnished in similar clinical scenarios. One commenter specifically requested further parameters of a separate encounter be defined to include the same exam room, a specific timeframe, or a specific action. Another commenter noted that distinguishing separate sessions is a particular challenge for ultrasound imaging.

Response: In the CY 2006 PFS final rule with comment period (70 FR 70262), we indicated that a single imaging session is one encounter where a patient could receive one or more radiological studies. If a patient has a separate encounter on the same day for a medically necessary reason and receives a second imaging service, this would represent a separate session. Physicians would report the -59 modifier to indicate multiple sessions and the MPPR would not apply. This same policy would continue in CY 2011 under the consolidation of the imaging families to expand the imaging MPPR under the PFS. We believe that providers' 5 years of previous experience with this policy should allow them to continue to appropriately distinguish separate imaging sessions by reporting the -59 modifier, even under the expanded MPPR policy. We may provide further subregulatory guidance to providers on this issue in the future in view of our CY 2011 expanded imaging MPPR policy if specific issues arise that we believe warrant further clarification regarding the characteristics of separate imaging sessions.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to apply the 50 percent imaging MPPR to all of the ultrasound, CT, CTA, MRI, and MRA services to which the current contiguous body area and modality-specific policy applies, regardless of the specific combinations of imaging services furnished to the patient in a single session. We believe this proposal is consistent with our overall strategy to pay more appropriately for services that are commonly furnished together,

consistent with section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) that instructs the Secretary to identify multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values.

As stated earlier in this section; expenditures attributable to the increase in the MPPR for multiple imaging procedures to consecutive body parts (that is, those previously designated in the same family of codes) are exempt from the budget neutrality provision of the PFS. However, the reduced expenditures attributable to the MPPR for new combinations of multiple imaging procedures that we are finalizing for CY 2011 (the MPPR for multiple imaging procedures not involving consecutive body parts) would be subject to budget neutrality adjustment under the PFS. We note that this formulation for whether reduced expenditures are exempt from budget neutrality applies both to procedures currently subject to the imaging MPPR and to new codes that are subject to the policy in CY 2011 and in future years. To the extent that imaging procedures described by the new codes are furnished in combination with other procedures that are subject to the imaging MPPR on consecutive body areas, the reduced expenditures attributable to the MPPR for these combinations would be exempt from the PFS budget neutrality adjustment.

The complete list of codes subject to the CY 2011 MPPR policy for diagnostic imaging services is included in Addendum F to this final rule with comment period and the CY 2011 code additions to the MPPR policy are listed in Table 17. The codes being added to the policy are those we proposed, as well as new CY 2011 codes or newly covered codes that are clinically similar to the imaging codes subject to the MPPR in CY 2010. The new codes include CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material); 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)); and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions). The newly covered codes are CPT codes 72159 (Magnetic resonance angiography, spinal canal and contents, with or without contrast material) and 73225 (Magnetic resonance angiography, upper extremity, with or without contrast material). These codes are being added on an interim final

basis and are open to public comment on this final rule with comment period.

The complete list of CPT codes newly added to the diagnostic imaging MPPR

for CY 2011 is displayed in Table 17 below.

TABLE 17—CPT CODE ADDITIONS TO THE DIAGNOSTIC IMAGING MPPR POLICY FOR CY 2011

CPT code	Short descriptor	Subject to comment in CY 2011 PFS final rule
72159	Mr angio spine w/o & w/dye	Yes.
73225	Mr angio upr extr w/o & w/dye	Yes.
74176	Ct abd & pelvis w/o contrast	Yes.
74177	Ct abdomen & pelvis w/contrast	Yes.
74178	Ct abd & pelv 1+ section/regns	Yes.
75571	Ct hrt w/o dye w/ca test	No.
75572	Ct hrt w/3d image	No.
75573	Ct hrt w/3d image, congen	No.
75574	Ct angio hrt w/3d image	No.

c. CY 2011 Expansion of the MPPR Policy to Therapy Services

In the July 2009 GAO report entitled, "Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together," the GAO found efficiencies when multiple physical therapy services were furnished in one session and concluded that an MPPR policy could be appropriate for these services. In the report, the GAO noted that officials from the AMA RUC explained that time spent on pre-service and post-service therapy activities is spread across the number of services in a typical session in order to avoid duplication of the PE for the services. Nevertheless, the GAO found that there was duplication of certain activities in the intra-service period, and provided the example of time spent testing range of motion or muscle flexibility that was duplicated in commonly observed code pairs.

In the typical clinical scenario for therapy services, we believe that therapy services are misvalued for PFS payment when multiple services are furnished to a patient in a single session because duplicate clinical labor and supplies are included in the PE of the services furnished. We believe this duplication should be accounted for under the PFS, as we currently account for efficiencies in multiple surgical and multiple diagnostic imaging procedures furnished in a single session. Over the past 2 years, the AMA RUC has examined several services billed 90 percent or more of the time together as part of its potentially misvalued service initiative and, in several cases, created one code to describe the complete service, with a value that reflects the expected efficiencies. Notwithstanding the AMA RUC's analyses, in most cases it has not created one code to describe a complete therapy service, in part

because many of the core therapy CPT codes are timed codes based on increments of treatment time.

Therefore, in the CY 2011 PFS proposed rule (75 FR 40075), we proposed a further step to implement section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) that specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service. For CY 2011 we proposed an MPPR policy for the HCPCS codes listed in Table 18, specifically the separately payable "always therapy" services that are only paid by Medicare when furnished under a therapy plan of care. These services are designated "always therapy" services regardless of who furnishes them and always require therapy modifiers to be reported, specifically -GP (Services rendered under outpatient physical therapy plan of care); -GO (Services rendered under outpatient occupational therapy plan of care); or -GN (Services rendered under outpatient speech-language pathology plan of care). The therapy codes are available in a file on the CMS Web site at: <http://www.cms.gov/TherapyServices/>. We excluded both contractor-priced and bundled codes from Table 18 because, under our proposal, an MPPR would not be applicable for "always therapy" services furnished in combination with these codes. In the case of bundled codes that are not separately paid, there are no explicit efficiencies in the direct PE to be reflected in payment for the second and subsequent therapy services furnished to the patient on the same day. In the case of contractor-priced codes, there is no nationally established pricing that could be uniformly adjusted to reflect the expected efficiencies when multiple therapy services are furnished.

TABLE 18—SEPARATELY PAYABLE "ALWAYS THERAPY" SERVICES PROPOSED AS SUBJECT TO THE CY 2011 MPPR POLICY *

CPT/HCPCS code	Short descriptor
92506	Speech/hearing evaluation.
92507	Speech/hearing therapy.
92508	Speech/hearing therapy.
92526	Oral function therapy.
92597	Oral speech device eval.
92607	Ex for speech device rx, 1hr.
92608	Ex for speech device rx addl.
92609	Use of speech device service.
96125	Cognitive test by hc pro.
97001	Pt evaluation.
97002	Pt re-evaluation.
97003	Ot evaluation.
97004	Ot re-evaluation.
97010	Hot or cold packs therapy.
97012	Mechanical traction therapy.
97016	Vasopneumatic device therapy.
97018	Paraffin bath therapy.
97022	Whirlpool therapy.
97024	Diathermy eg, microwave.
97026	Infrared therapy.
97028	Ultraviolet therapy.
97032	Electrical stimulation.
97033	Electric current therapy.
97034	Contrast bath therapy.
97035	Ultrasound therapy.
97036	Hydrotherapy.
97110	Therapeutic exercises.
97112	Neuromuscular reeducation.
97113	Aquatic therapy/exercises.
97116	Gait training therapy.
97124	Massage therapy.
97140	Manual therapy.
97150	Group therapeutic procedures.
97530	Therapeutic activities.
97533	Sensory integration.
97535	Self care mgmt training.
97537	Community/work reintegration.
97542	Wheelchair mgmt training.
97750	Physical performance test.
97755	Assistive technology assess.
97760	Orthotic mgmt and training.
97761	Prosthetic training.
97762	C/o for orthotic/prosth use.
G0281	Elec stim unattnd for press.

TABLE 18—SEPARATELY PAYABLE “ALWAYS THERAPY” SERVICES PROPOSED AS SUBJECT TO THE CY 2011 MPPR POLICY*—Continued

CPT/HCPCS code	Short descriptor
G0283	Elec stim other than wound.
G0329	Electromagnetic tx for ulcers.

*Excludes contractor-priced and bundled codes.

We did not propose an MPPR policy for “sometimes therapy” services, specifically those services that may be furnished under a therapy plan of care or otherwise by physicians or NPPs as medical services. We believe that the care patterns are different for the latter group of services that may sometimes be furnished as therapy services, and we noted that they are less commonly furnished with multiple services in a single session than the “always therapy” services. In the discussion that follows, our reference to therapy services means those HCPCS codes designated annually as “always therapy” services by CMS.

Based on CY 2009 PFS claims data, we identified over 500 therapy service code pairs billed for the same patient in a single session. We then reviewed a sample of the most common therapy code pairs, specifically those high volume code pairs with more than 250,000 combined services per year, to examine the potential for duplication in

the PE. These code pairs represented more than half of the occurrences of therapy services billed together. While we acknowledged that the PE inputs per service for some therapy services were included in the direct PE database based on one-half of the total PE inputs required for two services furnished in a single session, which would account for some duplication, this was not the case for all combinations of therapy services. Of the high volume therapy services examined, approximately one-fourth of the code pairs were not valued based on two services. In addition, we noted that the CY 2009 PFS claims data for services paid under the PFS (excluding services furnished in facility settings that were paid at PFS rates) show that when multiple therapy services are billed on a claim for the same date of service, the median number is four services per day. Therefore, even for those clinical labor times that may reflect the allocation of total time across two units of therapy services, we believe that some elements of the current PE inputs are duplicated based on current patterns of therapy service delivery where most multiple service claims involve delivery of more than two services in a session.

In the CY 2011 proposed rule (75 FR 40076), we stated that duplicate labor activities currently included in the PE for the service period for these high volume pairs of therapy services are as follows: clean room/equipment;

education/instruction/counseling/ coordinating home care; greet patient/ provide gowning; obtain measurements, for example, ROM/strength/edema; and post-treatment patient assistance. The most common duplicate supply item included in the PE was the multispecialty visit pack. Examples of duplicated and unduplicated labor activities and supplies for two sample therapy code pairs and our estimates of potential clinically appropriate time and quantity reductions for multiple service sessions (which were also included in our proposed rule) are displayed in Table 19. We note that CY 2009 PFS claims data for these sample code pairs include over 3.4 million pairs of CPT codes 97112 (Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities) and 97110 (Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility) furnished by the same practitioner on the same day and over 500,000 pairs of CPT codes 97001 (Physical therapy evaluation) and 97140 (Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction); 1 or more regions, each 15 minutes).

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TABLE 19: Examples of Duplicate PE Inputs for Therapy Services that Should be Accounted for When Multiple Services are Furnished in One Session

Example 1: CPT code 97112 (Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and /or proprioception for sitting and/or standing activities) and CPT code 97110 (Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility)

Staff Description	Labor Task Description	Time Period	Code A 97112 Labor Task Time	Code B 97110 Labor Task Time	Total Minute Reduction
Physical Therapy Aide	Clean room/equipment	Service Period, Post-Service	1	1	1
Physical Therapy Assistant	Education/instruction/counseling/coord home care	Service Period, Post-Service	2.5	2.5	2.5
Physical Therapy Aide	Greet patient/provide gowning	Service Period, Pre-Service	1.5	1.5	1.5
Physical Therapy Assistant	Obtain measurements, eg, ROM/strength/edema	Service Period, Pre-Service	1.5	1.5	1.5
Physical Therapy Assistant	Obtain vital signs	Service Period, Pre-Service	1	1	1
Physical Therapy Assistant	Phone calls between visits with patient, family	Post-Service Period	1	1	1
Physical Therapy Aide	Post treatment patient assistance	Service Period, Post-Service	1	1	1
Physical Therapy Assistant	Review/read documentation, plan of care, treatment goals	Pre-Service Period	1.5	1.5	1.5
Physical Therapy Aide	Verify/Coordinate availability of resources/equip	Pre-Service Period	1.5	1.5	1.5

Supply Description	Price	Code A 97112 Quantity	Code B 97110 Quantity	Code B 97110 Quantity Reduction
pack, minimum multi-specialty visit	\$1.14	0.5	0.5	0
Thera-bands (6in width)	\$0.06	1.5	1.5	1.5

Example 2: CPT code 97001 (Physical therapy evaluation) and CPT Code 97140 (Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes)

Staff Description	Labor Task Description	Time Period	Code A 97001 Labor Task Time	Code B 97140 Labor Task Time	Total Minute Reduction
Physical Therapy Aide	Clean room/equipment	Service Period, Post-Service	3	1	1
Physical Therapy Assistant	Education/instruction/counseling/coord home care	Service Period, Post-Service	2	1	1
Physical Therapy Aide	Greet patient/provide gowning	Service Period, Pre-Service	3	1.5	1.5
Physical Therapy Assistant	Obtain measurements, eg, ROM/strength/edema	Service Period, Pre-Service	8	1.5	1.5
Physical Therapy Assistant	Obtain vital signs	Service Period, Pre-Service	3	1	1
Physical Therapy Assistant	Phone calls between visits with patient, family	Post-Service Period	2	1	1
Physical Therapy Assistant	Review/read documentation, plan of care, treatment goals	Pre-Service Period	1	.5	.5
Physical Therapy Aide	Verify/Coordinate availability of resources/equip	Pre-Service Period	3	1.5	1.5
Physical Therapy Aide	Prep and position patient	Service Period, Pre-Service	2	0	0
Physical Therapy Aide	Prepare room, equipment, supplies	Service Period, Pre-Service	2	0	0
Physical Therapy Aide	Post treatment assistance	Service Period, Post-Service	0	1	0

Supply Description	Price	Code A 97001 Quantity	Code B 97140 Quantity	Code B 97140 Quantity Reduction
pack, minimum multi-specialty visit	\$1.14	1	0.5	0.5
lotion, message, unscented	\$0.158	0	0.5	0

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In the CY 2011 PFS proposed rule (75 FR 40078), we did not remove minutes for clinical labor tasks that were not duplicated. For example, for CPT code pair 97001 and 97140 the following tasks were not duplicated: post treatment patient assistance; prep and position patient; and prepare room, equipment, and supplies. In addition, we did not remove any supply items that would be required for only one of the separate services because these would not be duplicated in the PE

applicable to the combination of services. We estimated no reduction for equipment time, even though efficiencies would be expected for equipment that is used in both services when they are furnished together. Finally, a corresponding reduction to the indirect expenses would be appropriate since indirect costs are allocated partially based on direct costs. For five high volume therapy code pairs that each occur over 2 million times in PFS claims for multiple therapy services and account for almost half of such

claims, we estimated that the resulting reduction in the PE for the lower paying code would range from 28 to 56 percent.

As we summarized in the CY 2011 PFS proposed rule (75 FR 40078), given the duplicative clinical labor activities and supplies as shown in the code combination examples, we believe it would be appropriate to extend the MPPR policy that is currently applied to surgical services and the TC of imaging services, to the PE component of certain therapy services. Specifically, we proposed to apply a 50 percent payment

reduction to the PE component of the second and subsequent therapy services for multiple "always therapy" services furnished to a single patient in a single day. Because we believed it would be difficult to determine the precise beginning and end of therapy sessions and we did not believe that beneficiaries would typically have more than one therapy session furnished in a single day, we proposed to apply the 50 percent MPPR policy to the PE component of subsequent therapy services furnished to the same patient on the same day, rather than limiting the proposed policy to services furnished in the same session.

We noted that many therapy services are time-based CPT codes, so multiple units of a single code may be billed for a single session that lasts for a longer period of time than one unit of the code.

The proposed MPPR policy would apply to multiple units of the same therapy service, as well as to multiple different services, when furnished to the same patient on the same day. Therefore, we proposed that full payment would be made for the service or unit with the highest PE and payment would be made at 50 percent of the PE component for the second and subsequent procedures or units of the same service.

We proposed that the work and malpractice components of the therapy service payment would not be reduced. For therapy services furnished by an individual or group practice or "incident to" a physician's service, the MPPR would apply to all "always therapy" services furnished to a patient on the same day, regardless of whether the services are furnished in one therapy

discipline or multiple disciplines, for example, physical therapy, occupational therapy, or speech-language pathology. The MPPR policy would apply to both those services paid under the PFS that are furnished in the office setting and those services paid at the PFS rates that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid by Medicare for outpatient therapy services. Table 20 provides a sample calculation of the current and proposed CY 2011 payment for multiple therapy services furnished in on the same day. For those services paid under the PFS, the PFS budget neutrality provision would apply so that the estimated reduced expenditures for therapy services would be redistributed to increase payment for other PFS services.

TABLE 20—SAMPLE PAYMENT CALCULATION FOR MULTIPLE THERAPY SERVICES FURNISHED TO A SINGLE PATIENT ON THE SAME DAY

	Procedure 1 Unit 1	Procedure 1 Unit 2	Procedure 2	Current total payment	Proposed CY 2011 total payment	Proposed payment calculation
Work	\$7.00	\$7.00	\$11.00	\$25.00	\$25.00	no reduction
PE	\$10.00	\$10.00	\$8.00	\$28.00	\$19.00	\$10 + (0.5 × \$10) + (0.5 × \$8)
Malpractice	\$1.00	\$1.00	\$1.00	\$3.00	\$3.00	no reduction
Total	\$18.00	\$18.00	\$20.00	\$56.00	\$47.00	\$18 + \$7 + (0.5 × \$10) + \$1 + \$11 + (0.5 × \$8) + \$1

In the CY 2011 PFS proposed rule (75 FR 40078), we stated that we believe the proposed therapy MPPR policy would provide more appropriate payment for therapy services that are commonly furnished together by taking into account the duplicative clinical labor activities and supplies in the PE that are not furnished more than once in the single therapy session. This approach is consistent with the statutory requirement for the Secretary to identify, review and adjust the relative values of potentially misvalued services under the PFS as specified by section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA). We also believe this proposed policy is responsive to continued concerns about significant growth in therapy spending and to MedPAC and GAO recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies. We observed that paying more appropriately for therapy services based on PE relative values that are adjusted for the clinical scenario under which the services are furnished would

result in reduced therapy expenditures, and beneficiaries would be able to receive more medically necessary outpatient therapy services before reaching the therapy cap. For a further discussion of potential alternatives to the therapy caps, we refer readers to section III.A.2. of this final rule with comment period.

Comment: Many commenters opposed application of the proposed MPPR policy to therapy services. The commenters characterized the proposal as drastic, arbitrary, and unfair, resulting in across-the-board cuts based on flawed assumptions that would lead to therapy underpayments that would jeopardize access to necessary care and harm patients. The commenters requested that CMS withdraw the proposal, study the issue further, and share the analyses with the public.

In contrast, MedPAC supported the general direction of the proposed policy, but suggested that CMS better justify how a 50 percent reduction would capture the duplicate inputs related to multiple therapy services performed in a single session. MedPAC also recommended that CMS request that the

AMA RUC review the values of all outpatient therapy codes to ensure that the practice expenses are not duplicated, regardless of whether or not the current values of those codes assume that two services are furnished during a single visit.

Numerous commenters requested a detailed justification for the proposed policy's 50 percent reduction, including an explanation of the methodology used to calculate the new payments that would result. These commenters asked CMS to work with stakeholders to finalize a policy that would not adversely impact access to care, particularly in rural and other underserved areas. The commenters further urged consideration of other payment methods and alternatives to the therapy caps that would preserve and improve access to therapy services. The commenters stated that between 80 to 90 percent of physical therapy services furnished in private practices would potentially be subject to the MPPR, concluding that the policy would result in payment decreases of 19.2 percent and 17.8 percent for physical therapy services in facilities

and offices, respectively, notably more than the CMS' impact estimate of 11 percent for the proposed rule.

The commenters provided analyses to show that the duplication of supplies is very limited and argued that a more thorough analysis of duplication based on expert clinical review would result in considerably lower estimates of duplication. For example, the AMA RUC explained that for a typical single session combination of 2 units of CPT code 97110 (Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility) and one unit of 97140 (Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes), a \$12 PE payment reduction from the MPPR would be applied to adjust for \$3.60 in potentially duplicated costs.

Before implementing an MPPR, the commenters urged CMS to take time to ensure that individual services were valued correctly based upon the resources needed to deliver them. The commenters advised CMS to conduct a more thorough analysis, taking into consideration the fact that the direct PE inputs for therapy services were already reduced to avoid duplication. The commenters alleged that CMS provided incorrect examples of duplication in the proposed rule examples by overestimating the duplication compared to the standard time allocated by the AMA RUC for certain activities. The commenters explained that PE for therapy services was valued by the AMA RUC based upon three units of service, not two units of service as stated by CMS in the proposed rule. Three units of service are typical, and the commenters contended that no duplication of PE exists when the typical three units of service are delivered using typical time allotments for clinical labor activities. The commenters submitted multiple examples of combinations of therapy services, using the most frequently billed therapy codes and providing valuations for each of the components of PE, such as pre-service and post-service physical therapy assistant activities. The commenters pointed out that in the case of single unit therapy claims, or claims with one therapeutic procedure and one modality, there would currently be underpayment based on how therapy services are valued. The commenters further argued that it would not be fair to apply the MPPR to all subsequent services when some of the code combinations are already undervalued.

Many commenters observed that the AMA RUC has worked in good faith to resolve any duplication in the PE inputs over the past few years and pointed out that CMS has historically accepted over 90 percent of the AMA RUC's recommendations. In April 2010, some commenters reported that the AMA RUC reviewed high volume therapy code pairs that included the most frequently billed therapy CPT code 97110, and the commenters conveyed the AMA RUC's conclusion that there is no duplication in the work or PE inputs for the most frequently reported therapy codes.

The commenters pointed out that single comprehensive codes for certain bundles of component services were implemented in CY 2010, and that additional ones would be created in the future. Therefore, the commenters disagreed with CMS' reasoning for proposing a general MPPR that is not code pair-specific in the context of these ongoing efforts of the CPT Editorial Panel and the AMA RUC to revise the coding and values for services that are commonly furnished together. Instead, the commenters urged CMS to continue to work within the established processes and resolve duplication, where it exists, at the code pair level rather than with payment.

Response: We appreciate the detailed information provided by the commenters regarding the historical AMA RUC process to value the therapy codes and the additional examples of the practice expenses as they apply to the many combinations of therapy services that may be reported. We understand that the AMA RUC valued many of the therapy services based on certain assumptions about the typical combinations of services furnished in a therapy session. However, as the commenters pointed out, there are numerous combinations of therapy services observed in the PFS claims data that we posted on the CMS Web site under supporting files for the CY 2011 PFS proposed rule that are commonly furnished in the physician's office setting. In the context of this large number of commonly observed combinations, we do not believe that our usual PFS methodology of valuing the typical service adequately accounts for the duplication in PE that occurs in the many possible therapy service combinations. Although they are frequent, they do not represent the typical case used by the AMA RUC in valuing the individual component services and, thus, do not fully account for duplications in PE. We proposed the therapy MPPR in order to pay more appropriately for therapy services in

general by adjusting for the duplicate payment for the PE that may occur when combinations of therapy services are furnished together.

We agree with the commenters that, when considering all claims for therapy services paid under the PFS, the median number of services is three. Thus, that number may have been appropriate for the AMA RUC to use in valuing therapy services. However, the median number of four services that we presented in the CY 2011 PFS proposed rule was based upon all claims for multiple therapy services, and did not include claims for a single therapy service. It was the multiple service claims that we examined for purposes of the MPPR analysis, and it is these claims to which the MPPR would apply. Therefore, we continue to believe that the median number of four is the appropriate reference point when evaluating an MPPR. We note further that when the AMA RUC valued certain therapy services based on the assumption that a combination of three types of therapy services would be furnished to the patient, then in the case of multiple service claims where the median number of services is four, some PE duplication would clearly occur for the typical multiple service case with more than three services.

Although we continue to believe that 50 percent would generally be an appropriate level for an MPPR for the PE component of payment for therapy services, consistent with the current PFS MPPR policies for imaging and surgical services and our PE overlap analysis of certain therapy code combinations for the CY 2011 PFS proposed rule, we acknowledge there are particular challenges associated with establishing an MPPR for therapy services to account for the duplication in PE. For example, the current coding structure for therapy services relies upon timed units in many cases, and as a result, the number of commonly observed combinations is very large. The PE overlaps vary depending upon the specific combinations of services furnished to the patient, which may include evaluation services, therapeutic procedures, and therapeutic modalities. The common occurrence of such a great variety of multiple therapy code combinations contrasts with the relatively lesser number of combinations and/or frequency of combinations of surgical procedures or diagnostic imaging procedures to which the established PFS MPPR policies apply.

As the commenters pointed out, the direct PE inputs for certain therapy services were systematically established

based upon a standard AMA RUC methodology of three therapy services furnished in a session that included two therapeutic procedures and one therapeutic modality and that assigned certain PE inputs solely to the two therapeutic procedures. However, the scenarios utilized by the AMA RUC in this process are an incomplete representation of the usual combinations of services reported when therapy services are furnished in a practitioner's office. For example, the most common combination of CPT codes for therapy services in CY 2009 PFS claims data consisted of an average of 3.5 services which were comprised of some combination of one or more units of a single therapeutic procedure CPT code and one or more units of a single modality CPT code, rather than 3 total units of the services. The second most common combination was a therapeutic procedure CPT code alone, with an average of 2.8 units, while the AMA RUC relied upon 2 therapeutic procedures in a session for its assignment of certain PE inputs. Other commonly observed combinations of codes included 3.4 to 4.6 therapy services, with different numbers of therapeutic procedures and therapeutic modalities furnished to the patient than were assumed by the AMA RUC under the scenarios that were the basis for establishing the PE inputs for certain therapy CPT codes. Therefore, despite the AMA RUC's consideration of multiple services for valuation, the therapy code combinations as actually reported by practitioners would typically have some additional duplication in their PE. Thus, while the current PFS values for therapy services may reflect some efficiencies in the PE for certain code combinations based on the AMA RUC approach to valuation (to the extent we accepted the AMA RUC recommendations), the actual efficiencies are not fully recognized in the PE inputs for the most commonly reported therapy code combinations, nor are they necessarily recognized in the many other common code combinations that were not considered by the AMA RUC as the typical case.

Based on our review of the scenarios submitted by the commenters, we continue to believe that there is significant overlap in the PE when many combinations of therapy services are furnished together and that this overlap has not been adequately accounted for in the direct PE inputs that the AMA RUC has recommended to us for the component services. We believe the overlaps remain substantial and they can be potentially higher than 50

percent for some combinations while lower for others. Our analysis of five high volume therapy code pairs as noted in the CY 2011 PFS proposed rule (75 FR 40078) suggested a reduction in the PE for the lower paying code of 28 to 56 percent to account for PE duplication.

In response to the commenters who projected that the impact on physician's office payment for physical therapy services would be greater than the 11 percent reduction we modeled for the proposed rule (75 FR 40232), we note that an additional element of our analysis was the continued transition to setting the PE RVUs based on the PPIS data. The PPIS transition is expected to significantly increase payment for the PE component of therapy services in CY 2011. While we acknowledge that the estimated change in PE RVUs due to the proposed therapy MPPR alone would result in a payment decrease for the specialty of physical and occupational therapy of somewhat more than 11 percent, it is the combined consideration of all factors affecting the CY 2011 PE RVUs that resulted in the 11 percent decrease for physical and occupational therapists in the proposed rule specialty impact table (75 FR 40232). We note further that the estimated impact of all the PE RVU changes for physical and occupational therapy based upon our proposals for CY 2011 if there were no remaining transition to the new PE RVUs using the PPIS data would be -7 percent.

Any MPPR policy, such as the MPPR that currently applies to surgical services and imaging procedures, is a relatively blunt payment policy tool that improves the overall accuracy of payment when combinations of services are furnished together but is not, by its nature, a specific policy that precisely values each code combination. A general MPPR is not unlike the well-established PFS pricing methodology that relies on the typical case, where we readily acknowledge that the clinician's resources used to furnish a specific service to a specific patient on a specific day may be more or less than those used in the typical case. Similarly, while we believe that an MPPR would generally improve the accuracy of PFS payment when multiple therapy services are furnished to a single patient in a single session, we understand that for a specific combination of services for a given patient, the resources required may be more or less than those recognized for payment under the MPPR policy. In view of the requirements of section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) which specify that the Secretary shall identify potentially misvalued codes by

examining multiple codes that are frequently billed in conjunction with furnishing a single service and make RVU adjustments, we continue to believe it would be appropriate to expand the current PFS MPPR policies to address those scenarios where we conclude that combinations of services commonly furnished together are systematically overvalued.

We believe the more specific valuation of common code combinations is best conducted with input from the AMA RUC as it evaluates single new comprehensive codes for a bundle of component services when those new codes are established by the CPT Editorial Panel. In such cases where a single code is used to report a comprehensive service, an MPPR would no longer apply, which would be appropriate because the potential for PE duplication would have been explicitly considered in determining the PE inputs for the comprehensive service. As we stated earlier in this section concerning the MPPR for imaging services, the MPPR is not intended to supersede the AMA RUC process. We encourage the AMA RUC to reexamine the values and direct PE inputs for therapy services, including code pairs, for duplication in the PE, and to recommend therapy services to the CPT Editorial Panel for consideration of bundling into comprehensive codes. However, we believe it is appropriate to use an MPPR to address the PE duplication that is currently present within the PFS RVUs for the therapy codes when more than one service is furnished to a patient.

After consideration of the public comments we received, we are adopting, with modifications, our proposal to establish a MPPR policy for "always therapy" services for CY 2011. However, given the complexities involved in establishing an MPPR for the very large number of therapy codes and combinations, rather than the proposed 50 percent payment reduction to the PE component of the second and subsequent "always therapy" services billed by the same practitioner or facility on the same date of service for the same patient, we are adopting a 25 percent MPPR for "always therapy" services furnished in CY 2011. We continue to believe that a 50 percent MPPR for therapy services may be appropriate in light of our analysis of five high volume therapy code pairs that each occur over 2 million times in PFS claims for multiple therapy services and account for almost half of such claims, and for which we estimated that the resulting reduction in the PE for the lower paying code would range from 28 to 56 percent. However, we believe a 25

percent MPPR represents an appropriate and conservative first step toward eliminating payment for duplicative PE when multiple "always therapy" services are furnished to the same patient by the same therapy provider on the same date of service. We note that a 25 percent MPPR represents half the proposed reduction, and is slightly less than the lower range of the reduction suggested by our analysis of high volume code pairs. During CY 2011 and future years, we will continue to refine our analyses and consider whether further modifications to the policy would be appropriate, including the possible adoption of a 50 percent MPPR or a different payment percentage reduction. Any further changes to the MPPR for therapy services will be addressed in future rulemaking, including the possible adoption of any alternative percentage payment reduction to the 25 percent MPPR that will be in place for CY 2011. We will also closely follow the work of the CPT Editorial Panel and the AMA RUC with respect to the coding and valuation for therapy services over the next few years as we assess the potential merits of further changes to the MPPR policy. We note that the typical reductions in total PFS payment for high utilization therapy code combinations due to the MPPR alone would fall within the range of 7 to 9 percent under our final policy, but this decrease will be mitigated by the continued transition to use of the PPIS data. As displayed in Table 101 of this final rule with comment period, we estimate that the CY 2011 impact on the PE RVUs of the new therapy MPPR and continued PPIS transition is a reduction in PFS payment to physical and occupational therapists of approximately -3 percent.

The final list of CY 2011 CPT codes for "always therapy" services that are subject to the therapy MPPR is displayed in Table 21 at the end of this section.

Comment: Some commenters pointed out that CMS' analysis was based only on data from physicians and private practice therapists, which the commenters opposed as unrepresentative of the typical therapy session because the data represent only 35 percent of outpatient therapy services paid under Medicare. The commenters objected that no data from skilled nursing facilities (SNFs), rehabilitation agencies, CORFs, and hospital outpatient departments were considered in the analysis. The commenters reported that application of the MPPR policy on a per-day basis would be inconsistent with the delivery of therapy services in provider settings

where multiple sessions of the same or different disciplines of therapy on the same day are commonly furnished to "captive" patients and would unfairly reduce payment for the resources used to provide these services. The commenters believe there is no duplication in the PE in such circumstances. Some commenters suggested that reductions should not be applied when there is a break in services into more than one session in the same day.

Response: With respect to payment under the PFS, according to section 1848(c)(1)(B) of the Act, the term "practice expense component" means the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses. Under section 1848(c)(2)(C)(ii) of the Act, we are required to determine PE RVUs based on the relative practice expense resources involved in furnishing services. We develop these resource-based PE RVUs by looking at the direct and indirect physician practice resources involved in furnishing each service. To establish the direct PE inputs for services paid under the PFS, we consider the typical clinical scenario in which those services are delivered and paid by Medicare. In the case of therapy services that are paid under the PFS, the scenarios we consider are office-based (not institutional) because these therapy services are the only ones that are actually paid under the PFS (section 1848 of the Act) and subject to all of the provisions of the PFS, including budget neutrality under section 1848(c)(2)(B)(ii)(II) of the Act. Section 1834(k)(3) of the Act then requires that we pay for all outpatient therapy services at the applicable PFS amount. Therefore, our analyses and policy development regarding the therapy MPPR were based solely on claims for office-based therapy services and, given the applicable statutory payment provisions; we do not believe it would have been appropriate for us to consider institutional patterns of care in setting PFS rates for therapy services.

We are required to establish the values for services paid under the PFS (office-based services) so that therapy services are valued appropriately in the context of all other services paid under the PFS, and that means ensuring that therapy services are appropriately valued for the office setting. In the case of other services paid under the PFS that may be furnished in both facility and nonfacility settings, we generally establish separate but related facility

and nonfacility values to differentially value the services when furnished in each of the two types of settings. However, therapy services are only paid under the PFS when furnished in the office setting, so we establish the PFS values for therapy services based on patterns of care in the office setting. This approach ensures equitable and relative treatment of all services paid under the PFS with respect to the statutory provisions that apply to the PFS, including year-to-year budget neutrality. In contrast to other services paid under the PFS, the statute then specifies that we pay for therapy services furnished in facility settings at the applicable PFS amount (which, as discussed above, is established based upon our resource-based methodology for services furnished in nonfacility settings). Although the statutory payment scheme for therapy services differs from most other services, we note that this treatment ensures that Medicare payment is the same across all settings for outpatient Part B therapy services.

We acknowledge the commenters' point that multiple therapy sessions furnished to one patient by one provider (one National Provider Identifier (NPI)) in a single day are more common in facility settings than in the office setting. However, we continue to believe that in these situations there would be some overlaps in the PE, including patient education and obtaining measurements, that would be appropriately accounted for through the therapy MPPR. Furthermore, given the nature of therapy services and the associated coding, we believe it would be very challenging to determine the medical necessity of multiple therapy sessions on one date of service or the precise beginning and ending of therapy sessions if we were to exclude from the MPPR those therapy services furnished by the same provider to a single patient on the same day but in different sessions, although we acknowledge that this modification would be consistent with our established policy for the imaging MPPR.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to apply the therapy MPPR when multiple therapy services are billed on the same date of service for the same patient by the same practitioner or facility under the same NPI, regardless of whether those therapy services are furnished in separate sessions.

Comment: Many commenters objected to applying the MPPR across therapy disciplines because the commenters argued that physical therapy,

occupational therapy, and speech-language pathology (SLP) are separate and distinct interventions furnished independently by individually licensed professionals, each of which is certified to provide unique and specialized services that do not cross discipline or service lines. Several commenters explained that each discipline involves entirely different skills, equipment, supplies, and treatment goals, and separate disciplines are often located in different treatment settings. Individual plans of care, explained the commenters, are separately maintained for each therapy discipline and contain specific goals and treatments. Some commenters compared the proposal to claiming that services furnished to a single patient on the same day by a cardiologist and internal medicine specialist contain duplicative PE inputs. The same commenters described administrative contact with the patient in this scenario as distinct and separate, observing that greeting and gowning the patient, cleaning, and assistant activities are furnished independently by the second or subsequent discipline, and cannot be shared.

The large majority of commenters argued that the proposal did not make logical distinctions between therapy treatments or specialties or even properly distinguish between the skills of rehabilitation practitioners. While physical therapists and occupational therapists report the same CPT codes, the commenters noted that the codes do not represent the same service and the plan and approach to treatments differ depending on the discipline.

Response: We recognize that the therapy disciplines are separately qualified professionals who address specific impairments using separate and unique skills. However, in the office setting which is the basis for our valuing therapy services for payment under the PFS as discussed previously, although we believe it would be uncommon for services to be furnished to a single patient by different therapy disciplines and billed by a single provider (one NPI) on the same date of service, we continue to believe that there would be some overlap in the PE in this circumstance. The PE overlaps that we would anticipate include greeting the patient, obtaining vital signs, and post-visit phone calls. We do not agree with the commenters that we should accept such multiple discipline cases from the therapy MPPR that would otherwise apply.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to apply the therapy MPPR to all therapy

services across the disciplines billed on the same date of service for the same patient by the same practitioner or facility under the same NPI.

Comment: Several commenters pointed out that, unlike other therapy services, many SLP services contain therapist work in their PE because SLPs have no assistants. These commenters requested that the therapy MPPR not be implemented, or at least be delayed, until the AMA RUC completes its plan to recommend moving SLP work from PE to work. In addition to bundled codes, the commenters also requested that add-on codes, such as CPT code 92608 (Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)), be exempted from the therapy MPPR, since the PE inputs for add-on codes explicitly take into consideration the PE inputs for a base code that is always reported. The commenters reported that the major SLP codes include a wide variety of service types and are essentially bundled already, meaning that SLP practitioners rarely bill two different services on the same day for the same patient. The commenters expressed concern because SLP services are furnished and valued differently than physical and occupational therapy, yet the proposed rule contained no SLP examples to justify including SLP codes in the MPPR or to estimate the impact on SLP services.

Response: We note that most of the SLP codes will have been valued with therapist work in the work component of the SLP service RVUs by CY 2011, although we do not see the continued valuation of therapist work in the PE as an impediment to application of the MPPR to SLP services. Since many single SLP codes represent multiple component services that are reported using a single comprehensive code, the impact of the therapy MPPR on PFS payment for SLP services would be minimal. For those services that may occasionally be billed with more than one SLP code for a session, we see no basis for treating SLP services differently than other therapy services because we believe there would also be PE duplication in these cases.

However, we agree with the commenters that add-on codes should not be subject to the MPPR for therapy services because their PE inputs already consider that the add-on code is always furnished along with a primary service.

Therefore, after consideration of the public comments we received, we are removing add-on therapy CPT code

92608 from the list of "always therapy" services that we proposed for application of the therapy MPPR policy. In addition, we are removing CPT code 97010 (Application of a modality to 1 or more areas; hot or cold pack) which is a bundled code that was inadvertently included on the proposed list. These changes are reflected in the final list of codes subject to the therapy MPPR policy that is displayed in Table 21 at the end of this section. This policy parallels our treatment of the MPPR for surgical services, where surgical add-on codes are not subject to the surgical MPPR.

Comment: Some commenters characterized the proposed therapy MPPR as contrary to the objectives of the ACA, which the commenters believe was designed to shift care to the most effective and efficient delivery setting to ensure beneficiary access to cost-effective, high quality and coordinated care. Because therapy services do not involve expensive drugs or testing, yet they assist patients in avoiding or reducing other medical costs, many commenters believe that physical therapy is the most efficient and cost-effective treatment to return patients to independent function. The commenters contended that growing Medicare expenditures for the treatment of common musculoskeletal problems could easily be controlled by earlier access of patients to physical therapy services.

The commenters were concerned that lower therapy payments would exacerbate the shortage of therapists, lead to restricted access to therapy services, especially in rural areas, and result in patients who are more prone to injuries and functioning at a lower level. Undertreated functional impairments, argued the commenters, would lead to increased spending for medication and medical costs associated with decreased mobility, pain and falls, increased emergency room services, longer inpatient stays, quicker returns to the hospital setting, and earlier placement in nursing homes.

In addition, some commenters were concerned that the MPPR would provide an incentive to schedule patients in a manner that would be inefficient, inappropriate, and inconvenient for patients. The commenters noted that research proves therapy is more effective for many elderly patients with several visits on the same day, separated by rest. The commenters indicated that patients in rural communities prefer multiple therapy service visits to minimize lengthy commutes.

Response: Through the CY 2011 proposed rule and its associated public comment period, we have invited public involvement in the process of policy development regarding an MPPR for therapy services. We believe the therapy MPPR policy is fully consistent with section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) which specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. Therefore, we do not agree with the commenters that the MPPR policy undermines the goals of the ACA but, instead, we believe the policy fulfills one of our statutory obligations by valuing more appropriately combinations of therapy services furnished to patients and paid under the PFS. We have no reason to believe that appropriately valuing services for payment under the PFS by reducing payment for duplication in the resource-based PE payment for the component services would contribute to therapist workforce shortages or limit patients' access to medically reasonable and necessary therapy services.

With respect to the ordering and scheduling of therapy services for Medicare beneficiaries, we require that Medicare-covered services be appropriate to patient needs and that a physician certifies each patient's plan of care. We would not expect the adoption of an MPPR for therapy services to result in therapy services being furnished on separate days by one provider so that the provider may garner increased therapy payment unless this pattern of care is the most clinically appropriate for the patient. We agree with the commenters that this unprofessional behavioral response on the part of practitioners would be inefficient and inappropriate and could result in patient compliance problems with the plan of care. We will continue to monitor access to care and patterns of delivery for therapy services, with particular attention focused on identifying any changes in the delivery of same day therapy services that may be inappropriate.

Comment: Several commenters noted that CMS has contracted with Computer Sciences Corporation (CSC) and RTI International to develop outpatient therapy payment alternatives and urged CMS to place a high priority on the development of an alternative payment approach for therapy services rather than applying the proposed MPPR. Many commenters supported bundled per-session codes that would vary based

on the severity of the patient and the complexity of evaluation and treatment services, and some commenters believe this payment approach would be more equitable than the proposed MPPR. The commenters argued for a scientific approach to the development of alternatives to the current payment system, which the commenters believe contrasts with the analysis presented by CMS to support the MPPR. However, most commenters encouraged further study and development before implementation of any alternatives. Many commenters pledged to work with CMS in the future to further develop a bundled service approach based on episodes of care.

Response: We appreciate the effort and useful information contributed by stakeholders to the discussion and development of alternatives to the therapy caps and we refer readers to section III.A.2. of this final rule with comment period for a further discussion of the public comments and our responses on this issue. We look forward to the continued cooperation of stakeholders as we continue our work in this area over the coming years. However, we do not believe short-term alternative payment options for therapy services are sufficiently developed to warrant immediate implementation, and the commenters on the CY 2011 PFS proposed rule generally shared that view. In contrast, we believe that we can implement an appropriate MPPR for therapy services beginning in CY 2011 that would immediately provide more appropriate payment for the PE component of therapy services when multiple therapy services are furnished to one patient on one date of service by one provider. Paying more appropriately for therapy services in CY 2011 will allow patients to receive more medically necessary therapy services before reaching the therapy cap. To the extent that the therapy MPPR encourages the future bundling of therapy codes into a single comprehensive service that would be specifically valued, we support the exploration of that concept to capture the specific efficiencies associated with certain combinations of therapy services.

Comment: Several commenters asserted that the therapy MPPR proposal violated the Administrative Procedure Act (APA), alleging the proposal was arbitrary and capricious. In addition, some commenters argued that CMS did not provide sufficient information regarding the data and analysis used to develop the policy to allow the informed public input from qualified providers of therapy services.

Response: Consistent with the requirements of the APA, a full description of our analysis and the rationale we used as the basis for the proposed therapy MPPR policy was presented in the proposed rule, the public comments on our proposal have been reviewed, and our responses are provided in this final rule with comment period. Although many commenters requested that we share more data to support the proposed policy, several commenters demonstrated that they have their own access to Medicare data by submitting reports to us along with their comments in order to support their views or to refute the examples we presented in the proposed rule. We note further that we posted therapy utilization data on the CMS web site after publication of the proposed rule to provide additional information regarding the specific combinations and utilization of therapy services on PFS claims. The information was posted under downloads for the CY 2011 PFS proposed rule at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>. Therefore, we believe the final MPPR for therapy services is being adopted in compliance with the notice and comment rulemaking process under the APA.

In summary, after consideration of the public comments we received, we are adopting our CY 2011 proposal to apply an MPPR to the PE component of Medicare payment for the second and subsequent outpatient "always therapy" services, with a modification to apply a 25 percent reduction for CY 2011 rather than the 50 percent reduction we had proposed. Specifically, beginning in CY 2011 we are adopting an MPPR for "always therapy" services under which a 25 percent reduction will be applied to the PE component of payment for the second and subsequent "always therapy" service(s) (those displayed in Table 21) that are furnished to a single patient by a single provider on one date of service in all settings where outpatient therapy services are paid under Part B. This policy applies to office-based therapy services paid under the PFS as well as to institutional therapy services paid under Part B at the PFS rates. We note that the MPPR would apply only when multiple therapy services are billed on the same date of service for one patient by the same practitioner or facility under the same NPI. This policy does not apply to add-on, bundled, or contractor-priced "always therapy" codes. It does, however, apply to all "always therapy" services furnished on a single date of service by the same provider to a single

patient, including "always therapy" services furnished in different sessions or in different therapy disciplines.

For those therapy services paid under the PFS, we are required to make a budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act. As a result, the estimated reduced expenditures for therapy services due to the 25 percent MPPR will be redistributed to increased CY 2011 payments for other PFS services. We refer readers to XI.A.2. of this final rule with comment period for further discussion of the impact of this policy. The final list of CY 2011 "always therapy" CPT codes subject to the MPPR policy for therapy services is displayed in Table 21.

TABLE 21—"ALWAYS THERAPY" SERVICES SUBJECT TO THE CY 2011 MPPR POLICY*

CPT code	Short descriptor
92506	Speech/hearing evaluation.
92507	Speech/hearing therapy.
92508	Speech/hearing therapy.
92526	Oral function therapy.
92597	Oral speech device eval.
92607	Ex for speech device rx, 1 hr.
92609	Use of speech device service.
96125	Cognitive test by hc pro.
97001	Pt evaluation.
97002	Pt re-evaluation.
97003	Ot evaluation.
97004	Ot re-evaluation.
97012	Mechanical traction therapy.
97016	Vasopneumatic device therapy.
97018	Paraffin bath therapy.
97022	Whirlpool therapy.
97024	Diathermy eg, microwave.
97026	Infrared therapy.
97028	Ultraviolet therapy.
97032	Electrical stimulation.
97033	Electric current therapy.
97034	Contrast bath therapy.
97035	Ultrasound therapy.
97036	Hydrotherapy.
97110	Therapeutic exercises.
97112	Neuromuscular reeducation.
97113	Aquatic therapy/exercises.
97116	Gait training therapy.
97124	Massage therapy.
97140	Manual therapy.
97150	Group therapeutic procedures.
97530	Therapeutic activities.
97533	Sensory integration.
97535	Self care mgmt training.
97537	Community/work reintegration.
97542	Wheelchair mgmt training.
97750	Physical performance test.
97755	Assistive technology assess.
97760	Orthotic mgmt and training.
97761	Prosthetic training.
97762	C/o for orthotic/prosth use.
G0281	Elec stim unattend for press.
G0283	Elec stim other than wound.
G0329	Electromagnetic tx for ulcers.

*Excludes contractor-priced, bundled, and add-on "always therapy" codes.

5. High Cost Supplies

a. Background

MedPAC and the AMA RUC have long recommended that CMS establish a frequent price update process for high-cost supplies that are direct PE inputs in the PE database for services paid under the PFS because of their speculation that prices for these items may decrease over time as competition increases and new technologies disseminate into medical practice. MedPAC in particular has perennially noted that it is important for CMS to update the prices of high-priced supplies on a regular basis as inaccurate prices can distort PE RVUs over time, contributing to the misvaluation of established services under the PFS.

Most of the current prices for high-cost supplies included in the direct PE database are from 2004 or earlier. There are currently 62 unique supplies with prices of \$150 or more in the proposed CY 2011 PE database, which is available on the CMS Web site under the supporting data files for the CY 2011 PFS proposed rule at <http://www.cms.gov/PhysicianFeeSched/>. Finally, we note that we do not actually pay the supply prices included in the PE database but, instead, use them to develop the PE RVUs according to our standard PE methodology as described in section II.A.2. of this final rule with comment period. Payment for a procedure that uses a supply is based upon the PE RVUs that result from the PE methodology, and supplies are among the direct PE inputs for procedures. Therefore, it is the relativity of high-cost supply prices to prices for other PE items (equipment, low-cost supplies, and clinical labor) that is important.

Accordingly, in the CY 2009 PFS proposed rule (73 FR 38582), we proposed a process to update the prices for high-cost supplies priced at \$150 or more that are included in the PE inputs for procedures paid under the PFS PE methodology. The CY 2009 proposed rule described a publicly transparent process in which CMS would publish a list of the high-cost supplies in the PFS proposed rule (65 supplies were included in the CY 2009 PFS proposed rule), and specialty societies or other relevant organizations would provide acceptable documentation supporting the pricing for the supplies during the 60-day public comment period. Furthermore, in that same proposed rule (73 FR 38582), we provided guidance on what constitutes valid, reliable documentation that reflects the typical price of the high-cost item in the marketplace. We outlined examples of

acceptable documentation, such as a detailed description (including system components), sources, and current pricing information, confirmed by copies of catalog pages, invoices, and quotes from manufacturers, vendors, or distributors. We indicated that documentation that does not include specific pricing information such as phone numbers and addresses of manufacturers, vendors, or distributors or Web site links without pricing information would not be acceptable. We also noted that if acceptable documentation was not received within the proposed rule's 60-day public comment period, we would use prices from the Internet, retail vendors, and supply catalogs to determine the appropriate cost, and that we would use the lowest price identified by these sources (73 FR 38582). Finally, we solicited public comments on alternatives that could be used to update pricing information in the absence of acceptable documentation provided by specialty societies or other interested organizations.

In the CY 2009 PFS final rule with comment period (73 FR 69882), we indicated that we received many comments on the proposed process and, while some commenters expressed support, others believed the proposed process was flawed and burdensome. Moreover, although we received some data in response to our request for information on the 65 high-cost supplies with prices of \$150 or more, much of what we received was not complete or did not represent typical market prices. In particular, we expressed concern that the submitted data often represented manufacturer list prices for the premier models of many supplies, while we believed there were less expensive alternatives. Therefore, we were unable to determine the most appropriate, typical supply prices for our PFS payment methodology that prices the typical service described by a HCPCS code. Rather than finalizing the proposed process for updating high-cost supplies and revising the prices for the 65 supplies based on inadequate pricing information, we stated in the CY 2009 PFS final rule with comment period (73 FR 69882) that we would research the possibility of using an independent contractor to assist us in obtaining accurate pricing information. Furthermore, we informed the public that we planned to study the limitations of available pricing data and determine how to revise our proposed process to elicit better data.

In the CY 2010 PFS proposed rule and final rule with comment period (74 FR 33554 and 61776, respectively), we

stated that we were continuing to examine ways to obtain accurate pricing information for high-cost supplies. We noted again in the CY 2010 PFS proposed rule that we would depend upon the cooperation of the medical community to obtain typical prices in the marketplace, and we provided stakeholders with another opportunity to submit public comments on the process. In the CY 2010 PFS final rule with comment period, we acknowledged commenters' general support for an initiative to ensure accurate pricing of high-cost supplies. In general, the commenters strongly preferred a transparent and public process, and we stated that we would consider this perspective as we explore the best way to ensure that accurate supply pricing information is used in the PFS payment methodology.

b. Future Updates to the Prices of High-Cost Supplies

In working towards refining a process to update the prices of high-cost supplies and consistent with our intention expressed in the CY 2009 PFS final rule with comment period (73 FR 69882), we contracted with an independent contractor during CY 2009 to help us study the availability of accurate pricing information. We requested that the independent contractor, L&M Policy Research,

research pricing information for the 65 high-cost supplies listed in the CY 2009 proposed rule (73 FR 38583 through 38585) and determine what, if any, pricing information reflecting typical market prices could be obtained for these high-cost supplies.

We first requested that the contractor explore publicly available sources to obtain typical market prices for these supplies. The contractor utilized supply vendor catalogs and web sites and directly contacted vendors, manufacturers, group purchasing organizations (GPOs), and any other suppliers that the contractor identified in their research in order to identify prices for each of the supplies. Where more than one version of a supply item appeared to match a description of a high-cost supply and/or more than one possible vendor or manufacturer was identified, the contractor attempted to obtain prices from the multiple sources.

Upon review of the high-cost supply list, the contractor refined the list to 62 unique high-cost items with prices of \$150 or more for the study. The original list only consisted of 64 items but included one item inadvertently listed twice (CMS Supply Code SD207 (suture device for vessel closure (Perclose A-T))) and one item (CMS Supply Code SH079 (collagen implant)) that was deleted from the PE database after CY 2007 because it was no longer used as

an input for any codes. While the contractor was able to obtain prices for 37 of the 62 unique supplies, the contractor was unable to obtain pricing information for the remaining 25 supplies. Documentation of these prices, a requirement we discussed in the CY 2009 PFS proposed rule (73 FR 38582), was only obtained for 25 of the 36 supplies with new pricing information. For the remainder, while the contractor was given price quotes over the phone, the sales agents or customer service representatives declined to provide any form of written documentation, in some cases because company policies restricted providing pricing documentation to prospective customers without an account. Moreover, information on typical discounts was obtained for only seven products, and only one discount was documented. In the case of these products, companies disclosed the maximum available discounts, ranging from 18 percent to 45 percent. Relative to prices currently included in the PE database, the contractor found higher prices for the majority of the medical supplies that were researched, specifically 23 supplies with higher prices, 8 with lower prices, and 3 with the same price. The high-cost supplies studied by the contractor and their current database prices are displayed in Table 22.

TABLE 22: High-Cost Supplies with Prices of \$150 or Greater in the PFS Direct PE Database that were Studied by the CMS Contractor

CMS Supply Code	Supply Description	Current Database Unit Price	Associated CPT Codes
	stent, ureteral, wguidewire, 3cm flexible tip	\$235	52332
	probe, cryoablation, renal	\$1,175	50593
	catheter, intradiscal (spineCATH)	\$1,380	22526, 22527
	probe, cryoablation (Visica ICE 30 or 40)	\$1,589	19105
	kit, capsule, ESO, endoscopy w-application supplies (ESO)	\$450	91111
	catheter, balloon, lacrimal	\$306	68816
	catheter, CVA, system, tunneled w-port, dual (LifeSite)	\$1,750	36566
	stent, vascular, deployment system, Cordis SMART	\$1,645	37205, 37206
	agent, embolic, 2 ml uou	\$258	37210
	tube, jejunostomy	\$98	49441, 49446, 49451, 49452
SA005	kit, capsule endoscopy w-application supplies (M2A)	\$450	91110
SA010	kit, CVA catheter, tunneled, without portpump	\$308	36557, 36558, 36581
SA011	kit, CVA catheter, tunneled, with subcut port	\$495	36560, 36561, 36563, 36582, 36583
SA015	kit, for percutaneous thrombolytic device (Trerotola)	\$488	36870, 37184, 37186, 37187, 37188
SA020	kit, loop snare (Microvena)	\$275	36595, 37203
SA022	kit, percutaneous neuro test stimulation	\$305	63610, 64561
SA024	kit, photopheresis procedure	\$858	36522

CMS Supply Code	Supply Description	Current Database Unit Price	Associated CPT Codes
SA025	kit, PICC with subcut port	\$586	36570, 36571, 36585
SA036	kit, transurethral microwave thermotherapy	\$1,149	53850
SA037	kit, transurethral needle ablation (TUNA)	\$1,050	53852
SA038	kit, transurethral waterinduced thermotherapy	\$650	53853
SA039	kit, vertebroplasty (LP2, CDO)	\$696	22520, 22521
SA074	kit, endovascular laser treatment	\$519	36478
SA075	kit, hysteroscopic tubal implant for sterilization	\$1,245	58565
SA077	kit, pleural catheter insertion	\$329	32550, 96440
SA087	tray, RTS applicator (Mammosite)	\$2,550	19296
SA091	tray, scoop, fast track system	\$750	31730
SA092	kit, gene, MLL fusion	\$1,395	88385
SA093	kit, priming, random	\$463 (6 pack)	88385, 88386
SC085	tubing set, plasma exchange	\$173	36514
SD018	catheter, balloon, thermal ablation (Thermachoice)	\$727	58353
SD019	catheter, balloon, ureteral-GI (strictures)	\$166	43456, 45303, 45340, 45386, 46604
SD020	catheter, CVA, tunneled, dual (Tesio)	\$355	36565
SD023	catheter, enteroclysis	\$183	74251, 74260, 89100, 89105, 89130, 89132, 89135, 89136, 89140, 89141
SD058	electrode, grid	\$475	95829
SD072	eyelid weight implant, gold	\$218	67912
SD073	fiducial screws (set of 4)	\$558 (set of 4)	77011, 77301

CMS Supply Code	Supply Description	Current Database Unit Price	Associated CPT Codes
SD094	mammotome probe	\$200	19103
SD109	probe, radiofrequency, 3 array (StarBurstSDE)	\$1,995	20982, 32998, 41530, 50592
SD151	catheter, balloon, low profile PTA	\$432	35470, 35471, 35474
SD152	catheter, balloon, PTA	\$244	35472, 35473, 35475, 35476, G0392, G0393
SD154	catheter, microcatheter (selective 3rd order)	\$338	36217, 36247, 36481, 37183, 37210
SD155	catheter, RF endovenous occlusion	\$725	36475
SD175	guidewire, steerable (Transcend)	\$180	36217, 36247, 36481, 37183, 37205, 37206, 37210, 49440, 49441, 49442, 49446, 49450, 49451, 49452, 49460
SD177	hysteroscope, ablation device	\$1,146	58563
SD185	plasma antibody adsorption column (Prosorba)	\$1,150	36515
SD186	Plasma LDL adsorption column (Liposorber)	\$1,380	36516
SD189	plate, surgical, mini-compression, 4 hole	\$226	21208

CMS Supply Code	Supply Description	Current Database Unit Price	Associated CPT Codes
SD191	plate, surgical, reconstruction, left, 5 x 16 hole	\$719	21125, 21127, 21215
SD193	plate, surgical, rigid comminuted fracture	\$389	21461, 21462
SD204	sensor, pH capsule (Bravo)	\$225	91035
SD205	sheath, endoscope ultrasound balloon	\$154	31620
SD207	suture device for vessel closure (Perclose A-T)	\$225	35470, 35471, 35472, 35473, 35474, 35475, 37184, 37187, 37188, 37205, G0392
SD215	probe, endometrial cryoablation (Her Option)	\$1,250	58356
SD216	catheter, balloon, esophageal or rectal (graded distention test)	\$165	91040, 91120
SD218	stent, ureteral, without guidewire	\$162	50382, 50384, 50385
SF028	laser tip (single use)	\$290	30117, 52214, 52224, 52317
SF029	laser tip, bare (single use)	\$150	46917, 46924
SF030	laser tip, diffuser fiber	\$850	52647, 52648
SL055	DNA stain kit (per test)	\$150 (10 pack)	88358
SL209	array kit, Genosensor	\$2,121	88386
SL225	gas, nitrogen, ultra-high purity (compressed) grade 5.0	\$190	88385, 88386

Next, we directed the contractor to access the United States General Services Administration (GSA) medical supply schedule to augment the results obtained through review of vendor materials and direct contact with vendors, manufacturers, and GPOs. We

note that the GSA establishes long-term government-wide contracts with commercial firms for many products, negotiating contracts and determining prices to be fair and reasonable prior to placing them on schedule. Included on the schedule are thousands of medical

supplies at prices that, in most cases, are established through competition. The GSA schedule is an open solicitation and a business of any size, if it is stable and financially sound, can request to be included on the schedule. GSA's vendors usually are nationwide

vendors with substantial non-government sales, and products on the schedule must be manufactured in the U.S. or in a nation with a trade agreement with the United States. Submissions for the schedule are received 365 days per year, vendor contracts can be of varying lengths, and vendors can add or delete products from the schedule. Depending on the aggregate cost estimate associated with the vendor's supply items, the time to achieve inclusion on the schedule can vary from as short as several months to as long as 2 years. The GSA has delegated authority to the Department of Veterans Affairs (VA) to procure medical supplies under the VA Federal Supply Schedules Program.

Using the GSA general search engine under the category "Laboratory, Scientific, & Medical" available at https://www.gsaadvantage.gov/advgsa/advantage/main/start_page.do, the contractor obtained nine prices for items similar to the high-cost supplies in the PE database and that are displayed in Table 20 from the publicly available information on the Internet, including pricing for one product for which its prior work did not yield an updated price. We believe that additional items that are similar to the high-cost supplies in the PE database and that may be used with the same procedures may be on the GSA schedule but we are still working through the crosswalk between our supplies and the way the supplies are presented on the GSA schedule. In the proposed rule (75 FR 40081), we stated that examples of high-cost supplies in the PE database that the contractor located on the GSA schedule include: (1) Kit, capsule, ESO, endoscopy w-application supplies (ESO), priced at \$450 in the PE database and \$444 on the GSA schedule; and (2) tube, jejunostomy, priced at \$195 the PE database and \$60 to \$83 on the GSA schedule, depending on the characteristics of the tube. We note that the price of the "jejunostomy" tube that we included in the proposed rule was incorrect. The actual price of that supply item in the PE database is \$97.50, a lower value that is still substantially higher than the price range on the GSA schedule.

Since the GSA medical supply schedule is a source for pricing information that is public and transparent and reflects the best government contract price for a product, we believe it is a desirable resource for us to use in a refined process for updating the prices of high-cost supplies. For historical context, CMS has previously proposed to use VA prices that result from the competitive

marketplace as comparison points to limit the Medicare prices for oxygen and certain items of durable medical equipment and prosthetic devices (62 FR 38100 through 38107, and 64 FR 44227 through 44231) in 1997 and 1999, respectively. These prior proposals were based on our determination that the Medicare payment amounts for these items as durable medical equipment or prosthetics (not as physicians' services) were not inherently reasonable. We noted, however, that our current interest in the GSA schedule for pricing high-cost supplies for payment of physicians' services is not based on considerations of inherent reasonableness, and we do not actually pay the prices in the PE database for supplies under the PFS.

We further noted that public commenters on pricing high-cost supplies have consistently requested that we ensure that the pricing information used to update the prices is provided publicly. The commenters have observed that this transparency would enable stakeholders to evaluate and provide feedback to the agency on pricing accuracy (74 FR 61776). We also acknowledged that our past attempts over several years to identify typical market prices for the high-cost supplies have been inhibited by the limited availability of public data that meet the documentation requirements we have previously established. Individual vendors do not always publish their product prices or provide typical discounts. Moreover, discounts may vary depending on suppliers and the volume of supplies purchased. In the CY 2011 PFS proposed rule (75 FR 40082), we explained that our understanding of the GSA medical supply schedule is that the publicly listed fair and reasonable prices on the schedule generally do not include volume and/or certain other discounts that may be subsequently negotiated by the buyer. Consequently, we would consider the prices available on the GSA schedule to represent the "individual item ceiling" price for a single item purchase, which we believe would be appropriate to estimate the high-cost supply prices for physicians' office purchases. We solicited public comments regarding the high-cost supplies in the direct PE database for the CY 2011 PFS proposed rule, available on the CMS Web site as noted earlier in this section, and the corresponding supplies or alternative items that could be used for the same function that are currently on the GSA supply schedule. We encouraged commenters to provide a detailed analysis of the current relationships

between the items in the PE database and those on the GSA schedule.

In the CY 2011 PFS proposed rule (75 FR 40082), we described a refined process for regularly updating prices for high-cost supplies under the PFS and solicit comments on how we could improve on this process. The process could occur every 2 years beginning as soon as CY 2013, although we noted that we would propose the refined process through rulemaking before revising the prices for any high-cost supply item based on the GSA schedule. We could also consider establishing a different price update period depending on whether a high-cost supply was a new supply in the PE database or had been in use for some time, in which case we might expect that the price would have stabilized and, therefore, could be updated less frequently. In general, we would expect that the periodicity of updating prices for high-cost supplies that we eventually adopted would balance the associated administrative burden with the rate of price changes, to ensure that the associated procedures remain appropriately valued, rather than increasingly misvalued, over time.

We envisioned that we would base high-cost supply price inputs on the publicly available price listed on the GSA medical supply schedule. Since the medical community would have several years to examine the GSA medical supply schedule before the refined process would be adopted, and we had found no apparent limitations on vendors placing products on the GSA schedule, beyond the schedule's interest in competitive, best value procurements, stakeholders would have the opportunity to ensure that any high-cost direct PE input for a PFS service that may currently be missing from the GSA medical supply schedule would be included before CMS needs to access the publicly available price for the item. If a supply price were not publicly available on the GSA medical supply schedule by the time CMS needs to access the price, we would propose to reduce the current price input for the supply by a percentage that would be based on the relationship between GSA prices at that time and the existing PE database prices for similar supplies (currently an average 23 percent reduction). We believe that this refined process would be desirable because it is consistent with commenters' repeated requests for the updating methodology to be transparent and predictable.

Moreover, the VA (with responsibility delegated by the GSA) determines whether prices are fair and reasonable by comparing the prices and discounts that a company offers the government

with the prices and discounts that the company offers to commercial customers. Therefore, using the GSA medical supply schedule as a source for publicly available prices would also better account for product-specific market dynamics than the alternative of an across-the-board percentage reduction for supplies not on the GSA schedule based on general price trends for the high-cost supplies on the schedule. That is, if the market price of a particular supply were not to drop according to broad trends for other high-cost supplies, suppliers would have the opportunity to provide their price to the public on the GSA schedule in order to preclude any reduction in Medicare payment for procedures associated with that supply.

Finally, we reiterated our interest in receiving detailed public comments on the refined process discussed above, including all aspects of the price update methodology that we have presented. Moreover, we believe a similar approach could potentially be appropriate to update the prices for other supplies in the PE database that would not fall under our definition of high-cost supplies, and we welcomed further public comments on that possible extension. We also invited further suggestions for alternative approaches to updating high-cost supply prices, specifically those that would result in a predictable, public, and transparent methodology that would ensure that the prices in the PE database reflect typical market prices. These principles are particularly important in order to ensure that the services that utilize the high-cost supplies when provided in the physician's office are appropriately valued under the PFS and continue to be appropriately valued over time.

Comment: Many commenters agreed with the need for a frequent, transparent price update process for high-cost supplies based on publicly available sources of pricing information. MedPAC supported CMS' description of the process update the prices of high-cost supplies presented in the CY 2011 PFS proposed rule: "As an initial step, it is reasonable to use the GSA schedule as a source for the prices of high-cost supply items and to reduce the prices of items not on the GSA schedule by the average difference between the GSA prices and the prices in CMS' PE database for similar supplies."

Response: We appreciate the general affirmation by many stakeholders of the significance of accurate pricing of high-cost supplies relative to other PE items (equipment, low-cost supplies, and clinical labor). We also value MedPAC's support for the update process that we

described for the prices of high-cost supplies.

Comment: Many commenters asserted that because the medical supply prices on the GSA schedule reflect the best price for government entities, these prices are not representative of typical prices available to practitioners caring for Medicare beneficiaries. The commenters suggested that physicians in private practices do not have the requisite purchasing power to negotiate such large discounts on their own and that the sales environments for the government and private markets are vastly different. Therefore, the commenters argued, because the GSA schedule is a streamlined buying process that the government uses to buy products and services through registered vendors at pre-negotiated prices, the schedule does not provide an accurate reflection of prices faced by any physician practice. Some commenters also observed that the prices on this schedule have historically been used only by manufacturers and suppliers in the context of providing these high-cost supplies to the VA alone, and do not reflect prices to other non-governmental entities.

Response: We appreciate the differences in the purchasing power of the federal government and individual practitioners. However, we have reason to believe that prices on the GSA schedule do not reflect the full volume discounts available to large purchasers like the Federal government. In fact, while the GSA has delegated the authority to the VA to procure medical supplies under the VA Federal Supply Schedules Program, we understand that the prices that appear on the schedule do not reflect the prices the VA itself would usually pay for a medical supply. Instead, the VA determines the schedule prices to be fair and reasonable prior to placing them on the schedule, and uses that schedule price as a starting point for its own negotiations with supply vendors for specific purchases.

While several commenters explained how vendors provide the VA itself with discounts that are greater than those offered to other buyers, and a few additional commenters made uncorroborated claims that prices on the GSA supply schedule reflect discounts unavailable to other providers, we received no evidence that the prices contained on the schedule are atypical of medical supply prices in the private marketplace. We agree that the prices on the GSA schedule may reflect some discounting, but we do not believe that the prices reflect the full discounting available to the VA itself for many purchases. Instead, we believe that the

discounting on the GSA schedule reflects what the VA has deemed reasonable for other government buyers in the context of prices and discounts that a vendor offers to commercial customers.

We also believe that typical practitioners receive discounts from vendors' listed prices for supply items for a variety of reasons, although we acknowledge that the basis for the discounts reflected on the GSA schedule may differ from the basis for the discounts that are available to typical practitioners. Therefore, we do not necessarily agree with the premise underlying many commenters' concerns that the usefulness of the GSA schedule as a source for PFS high-cost supply prices is necessarily undermined solely because large government buyers benefit from some exclusive discounts.

We believe that in a relative payment system, maintaining the relativity of discounting among the prices for supply items may be more significant than any concern associated with the reasons different buyers receive particular discounts. At the moment, we have no reason to believe that the prices on the GSA schedule are atypical of the non-government market, despite broad assertions by the commenters that the government may receive discounts for different reasons than those available to private purchasers. As we consider this high-cost supply update process for the future, we would be interested in receiving further public comments that substantiate the claims that medical supply prices on the GSA schedule are not representative of actual prices paid by typical practitioners caring for Medicare patients.

Comment: Some commenters expressed concern that pricing high-cost supplies based on the GSA supply schedule could result in loss of appropriate relativity in PE RVUs because pricing for other supplies would be determined using other methodologies.

Response: As stated earlier in this section, we do not actually pay the supply prices included in the PE database but instead use them to develop the PE RVUs according to our standard PE methodology as described in section II.A.2. of this final rule with comment period. However, we believe that inaccuracies in the prices for high-cost supplies that are specific to a very few PFS services may disproportionately distort physician payment by leading to inaccurate PE RVUs for services using those high-cost supplies. We believe that neglecting to incorporate any discounts or typical reductions in the market price for a

high-cost supply that is sold to a practitioner for use in a specific service would result in a greater likelihood that the service would be misvalued under a relative payment system than would similar imprecision in the prices for lower-cost supplies that are commonly used in many services and where price changes are typically less extreme. Finally, we note that we also remain interested in the possibility of using the GSA supply schedule for all PFS supply and equipment price inputs, as we stated in the CY 2011 PFS proposed rule (75 FR 40082).

Comment: One commenter suggested that using the GSA schedule for supply price inputs might allow a single supplier furnishing a small volume of a product at a divergent price to distort the PE RVU calculations. On the other hand, MedPAC stated that the current CMS' process of "using price information voluntarily submitted by specialty societies, individual practitioners, suppliers, and product developers might not result in objective and accurate prices because each group has a financial stake in the process."

Another commenter recommended that if CMS were to use the GSA schedule prices as high-cost inputs, then CMS should guarantee that physicians may purchase supplies at the GSA schedule prices. The commenter claimed that failure to do so would result in inherently unfair, lower PE RVUs for certain procedures, which could ultimately create an access to care problem for Medicare beneficiaries.

Response: We believe that our current system of accepting voluntarily submitted invoices for supply and equipment price direct PE inputs may be problematic for high-cost supplies because the prices for such supplies may be particularly susceptible to distortions that significantly influence the PE RVUs that we use for payment of the associated services. We also believe that any attempt to account for these distortions and more appropriately value the services must be transparent to the stakeholders. Because the prices on the GSA supply schedule are developed based on the interaction between parties that have competing financial interests (the VA and supply vendors), we believe that these prices are more likely to be representative of competitive market prices than are prices that are voluntarily submitted by individuals with financial stakes in the PFS payment process. We agree that distortions—whether price overstatements or understatements—in the values of the direct PE inputs, resulting in misvalued services, have the potential to create financial

incentives for practitioners that are detrimental to ensuring access to medically necessary and reasonable care for Medicare beneficiaries. Based in part on prior analysis by MedPAC, we believe that the greater risk of misvalued PE RVUs results from overvaluing high-cost supplies since we believe that prices for these items may generally decrease over time as competition increases.

As we discussed in our response to a previous comment, we do not actually use the prices in the PE database for supplies but instead those prices are the basis for the PE RVUs for the associated services developed under the budget neutral PFS. Therefore, we do not agree with the commenter that we should guarantee that physicians may purchase supplies at the GSA schedule prices. Where our goal is for the high-cost supply prices we use for PFS ratesetting to reflect typical market prices for these items, especially in a relative sense, for many reasons different supplies may not be available to individual practitioners purchasing them at the prices in the PE database. The PFS is not a payment system that reimburses health care practitioners based on their individual costs, and the price available to an individual practitioner for a supply item may be high or lower than the price in the PE database that is used for setting the PFS PE RVUs for the associated procedure.

Comment: One commenter claimed that no U.S. manufacturer sells cryoablation probes through the GSA supply schedule and, therefore, asserted that the pricing process for high-cost supplies described in the CY 2011 PFS proposed rule would be inappropriate for that particular supply. Other commenters reported difficulty locating particular medical supplies on the GSA supply schedule.

Response: While we recognize that not all high-cost supplies are currently on the GSA supply schedule, as we stated in the CY 2011 PFS proposed rule (75 FR 40082), we believe that since we have provided the medical community several years to examine the GSA medical supply schedule before its use could be adopted under the PFS, stakeholders would have the opportunity to ensure that any high-cost direct PE input for a PFS service that may currently be missing from the GSA medical supply schedule would be included before CMS needs to access the publicly available price for the item. Furthermore, we have found that the use of multiple clinically related search terms under the GSA schedule search engine improves our ability to locate supply items that are related to those

that we currently include in the direct PE database for the PFS. We believe that the mistaken assumption that certain supplies are unavailable on the GSA supply schedule, resulting from some commenters' inconclusive searches, may have influenced many commenters' responses to the process we discussed in the CY 2011 PFS proposed rule.

Prior to adopting use of the GSA supply schedule to update the prices for high-cost supplies under the PFS, we believe it would be appropriate to work with interested stakeholders to consider developing a crosswalk between supply items included the direct PE database and the GSA supply schedule.

Comment: One commenter contended that implementation of a process to update high-cost supply prices based on the GSA schedule would disadvantage all medical device companies that have chosen to provide devices directly to the armed services or facilities for the treatment of veterans. A few commenters speculated that many supply vendors would resist placing their products on the GSA schedule for a variety of reasons, including avoiding any unnecessary regulatory burden or the scrutiny of GSA audits.

Response: We have no reason to believe that vendors who sell directly to the VA at discounts must incorporate negotiated discounted prices on the GSA schedule, so we do not believe that utilizing publicly available prices as direct PE inputs would have a disproportionately unfair impact on suppliers who sell directly to the VA. At the same time, we also understand that not every medical supply vendor would choose to place their products on the GSA schedule. That is why we stated in the proposed rule (75 FR 40082) that if a supply price were not publicly available on the GSA medical supply schedule by the time CMS needs to access the price, we would consider proposing to reduce the current price input in the PE database for the supply by a percentage that would be based on the relationship between GSA prices at that time and the existing PE database prices for similar supplies. Vendors would need to balance their concerns about placing their products on the GSA supply schedule with the alternative pricing policy that would apply.

Comment: Several commenters objected to a reduction of supply price inputs based on the relationship between GSA prices at the time the prices are being updated and the existing PE database prices for similar supplies. Many of the commenters stated that the 23 percent reduction presented as an example in the CY 2011 PFS proposed rule (75 FR 40082) was

based on a very small sample of items and appeared arbitrary. One commenter contended that the percentage reduction would need to be validated for application to current pricing and argued that it would be inappropriate for use on an item-specific basis.

Additional commenters, including the AMA RUC, pointed out the discrepancy between the price of the "jejunostomy tube" supply item listed in the chart of high-cost supplies and in the direct PE database. These commenters were concerned that this discrepancy may have led CMS to incorrectly calculate the average difference between GSA prices and current prices in the direct PE database. One commenter reasoned that it would be unfair for CMS to change the price inputs for innovative medical devices by relying on "speculation that prices for these items may decrease over time as competition increases and new technologies disseminate into medical practice."

Response: We appreciate the commenters' concerns regarding the example of the 23 percent reduction mentioned in the CY 2011 PFS proposed rule. We provided that sample percentage as an example based on a current analysis of a small sample of supplies. We appreciate commenters correctly pointing out that we displayed an outdated price input for the supply item "jejunostomy tube" in the CY 2011 PFS proposed rule (75 FR 40080 through 40081). As we explained in the proposed rule, we are still working through the crosswalk between our supplies and the way the supplies are presented on the GSA schedule. We included the 23 percent figure as a rough guide based on a comparison of current GSA schedule and PE database prices for a small sample of high-cost supply items.

Prior to implementing any price update based on GSA supply schedule prices, we would conduct a thorough analysis of the validity of the GSA pricing data in question. We believe that using such data for price comparisons, validated, and expanded to include all applicable supply items, may be more likely to approximate typical prices for these supplies than any available alternative—especially failing to update the high-cost supply price inputs with the necessary frequency. In cases where the prices for certain high-cost supplies do not follow the broad trends for other high-cost supplies, suppliers would have the opportunity to provide their price to the public on the GSA schedule in order to preclude any reduction in Medicare payment for procedures associated with that supply.

Comment: Some commenters asserted that CMS should conduct independent market research similar in kind to the research CMS claims that the VA conducts in placing supply items and their associated prices on the GSA schedule. Another commenter recommended that CMS use a particular market research contractor to price these supplies.

Response: As we stated in the CY 2011 PFS proposed rule (75 FR 40079), we contracted with an independent contractor during CY 2009 to help us study the availability of accurate pricing information for high-cost supplies. We believe such research needs to be conducted with transparency, including using publicly available sources and contacting supply vendors directly. The contractor reported tremendous difficulty in identifying typical market prices using these methods. We have no reason to believe that a different contractor using similar methods would have greater success in acquiring market pricing information without utilizing a methodology that would be burdensome to practitioners or supply vendors or other stakeholders. Because the supply vendors in contact with the VA generally have a financial incentive to cooperate with their market research directly, we believe that the VA's methodology in this case would yield more accurate information than information derived from market researchers who do not have such cooperation, like the contractor working previously on behalf of CMS.

Comment: Several commenters, including the AMA RUC, recommended that CMS consider creating HCPCS codes to be reported by rendering physicians for high-cost supplies when used for the care of a patient during procedure. The supplies could then be removed from the direct PE database and appropriate pricing for these supply HCPCS codes could be determined by CMS on an annual basis. One commenter requested that CMS explore whether such a methodology would be budget neutral under the PFS, since the commenter did not support an approach that would reduce PFS payments for cognitive services.

Response: We appreciate the commenters' suggestions, but we believe creating separately reportable HCPCS codes for high-cost supplies and paying separately for these items would merely shift the pricing challenge rather than resolve it, and could compound the problem of misvaluing services by explicitly paying for high-cost supplies at the expense of other low-cost supplies, equipment, and clinical labor included in the PE component of PFS

payment. We do not understand how this suggestion would help CMS price the supply items accurately, nor how it would lead to more appropriate payment for high-cost supplies under the relativity of the budget neutral PFS. This approach would be required to be budget neutral under the PFS and, to the extent that our current PE methodology pays less than the direct PE database cost for a supply item, payment for individual high-cost supplies at prices we establish could redistribute dollars from other PFS services to payment for these supply items if we were to pay more for them separately. Finally, unbundling payment for high-cost supplies from the associated procedures would be contrary to the current public policy interest in increasing the size of the payment bundles used for Medicare payment to encourage efficiencies in the delivery of services.

Comment: Several commenters expressed a readiness to provide any additional information that may help CMS in pricing high-cost supplies, in lieu of using the GSA schedule prices for that purpose.

Response: We appreciate commenters' offers of assistance regarding the pricing of direct PE inputs. However, based on the public comments from stakeholders that we received on the process we proposed in the CY 2009 PFS proposed rule and the experience of the CMS' contractor who attempted to acquire market pricing for supply items directly from supply vendors, we believe that use of the GSA schedule would have greater potential to provide us systematically and transparently with typical market prices for high-cost supply items that could be updated with an appropriate periodicity.

Comment: Some commenters expressed concern that CMS had not presented any information about how prices for Medicare PE purposes would actually be developed from the GSA supply schedule and had not specified how the Agency would do so nor whether (or when) CMS intended to make the approach available for public comment.

Response: We appreciate the commenters' concerns regarding the practical implementation of a high-cost supply price update process based on prices on the GSA supply schedule. In the CY 2011 PFS proposed rule (75 FR 40082), our discussion was intended to encourage broad stakeholder comment, including consideration of potential alternatives to the process presented. Prior to implementing a high-cost supply update methodology, such as the use of prices on the GSA schedule that was the focus of our proposed rule

discussion, we would expect to use annual rulemaking in order to propose a more detailed process that would be subject to modification based upon our consideration of the public comments.

In summary, we appreciate the many public comments we received on our discussion of a process that would use GSA schedule prices to update the prices for high-cost supplies utilized for developing PE RVUs under the PFS. In the context of our explicit responsibility to review and adjust the PFS values for potentially misvalued services under section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA), we believe it is especially important to soon establish a periodic and transparent process to update the cost of high-cost supplies to reflect typical market prices so that these supply items are appropriately considered in our ratesetting methodology. While public commenters expressed some concerns regarding our discussion of use of the GSA supply schedule prices in such a process, at this point we remain optimistic that this approach has significant potential to be used under the PFS and, based on our several year history of work in this area, we do not see other viable alternatives at this point. We will continue to study the issue of how to update the prices for high-cost supplies over the upcoming months, and we encourage stakeholders to also further consider the process we discussed in CY 2011 rulemaking and provide their additional thoughts and perspectives to us on an ongoing basis.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and malpractice). While requiring that the PE and malpractice GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the physician work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor in Alaska for services furnished beginning January 1, 2009. Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs not less often than every 3 years. This section also specifies that if more than 1 year has elapsed since the last GPCI revision,

we must phase in the adjustment over 2 years, applying only one-half of any adjustment in each year. As discussed in the CY 2009 PFS final rule with comment period (73 FR 69740), the CY 2009 adjustment to the GPCIs reflected the fully implemented fifth comprehensive GPCI update. CY 2010 would have typically included no adjustments to the GPCIs. However, section 3102(a) of the ACA amended section 1848(e)(1)(E) of the Act to extend the 1.0 work GPCI floor for services furnished through December 31, 2010. Additionally, section 3102(b) of the ACA added a new subparagraph (H) to section 1848(e)(1) of the Act, which specifies that for CY 2010 and CY 2011, the employee compensation and rent portions of the PE GPCI must reflect only one-half of the relative cost differences for each locality compared to the national average. The new subparagraph also includes a "hold harmless" provision for CY 2010 and CY 2011 for any PFS locality that would otherwise receive a reduction to its PE GPCI resulting from the limited recognition of cost differences. Additionally, section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA) established a 1.0 PE GPCI floor for services furnished in frontier States effective January 1, 2011. In May 2010, we provided our Medicare contractors with an updated CY 2010 payment file that included the 1.0 work GPCI floor and the PE GPCIs calculated according to the methodology required by section 1848(e)(1)(H) of the Act (as added by section 3102(b) of the ACA) for CY 2010, to be used for payment of services furnished on or after January 1, 2010.

For the CY 2011 PFS proposed rule, we completed the sixth review of the GPCIs and proposed new GPCIs. We noted that section 1848(e)(1)(E) of the Act (as amended by section 3102(a) of the ACA) extends the 1.0 work GPCI floor only through December 31, 2010. Under current statute, the 1.0 work GPCI floor will expire on January 1, 2011. Therefore, the CY 2011 physician work GPCIs, and summarized geographic adjustment factors (GAFs), do not reflect the 1.0 work floor. However, section 1848(e)(1)(G) of the Act (as amended by section 134(b) of the MIPPA) set a permanent 1.5 work GPCI floor in Alaska for services furnished beginning January 1, 2009 and, as noted above, section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA) provides for a permanent 1.0 PE GPCI floor for frontier States effective January 1, 2011. Therefore, as required by the statute, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for

frontier States will be in effect for CY 2011. In addition to the limited recognition of certain cost differences for the PE GPCIs, section 1848(e)(1)(H) of the Act (as added by section 3102 (b) of the ACA) also requires us to complete an analysis of the data sources used and cost share weights assigned to the PE GPCIs. Implementation of the ACA provisions related to the CY 2011 PE GPCIs is discussed in more detail in the GPCI update section below.

2. GPCI Update

As discussed in the CY 2011 PFS proposed rule (75 FR 40083), the updated GPCI values were developed by Acumen, LLC (Acumen) under contract to CMS. As mentioned above, there are three GPCI components (physician work, PE, and malpractice), and all GPCIs are developed through comparison to a national average for each component. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below.

a. Physician Work GPCIs

The physician work GPCIs are designed to capture the relative cost of physician labor by Medicare PFS locality. Previously, the physician work GPCIs were developed using the median hourly earnings from the 2000 Census of workers in seven professional specialty occupation categories which we used as a proxy for physicians' wages and calculated to reflect one-quarter of the relative cost differences for each locality compared to the national average. Physicians' wages are not included in the occupation categories because Medicare payments are a key determinant of physicians' earnings. Including physicians' wages in the physician work GPCIs would, in effect, have made the indices dependent upon Medicare payments.

The physician work GPCIs were updated in CYs 2001, 2003, 2005, and 2008 using professional earnings data from the 2000 Census. However, wage and earnings data are no longer available from the Census long form and the 2000 data are outdated. Therefore, for the proposed sixth GPCI update, we used the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data as a replacement for the 2000 Census data. The use of BLS OES data as a replacement for the 2000 Census data is discussed in more detail in the update of the PE GPCIs section. As noted above, the 1.0 work GPCI floor is set to expire under current statute on December 31, 2010. Therefore, the CY 2011 proposed

physician work GPCIs reflected the removal of this floor.

b. Practice Expense GPCIs

(1) The Affordable Care Act Requirements for PE GPCIs

(A) General Methodology for the CY 2011 GPCIs

The ACA added a new subparagraph (H) to section 1848(e)(1) of the Act which revised the methodology for calculating the PE GPCIs for CY 2010 and CY 2011 so that the employee compensation and rent portions of the PE GPCIs reflect only one-half of the relative cost differences for each locality compared to the national average. Additionally, under section 1848(e)(1)(H)(iii) of the Act (as added by section 3102(b) of the ACA), each PFS locality is held harmless so that the PE GPCI will not be reduced as a result of the change in methodology for PE GPCIs. In accordance with section 1848(e)(1)(H)(ii) of the Act (as added by section 3102(b) of the ACA), the employee compensation and rent components of the proposed CY 2011 PE GPCIs were calculated to reflect one-half of the cost differences for each PFS locality relative to the national average cost. Additionally, as required by the statute, physicians' services furnished in each PFS locality would be adjusted by the higher of the locality's PE GPCI calculated with the limited recognition

of employee compensation and rent cost differences or the PE GPCI calculated without the limited recognition of cost differences.

(B) Phase-In of PE GPCIs

Section 1848(e)(1)(C) of the Act requires us to phase in GPCI adjustments over 2 years if there was more than 1 year between GPCI adjustments. In accordance with the statute, we proposed to phase in the updated PE GPCIs using one-half of the CY 2010 values and one-half of the fully implemented values (as described in this section). To apply the phase-in and hold harmless provisions of the Act, we calculated transitional PE GPCIs based on two scenarios. Under the first scenario, we calculated transitional CY 2011 PE GPCIs using the full recognition of employee compensation and rent cost differences for each locality as compared to the national average. As discussed below, the first scenario reflects the "hold harmless" transitional PE GPCI value that would apply to any PFS locality receiving a reduction to its PE GPCI resulting from the application of the limited recognition of PE cost differences. The CY 2011 transitional PE GPCI values with full recognition of cost differences were calculated using one-half of the CY 2010 PE GPCI values with full recognition of cost differences and one-half of the updated PE GPCIs with full recognition of cost differences. The

first scenario represents the transitional PE GPCI values prior to the limited recognition of cost differences (the pre-ACA CY 2011 transitional values). In other words, this scenario does not include the effects of sections 1848(e)(1)(H)(i) and (ii) of the Act (as added by section 3102(b) of the ACA).

For the second scenario, we calculated transitional CY 2011 PE GPCIs with the limited recognition of cost differences for the employee compensation and rent components (as required by sections 1848(e)(1)(H)(i) and (ii) of the Act (as added by section 3102(b) of the ACA)). The CY 2011 transitional PE GPCI values with the limited recognition of cost differences were calculated using one-half of the CY 2010 PE GPCIs with the limited cost differences and one-half of the updated PE GPCIs with the limited cost differences. The hold harmless provision under section 1848(e)(1)(H)(iii) of the Act (as added by section 3102(b) of the ACA) was applied by selecting the greater of the CY 2011 transitional PE GPCI value calculated with the limited recognition of cost differences or the CY 2011 transitional PE GPCI value calculated with full recognition of cost differences (the pre-ACA CY 2011 transitional values). The phase-in of the CY 2011 PE GPCIs and application of the hold harmless provision are illustrated in Table 23 below.

TABLE 23—PHASE-IN OF THE CY 2011 PE GPCIS

	CY 2010	Updated GPCIs	CY 2011 (transitional year)	Hold harmless
File 1: PE GPCI <i>Without</i> 3102(b) of ACA.	Without ACA	Without ACA (Updated Data).	(1/2 of 2010) + (1/2 Updated GPCI)	Greater of File 1 Transitional Value or File 2 Transitional Value.
File 2: PE GPCI <i>With</i> 3102(b) of ACA.	With ACA	With ACA (Updated Data).	(1/2 of 2010 w/ACA) + (1/2 Updated GPCI w/ACA).	

(C) Data Analysis

Section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA) also requires the Secretary to "analyze current methods of establishing practice expense adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the cost of operating a medical practice in different fee schedule areas." Section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA) requires that such analysis shall include an evaluation of the following:

- The feasibility of using actual data or reliable survey data developed by

medical organizations on the costs of operating a medical practice, including office rents and non-physician staff wages, in different fee schedule areas.

- The office expense portion of the practice expense geographic adjustment, including the extent to which types of office expenses are determined in local markets instead of national markets.
- The weights assigned to each area of the categories within the practice expense geographic adjustment.

This section also requires the Secretary to make appropriate adjustments to the PE GPCIs no later than by January 1, 2012. To begin to implement this statutory requirement based on our initial analysis, we

proposed to implement changes in PE data sources and cost share weights discussed herein effective beginning in CY 2011.

In accordance with section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA), we initially analyzed the current methods and data sources used in the establishment of the PE GPCIs. With respect to the method used, we began with a review of the GAO's March 2005 Report entitled, "MEDICARE PHYSICIAN FEES: Geographic Adjustment Indices Are Valid in Design, but Data and Methods Need Refinement" (GAO-05-119). While we have raised concerns in the past about some of the GAO's GPCI

recommendations, we noted that with respect to the PE GPCIs, the GAO did not indicate any significant issues with the methods underlying the PE GPCIs. Rather, the report focused on some of the data sources used in the method. For example, the GAO stated that the wage data used for the PE GPCIs are not current. Similarly, upon our reexamination of public comments we had received on the PE GPCIs for previous updates, we noted that the commenters predominately focused on either the data sources used in the method or raised issues such as incentivizing the provision of care in different geographic areas. However, the latter issue (incentivizing the provision of care) is outside the scope of the statutory requirement that the PE GPCIs reflect the relative costs of the mix of goods and services comprising practice expenses in the different fee schedule areas relative to the national average.

One key component of the PE GPCI method that our analysis identified involved the office expense portion of the PE GPCIs and the cost share weight assigned to this component. Most significantly, we proposed that the weight for the office rent component be revised from 12.209 percent to 8.410 percent to reflect our more detailed breakout of the types of office expenses that are determined in local markets instead of national markets. For example, for previous GPCI updates, we used the office expenses cost category as the cost share weight for office rent and, therefore, all individual components previously included in the office expenses category were adjusted for local area cost differences by the GPCIs. As discussed in section II.E. of this final rule with comment period, we proposed to disaggregate the broader office expenses component into 9 new cost categories as part of the proposed CY 2011 MEI rebasing. The disaggregation of the office expenses category indicates that the fixed capital cost category, for which the consumer price index (CPI) for owner's equivalent rent is the price proxy, is the office expense category applicable to the office rent component of the PE GPCI. Therefore, the fixed cost capital cost category is the only component of office expenses that we proposed to adjust for local area cost differences beginning in CY 2011. We proposed to assign other newly defined components of the office expenses category (for example, utilities, chemicals, paper, rubber and plastics, telephone, postage, and moveable capital) to the medical equipment, supplies, and other miscellaneous expenses cost component of the PE

GPCIs. As discussed later in this section, the medical equipment, supplies, and other miscellaneous expenses component of the PE GPCIs is assumed to have a national market and, therefore, this component is not adjusted for local area cost differences.

The proposed expense categories for the PE GPCIs, along with their respective cost share weights, are primarily derived from the 2006 American Medical Association (AMA) Physician Practice Information Survey (PPIS) for self-employed physicians and selected self-employed non-medical doctor specialties. The PPIS is the most comprehensive, multispecialty, contemporaneous, and consistently collected PE data source available. It was developed by medical organizations and captures the costs of operating a medical practice, including office rents and nonphysician staff wages. Moreover, we also examined the feasibility of using the American Community Survey (ACS) and the Bureau of Labor and Statistics (BLS) Occupational Employment Statistics (OES) data for the employee compensation component of the PE GPCI. For previous updates, the employee compensation component was based on the 2000 Decennial Census long form data. Since the Census data are significantly outdated and the 2010 Census no longer includes occupational wage data, we believe the ACS or BLS OES data might be viable alternatives. While the ACS 3-year public use microsample (PUMS) is currently available, it reflects only about 3 percent of households and the data exhibit significant variation due to the small sample. In particular, the ACS PUMS has fewer than 10 observations of pharmacists in the Manhattan; Beaumont, Texas; and Southern Maine localities. Therefore, we believe it would be premature to use the ACS data for determining GPCI values. The 2006, 2007, and 2008 panels from the BLS OES represent a larger sample than the ACS PUMS and more recent data than the 2000 Census. As such, we proposed to use the BLS OES data for updating the GPCIs. We look forward to exploring the use of the full ACS data when they become available. Additionally, we explored other sources of rent data (including commercial rental data and survey data) for use in calculating the PE GPCIs. We could not identify a reliable alternative rental data source available on a national basis with coverage of nonmetropolitan areas.

We do not believe there is a national data source better than the Housing and Urban Development (HUD) data for determining the relative cost differences

in office rents. Therefore, based on our review of the available data sources, we proposed to use the 2010 apartment rental data produced by HUD at the 50th percentile as a proxy for the relative cost difference in physician office rents.

In the proposed rule (75 FR 40085), we indicated that we believe our analysis of the current methods of establishing PE GPCIs and our evaluation of data that fairly and reliably establish distinctions in the cost of operating a medical practice in the different fee schedule areas meet the statutory requirements of section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA). A more detailed discussion of our analysis of current methods of establishing PE GPCIs and evaluation of data sources is included in Acumen's draft report. Acumen's draft report and associated analysis of the sixth GPCI update, including the PE GPCIs, was posted on the CMS Web site after display of the CY 2011 PFS proposed rule. The draft report may be accessed from the PFS Web site at: <http://www.cms.gov/PhysicianFeeSched/> under the "Downloads" section of the CY 2011 PFS proposed rule Web page. Acumen's final report and associated analysis of the sixth GPCI update will be posted on the CMS Web site after publication of the CY 2011 PFS final rule with comment.

(D) Determining the PE GPCI Cost Share Weights

To determine the cost share weights for the CY 2011 GPCIs, we proposed to use the proposed 2006-based Medicare Economic Index (MEI) as discussed in section II.E. of this final rule with comment period. The proposed MEI was rebased and revised to reflect the weighted-average annual price change for various inputs needed to provide physicians' services. As discussed in detail in that section, the proposed expense categories in the MEI, along with their respective weights, were primarily derived from data collected in the 2006 AMA PPIS for self-employed physicians and selected self-employed non-medical doctor specialties.

For the cost share weight for the PE GPCIs, we used the 2006-based MEI weight for the PE category of 51.734 percent minus the professional liability insurance category weight of 4.295 percent. Therefore, we proposed a cost share weight for the PE GPCIs of 47.439 percent. For the employee compensation portion of the PE GPCIs, we used the nonphysician employee compensation category weight of 19.153 percent. The fixed capital category weight of 8.410, for which the CPI for

owner's equivalent rent is the price proxy, was used for the office rent component. To determine the medical equipment, supplies, and other miscellaneous expenses component, we removed professional liability (4.295 percent), nonphysician employee compensation (19.153 percent), and fixed capital (8.410 percent) from the PE category weight (51.734 percent). Therefore, we proposed a cost share

weight for the medical equipment, supplies, and other miscellaneous expenses component of 19.876 percent. Furthermore, the physician compensation cost category and its weight of 48.266 percent reflected the proposed work GPCI cost share weight and the professional liability insurance weight of 4.295 percent was used for the malpractice GPCI cost share weight. In the proposed rule (75 FR 40085), we

stated that we believe our analysis and evaluation of the weights assigned to each of the categories within the PE GPCIs meets the statutory requirements of section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA).

The proposed cost share weights for the CY 2011 GPCIs are displayed in Table 24 below.

TABLE 24—COST SHARE WEIGHTS FOR CY 2011 GPCI UPDATE

Expense category	Current cost share weight (%)	Proposed cost share weight (%)
Physician Work	52.466	48.266
Practice Expense	43.669	47.439
—Employee Compensation	18.654	19.153
—Office Rent	12.209	8.410
—Equipment, Supplies, Other	12.806	19.876
Malpractice Insurance	3.865	4.295
Total	100	100

(E) PE GPCI Floor for Frontier States

Section 10324(c) of the ACA added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier States. In accordance with section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA), beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be frontier States. The statute requires us to define any State as a frontier State if at least 50 percent of the State's counties are determined to be frontier counties, which the statute defines as counties that have a population density less than 6 persons per square mile. However, section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA) also specifies that this provision shall not apply to States receiving a non-labor related share adjustment under section

1886(d)(5)(H) of the Act (which excludes Alaska and Hawaii from qualifying as a frontier State).

Consistent with the proposed FY 2011 hospital inpatient prospective payment system (IPPS) 1.0 wage index floor for frontier States (as required by section 10324(a) of the ACA) (75 FR 30920 through 30921), we proposed to identify frontier counties by analyzing population data and county definitions based upon the most recent annual population estimates published by the U.S. Census Bureau. We divided each county's population total by each county's reported land area (according to the decennial census) in square miles to establish population density. We also proposed to update this analysis from time to time, such as upon publication of a subsequent decennial census, and if necessary, add or remove qualifying States from the list of frontier States based on the updated analysis.

For a State that qualifies as a frontier State, in accordance with section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA), we proposed that physicians' services furnished within that State would receive the higher of the applicable PE GPCI value calculated according to the standard CY 2011 methodology or a minimum value of 1.00. Furthermore, in accordance with section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA), the frontier-State PE GPCI floor is not subject to budget neutrality and would only be extended to physicians' services furnished within a frontier State.

For determining the proposed CY 2011 PFS PE GPCI values, the frontier States are the following: Montana; Wyoming; North Dakota; Nevada; and South Dakota (as reflected in Table 25).

TABLE 25—FRONTIER STATES UNDER SECTION 1848(E)(1)(I) OF THE ACT [as Added by Section 10324(c) of the ACA]

State	Total counties	Frontier counties	Percent frontier counties
Montana	56	45	80
Wyoming	23	17	74
North Dakota	53	36	68
Nevada	17	11	65
South Dakota	66	34	52

(2) Summary of the CY 2011 PE GPCIs

The PE GPCIs include three components: employee compensation,

office rent, and medical equipment, supplies and miscellaneous expenses as discussed below:

- Employee Compensation: We used the 2006 through 2008 BLS OES data to determine the proposed employee

compensation component of the PE GPCIs. The proposed employee compensation component accounted for 40.4 percent of the total PE GPCIs.

- **Office Rents:** Consistent with the previous GPCI update, we used the most recent residential apartment rental data produced by HUD (2010) at the 50th percentile as a proxy for the relative cost differences in physician office rents. The proposed office rent component accounted for 17.7 percent of the PE GPCIs.

- **Medical Equipment, Supplies, and other Miscellaneous Expenses:** We assumed that items such as medical equipment and supplies have a national market and that input prices do not vary among geographic areas. As discussed in previous GPCI updates in the CY 2005 and CY 2008 PFS proposed rules, specifically the fourth GPCI update (69 FR 47503) and fifth GPCI update (72 FR 38138), respectively, some price differences may exist, but we believe these differences are more likely to be based on volume discounts rather than on geographic market differences. For example, large physicians' practices may utilize more medical equipment and supplies and therefore may or may not receive volume discounts on some of these items. To the extent that such discounting may exist, it is a function of purchasing volume and not geographic location. The proposed medical equipment, supplies, and miscellaneous expenses component was factored into the PE GPCIs with a component index of 1.000. The proposed medical equipment, supplies, and other miscellaneous expense component accounted for 41.9 percent of the PE GPCIs.

c. Malpractice GPCIs

The malpractice GPCIs are calculated based on insurer rate filings of premium data for \$1 million to \$3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). The CY 2011 malpractice GPCI update reflects 2006 and 2007 premium data.

d. Public Comments and CMS Responses on the Proposed 6th GPCI Update

We received many public comments regarding the CY 2011 proposed GPCIs. Summaries of the comments and our responses follow.

Comment: Many commenters requested that CMS delay implementation of the changes in underlying PE GPCI data and cost share weights until complete findings and recommendations from the Institute of Medicine's study of geographic

adjustment factors for physician payment, the Secretary's Medicare Geographic Payment Summit, and the MEI technical advisory panel have been developed and considered. A few commenters acknowledged that the BLS OES data is the best data source for updating the GPCIs for CY 2011 but expressed concern that it provides data for MSAs and rest of state areas and not counties. The commenters believe that collecting data at the MSA level distorts the accuracy of the input costs and requested that CMS delay the update until the full ACS data can be evaluated and compared with the BLS OES data. A few commenters requested that CMS delay the GPCI update for CY 2011 as was done in the CY 2004 PFS final rule with comment period for the 4th GPCI update.

Additionally, several commenters stated that a more comprehensive analysis and evaluation of the PE GPCI is required by the ACA, further noting that section 1848(e)(1)(H)(v) of the Act (as added by section 3102(b) of the ACA) allows CMS until January 1, 2012 to implement the findings from the analysis of PE data. To that end, several commenters requested a more comprehensive analysis of the occupational groups used to determine the employee wage component of the PE GPCI to reflect the "true costs" incurred by physician groups in the delivery of health care to Medicare beneficiaries. The commenters cited pharmaceutical, accounting, legal, computer science, and management professionals as examples of the types of nonphysician labor costs that should be included in the determination of the employee compensation index. Several commenters also stated that HUD rental data does not reflect the "actual costs" of physician office rent and therefore should be replaced by another data source.

Response: Section 1848(e)(1)(C) of the Act requires us to review and update the GPCIs at least every 3 years. When updating the GPCIs we believe we should use the best data that are currently available. As mentioned by the commenters, the BLS OES data are more timely data than the 2000 census data (which has been used for previous GPCI updates). We believe that the BLS OES data, which are currently available, are an appropriate and relevant data source for updating the work GPCIs and employee compensation component of the PE GPCIs. Also because of the timeliness of the data, we believe that using the BLS OES data would result in a more accurate reflection of the geographic practice cost differences

among PFS localities than not updating the GPCIs for CY 2011.

While we believe it is appropriate to finalize updated GPCIs for CY 2011 using the most current data, we also acknowledge that there is much ongoing analysis that may inform future GPCI changes. Therefore, as discussed below, we are not using the revised cost share weights for the CY 2011 GPCIs that would apply under the revised and rebased MEI for CY 2011. We will address the GPCI cost share weights once again in the CY 2012 PFS proposed rule, and we may make additional proposals that would further modify the GPCI data and/or methods for CY 2012.

Additionally, we will review the complete findings and recommendations from the Institute of Medicine's study of geographic adjustment factors for physician payment, the Secretary's Medicare Geographic Payment Summit, and the MEI technical advisory panel, and we will continue to study the issues as required by section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA). We will once again consider the GPCIs for CY 2012 in the context of our annual PFS rulemaking beginning in CY 2011 based on the information available at that time. The CY 2011 GPCIs arising from the 6th GPCI update reflect our initial review and response to the currently available GPCI data, methods, and cost share weights. Once the full ACS data are available, we will reassess the occupational groups used to determine the employee compensation component of the PE GPCI and continue to explore the use of commercial rent data as part of our ongoing analysis of the GPCIs. We anticipate that further information, including our review of the full ACS data, may lead to proposed additional refinements to the GPCIs for future years. We have addressed the CY 2011 GPCI cost share weights in response to other public comments received on the CY 2011 PFS proposed rule that are summarized later in this section.

With regard to the commenters who expressed concern that the BLS OES data are not collected at the county level, we note that the 2000 Decennial Census data are only available at the county level for approximately 10 percent of counties. For previous updates, the GAFs for more than 90 percent of counties were developed based on MSAs or larger geographic areas (for example, data for all rural areas in a State were combined and used to proxy values for each rural county in a State). Therefore, using BLS OES data and disaggregating data to the county

level is not a significant departure from previous GPCI updates.

Moreover, we acknowledge that in the CY 2004 PFS proposed and final rules (68 FR 49042 and 68 FR 63213 respectively), we updated only the malpractice GPCI because the special tabulation of census data used for the physician work GPCI and employee compensation portion of the PE GPCI was not yet available. We explained that no acceptable data sources could be found to update the work GPICs and the employee compensation portion of the practice expense GPICs. Therefore, we made no changes to the work GPICs and PE GPICs for CY 2004. However, in view of the statutory requirement to update the GPICs at least every 3 years, we do not believe it would be appropriate to finalize an update only for malpractice GPICs for CY 2011, while delaying the update of the work GPCI and PE GPCI, when we currently have appropriate updated data available to us for this purpose. As discussed previously, we will review the GPICs as part of the CY 2012 PFS rulemaking cycle (beginning in CY 2011) based on the information available at that time, and we may propose changes to the GPICs prior to the next 3-year GPCI update.

Comment: Several commenters stated that the use of HUD rental data is not an appropriate proxy for determining the office rent index and suggested that CMS use data on actual physician office rents instead. Additionally, one commenter questioned CMS' analysis of the Medical Group Management Association's (MGMA's) survey data on rent. The commenter raised questions as to why CMS rejected the use of MGMA rental data due to insufficiency in sample size and representation, despite admitting that the physician response rate on the MGMA survey was typical for surveys of business.

Response: As we have previously explained in the CY 2005 and CY 2008 final rules with comment period (69 FR 66262 and 72 FR 66245 respectively), we recognize that apartment rents may not be a perfect proxy for measuring the relative cost differences in physician office rents. However, we believe the HUD rental data are the most comprehensive and valid indicator that is available of the real estate rental market in all areas of the country. We continue to believe that HUD rental data remain the best data source for determining the relative cost differences in physicians' office rent among all areas of the country. The data are regularly updated and available nationally, and retain consistency area-to-area and year-to-year. We would welcome any alternative rental data

source that is available nationally with sufficient representation among PFS localities.

With regard to our review of MGMA survey data, we have concerns with both the sample size and representativeness of the MGMA data. For example, the responses represent only about 2,250 physician practices nationwide and have disproportionate sample sizes by State, suggesting very uneven response rates geographically. In addition, we also have concerns that the MGMA data have the potential for response bias. The MGMA's substantial reliance on its membership base suggests a nonrandom selection into the respondent group. Some evidence for such issues in the MGMA data arises from the very different sample sizes by State. For example, in the MGMA data, 10 States have fewer than 10 observations each, and California, New York, and New Jersey have fewer than 10 observations per locality. Therefore, we continue to believe the MGMA survey data would not be a sufficient rental data source for all PFS localities.

Comment: One commenter expressed concern that the BLS OES wage data may result in the undervaluation of physician earnings because the data exclude incomes of self-employed professionals.

Response: The GPICs are not an absolute measure of physician earnings; rather, they are a measure of the relative cost differences for each of the three PFS components. We have no evidence to suggest that self-employment income would have different geographic variation than non-self-employed income. Absent such evidence, we would expect that including wage data from self-employed professionals would result in a geographic distribution of professional wages similar to the BLS OES data source.

Comment: Many commenters stated that implementing PE GPCI changes in CY 2011 would reduce payment to urban areas and, therefore, would violate the "hold harmless" provision as required by the ACA.

Response: Section 1848(e)(1)(H) of the Act (as added by section 3102 (b) of the ACA) requires that we apply a limited recognition of cost differences for the rent component and employee compensation component of the PE GPCI as compared to the national average. This section also includes a "hold harmless" provision for CY 2010 and CY 2011 for any PFS locality that would receive a reduction to its PE GPCI resulting from the limited recognition of PE cost differences. For CY 2010 and CY 2011, we applied the limited recognition of PE cost differences and

"hold harmless provision" in accordance with the statutory requirement, which is specific only to the limited recognition of rent and employee wage cost differences. In other words, the "hold harmless" (non-budget neutral) provision under section 1848(e)(1)(H)(iii) of the Act (as added by section 3102 (b) of the ACA) does not apply to the effects of updated data incorporated into the GPICs as a result of our normal GPCI update process. As discussed earlier in this section, the proposed GPCI update reflected our preliminary review based on the best information currently available. We anticipate that further information may lead to proposed additional refinements to the GPICs in future years.

Comment: One commenter recommended that CMS track the "hold harmless" transitional GPICs to determine whether certain regions of the country are underpaid as a result of the application of the limited recognition of PE cost differences.

Response: The "hold harmless" provision under section 1848(e)(1)(H)(iii) of the Act (as added by section 3102(b) of ACA) was applied by selecting the greater of the CY 2011 transitional PE GPCI value calculated with the limited recognition of cost differences or the CY 2011 transitional PE GPCI value calculated with full recognition of cost differences. Therefore, no locality is "underpaid" by the application of the limited recognition of PE cost differences.

Comment: One commenter requested that CMS consider applying a 1.0 GPCI floor to non-frontier States that serve significant rural populations. The commenter was not specific as to which GPCI (work, PE, or malpractice) the floor should be applied.

Response: As discussed previously in this section, section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA) established a permanent 1.0 PE GPCI floor only for frontier States, and section 3102(a) of the ACA amended section 1848(e)(1)(E) of the Act to extend the 1.0 work GPCI floor for services furnished only through December 31, 2010. We do not otherwise have the authority to establish GPCI floors that do not consider the differences in physicians' resource costs among localities.

Comment: A few commenters requested that CMS release underlying data sources, including county level GPCI values and budget neutrality estimates, which would allow interested parties to replicate GPCI calculations.

Response: We strive to be as transparent as possible in all of our proposals. To that end, we have made

numerous files available on the CMS Web site under the downloads for the CY 2011 PFS proposed rule to assist in the public's review of the CY 2011 proposal. These files include: The preliminary contractor's report on data for the 6th GPCI update; the CY 2010 through CY 2012 GPICs, both as proposed (including the ACA provisions) and without the ACA provisions to permit isolation of the impacts of the updated data; and web links to the publicly available source data and copies of data files that are not otherwise publicly available, for example county and locality-specific RVUs from Medicare claims data and malpractice insurance premium data. In combination, this information allows the public to apply our methodology to replicate our calculations for the proposed GPICs.

Comment: Many commenters expressed concern about the proposed cost share weights for the rent component and medical equipment, supplies, and other miscellaneous component of the PE GPCI. The commenters stated that the proposed cost share weights would unjustifiably shift Medicare payment away from urban localities to rural localities. Several commenters suggested that portions of the "all other services" component of the office expenses cost category, (which includes maintenance services, storage, security and janitorial services, office equipment, information technology systems, and medical record systems) and the stand-alone "other professional services" cost category (which includes accounting services, legal services, office management services, continuing education, professional association memberships, journals, and professional care expenses) are wage-related and, therefore, should be adjusted for locality cost differences. Additionally, a few commenters stated that the cost share weight attributed to the rent component of the PE GPCI should vary by region because one national cost share weight for rent penalizes areas where office rent is a higher portion of practice expenses.

Response: Although we typically update the GPCI cost share weights concurrently with the most recent MEI revision and rebasing, the commenters raised many points regarding the reallocation of labor-related costs from the medical equipment and supplies and miscellaneous component to the employee compensation component of the PE GPCI. After consideration of the public comments we received on this issue, we will continue to use the current GPCI cost share weights for CY 2011. We have asked the Institute of

Medicine to evaluate the accuracy of the geographic adjustment factors used for Medicare physician payment. The Institute of Medicine will prepare two reports for Congress and the Secretary of the Department of Health and Human Services. The first report, expected in spring 2011, will include an evaluation of the accuracy of geographic adjustment factors, and the methodology and data used to calculate them. The second report, expected in spring 2012, will evaluate the effects of the adjustment factors on the distribution of the health care workforce, quality of care, population health, and the ability to provide efficient, high-value care. For more information on the Institute of Medicine's study on Medicare geographic adjustment factors, we refer readers to the Institute of Medicine Web site: <http://iom.edu/Activities/HealthServices/GeographicAdjustments.aspx>.

We will explore further the options that were raised to us by the commenters and the recommendations in the forthcoming Institute of Medicine report(s). We will also continue our analysis of the cost share weights attributed to the PE GPCI as required by section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA), including the possibility of assigning cost share weights to the rent component of the PE GPCI that vary among fee schedule areas. We will address the GPCI cost share weights again in the CY 2012 PFS proposed rule.

Comment: MedPAC suggested an alternative method for calculating the PE GPCI. This alternative PE GPCI method would account for variations in the cost share of equipment and supplies across services.

Response: We appreciate MedPAC's suggestion of an alternative method that would vary the portion of PE that is geographically adjusted for locality differences based on the characteristics of individual services, rather than applying a uniform percentage across all PFS services. We recommend that MedPAC continue to analyze this or other alternative geographic adjustment methods, including their administrative feasibility.

Comment: A few commenters stated that the "range of disparity" between the highest and lowest paid PFS localities is too large and contradicts data studies showing little to no distinction in physician practice expenses throughout the nation. For example, the commenters stated that the AMA's analysis of its own PPIS data concluded that "expenses did not differ significantly by either metro location or

Census region." One commenter requested an explanation of the discrepancy between the AMA's findings of no measurable practice expense distinctions and CMS' findings that continue to show substantial distinctions in physician practice expenses among the Medicare payment localities. Another commenter stated that a 2007 survey conducted by the journal, *Medical Economics*, indicated that the average practice expenses are highest in the Midwestern States (which is contrary to the proposed CY 2011 GPICs).

Response: We have reviewed the studies referenced by the commenters and compared their findings with the GPCI values calculated for the CY 2011 PFS proposed rule. As mentioned by the commenters, both the AMA and *Medical Economics* studies aggregated per-physician expenses at the Census region level. The AMA PPIS analysis showed the Northeast as having the lowest per-physician expenses, followed by the Midwest then the West, with the South identified as having the highest expenses. Although there is about a 20 percent difference in total expenses between the Northeast and South, the study noted that the difference was not significant after controlling for practice setting and physician specialty. The *Medical Economics* survey findings showed about a 30 percent difference in costs, with the East showing the lowest expenses and the Midwest with the highest. Both studies demonstrated that rural areas have the highest per-physician expenses and highly populated areas the lowest.

To compare the variation of PE GPCI values calculated for the CY 2011 PFS proposed rule to the AMA and *Medical Economics* studies, we used PE RVUs to create weighted averages of the PE GPICs by Census region. Additionally, because the AMA and *Medical Economics* data reported total per-physician practice expenses, whereas the GPCI is a cost index, we produced indices for each source to create comparable measures of variation. We then normalized each index to the lowest cost area from each data source. Consequently, the index values show the percent difference in costs relative to the lowest cost area. For example, the AMA study shows the Northeast as having the lowest per-physician expenses, thus establishing an index value of 1.00 for that area. For the AMA study, the Midwest index value is 1.07 which signifies that costs in the Midwest are 7 percent above the Northeast AMA values. The PE GPCI data indicate that the Midwest has the lowest costs; and the South, with an

index value of 1.01, has costs that are 1 percent above the Midwest GPCI values. When aggregated to the Census region, the PE GPICs showed less variation in costs than the comparison data sources (AMA PPIS and *Medical*

Economics). Using the PE GPCI data to calculate Census region indices produced only a 16 percent difference in costs between the most costly and least costly areas, equating to roughly half the variation found in the *Medical*

Economics survey and about 75 percent of the variation found in the PPIS study. Table 26 compares the results on the disparity in costs by Census region.

TABLE 26—CENSUS REGION COST INDICES BY DATA SOURCE

	AMA	Medical economics	PE GPCI data	PE GPCI components		
				Rent	Wages	Office supplies
Midwest	1.07	1.29	1.00	1.00	1.04	1.00
South	1.21	1.20	1.01	1.12	1.00	1.00
West	1.11	1.06	1.14	1.47	1.17	1.00
Northeast	1.00	1.00	1.16	1.55	1.18	1.00

Additionally, the conceptual approaches to the GPICs and the data sources noted by the commenters are sufficiently different to make comparisons extremely difficult. The different rank ordering in the costs by regions, as shown in Table E4, may also reflect the different strategies used to measure costs. Specifically, the AMA and *Medical Economics* studies ordered areas based on total physicians' expenses, whereas the GPICs are intended to provide a local cost index that is then applied to each PFS component; work, practice expense, and malpractice expense. Based on our review of the AMA PPIS and *Medical Economics* studies, a key factor in explaining differences with the proposed GPCI values is differences in practice patterns across the different areas. Specifically, rural practitioners tend to see more patients, incurring higher expenses. However, as noted in the *Medical Economics* study, higher patient loads result in higher payment. To place this in the context of Medicare PFS payment, seeing more patients produces more billed services, allowed charges, and payments. Therefore, the greater number of patients seen by rural physicians is accounted for in total RVUs to the physician, rather than through the GPCI values.

Moreover, the very low cost ranking of the Northeast in both the AMA PPIS and *Medical Economics* datasets suggests a possible influence of economies of scale. The GPICs are designed to capture differences in the prices of inputs facing physicians in each region. The input prices are used to create GPCI values as a measure of the relative cost differences in operating a medical practice in one locality versus another. It is likely that the AMA and *Medical Economics* studies are capturing differences in the production of services, distinct from the input

prices. In particular, the geographic differences may reflect differences in economies of scale in more and less urbanized areas. More rural practitioners are less likely to work in large practices, leading to higher per-physician costs, all else being equal. For example, a two-physician practice may need the same number of front office staff as a one-physician practice. When this expense is measured on a per-physician basis, the single physician pays twice as much for front office support. This type of variation can occur within localities and may reflect the practitioner's choice to work in a small or large physician practice. Nevertheless, there is no mechanism within the existing GPCI approach to account for the influence of economies of scale, despite its potentially significant impact on the effective per-unit costs of providing care.

Comment: Several commenters recommended that CMS use data from a reliable survey of physicians' practices, such as the AMA PPIS or the MGMA survey, to develop the office rent index and employee compensation index.

Response: Because of the limited sample sizes of the AMA PPIS (n = 2,137) and MGMA studies (n = 2,246), we do not believe that it would be possible to calculate reliable indices for all Medicare PFS localities based upon these data. As mentioned previously, in the MGMA data, 10 States have fewer than 10 observations each, and California, New York, and New Jersey have fewer than 10 observations per locality.

In light of the comments received suggesting the use of survey data to determine GPCI values and the typical response rates for existing physician surveys, we are continuing to consider the possibility of establishing a physician cost report and requiring a sufficiently large sample of physicians

in each locality to report data on actual costs incurred. However, we believe that a physician cost report could take years to develop and implement, and could be prohibitively expensive. We also have some concerns about the administrative burden this approach would place on physician's office staff. Therefore, we are requesting specific public comments regarding the potential benefits to be gained from establishing a physician cost report and whether this approach is appropriate to achieve potentially greater precision in measuring the relative cost differences in physicians' practices among PFS localities. We are also requesting public comments on the potential administrative burden of requiring physicians to routinely complete and submit a cost report and whether this requirement should be mandatory for all physician practices. Additionally, we have asked the Institute of Medicine to look at the use of survey data in the context of their geographic adjustment analysis. It is also our understanding that MedPAC is considering the issue of data sources used to determine geographic payment adjustments under the PFS.

Comment: One commenter stated that all geographic adjustment factors should be eliminated from the Medicare PFS "except for those designed to achieve a specific public policy goal, for example, to encourage physicians to practice in underserved areas." The commenter requested that CMS utilize the most broadly applicable methodology allowed by law to reduce geographic payment disparity.

Response: We are required by section 1848(b)(1)(C) and (e)(1)(A) of the Act to develop and apply separate GPICs to adjust for resource cost differences among localities compared to the national average for each of the three PFS components: work, practice expense, and malpractice expense. The purpose of the GPICs is not to reduce

geographic payment disparity; rather, the GPCIs distribute PFS payments among areas in order to adjust for area cost differences. In general the data show that urban areas usually are higher cost, while rural areas are lower cost. However, there are several provisions currently in place that have the effect of reducing geographic payment disparities. For example, the statute requires that only one-quarter of area cost differences in physician work be recognized, and we assign a 1.0 index to the medical equipment, supplies, and miscellaneous component of the PE GPCI because we believe there is a national market for these items. In addition, 34 States and 2 territories are "Statewide" payment localities wherein all physicians, whether urban or rural, are paid the same. Moreover, many geographic areas are designated as Health Professional Shortage Areas (HPSAs). Physicians in these areas may be eligible for a 10 percent HPSA bonus payment in addition to the amount paid under the Medicare PFS for services they furnish. Beginning in CY 2011, general surgeons furnishing major surgical procedures in these areas may be eligible for the HPSA surgical incentive payment program (HSIP) that also pays 10 percent in addition to the amount paid under the PFS as discussed in section V.I.S.2. of this final rule with comment period. For complete information on the HPSA bonus payment program and a list of eligible areas for both programs by zip code, we refer readers to the CMS Web site at: http://www.cms.hhs.gov/hpsapsaphysicianbonuses/01_overview.asp. All of these factors mentioned above have the effect of reducing geographic payment disparities under the Medicare PFS.

Comment: One commenter encouraged CMS to follow the GAO's recommendations, as outlined in the GAO's March 2005 Report (GAO-05-119), for improving underlying GPCI data and methods by taking the following actions:

- Transition from Census Bureau's Decennial Census data to the annual ACS for earning and wage data.
- Include physician assistant wage data to improve the measurement of the PE GPCI.
- Consider the feasibility of using a commercial rent index or a residential rent index directly based on ACS data for determining the rent component of the PE GPCI.
- Collect malpractice premium data from all States, accounting for at least half of the malpractice business in a State.

- Standardize collection of malpractice premium data, for example by using data from Physician Insurer's Association of America.

Response: As previously discussed, the full ACS data were not available in time for the 6th GPCI update. We intend to explore the use of ACS data for determining the work GPCI and the employee compensation component of the PE GPCI, as well as evaluate its possible use as an office rent index once the data are fully available. We also intend to continue exploring the potential use of commercial rent data as part of our ongoing review and refinement of the GPCIs.

Additionally, we have considered the use of physician assistant wages in calculating the employee compensation index. However, since physician assistants can furnish medical services and bill the Medicare program directly, their wages are influenced by Medicare PFS payment. Therefore, we have some concern that a circular effect could occur if we included physician assistants among the occupational groups comprising the employee compensation component, similar to our concern with including physicians' salaries in the determination of the work GPCI.

With regard to the collection of malpractice premium data, the CY 2011 malpractice GPCI update reflects 2006 and 2007 premium data which were also used for the CY 2010 update to the malpractice RVUs. As compared to previous malpractice RVU updates, we substantially increased the number of States from which we were able to collect rate filings. We were able to collect malpractice premium data from every State except for Mississippi and Puerto Rico. Premium data were selected from at least two companies in each State, with more selected if necessary to reach 50 percent of the market share in that State. To ensure consistency across States we collected premium data from State Departments of Insurance. For States where we were not able to collect rate filings, we used premium information from the Medical Liability Monitor Survey data from 2005 through 2008.

e. Summary of Final CY 2011 GPCIs

After consideration of the public comments received on the GPCIs, we are finalizing the 6th GPCI update using the most current data, with modifications; we are not finalizing the proposal to change the GPCI cost share weights for CY 2011. Instead, we are continuing to use the current GPCI cost share weights for determining the PE GPCI values and locality GAFs in CY 2011, and we will

address the cost share weights again in the CY 2012 PFS proposed rule. As a result, the cost share weight for the physician work GPCI (as a percentage of the total) will be 52.5 percent (current and for CY 2011) rather than 48.3 percent (as proposed), and the cost share weight for the PE GPCI will be 43.7 percent (current and for CY 2011) rather than 47.4 percent (as proposed) with only a slight difference in the employee compensation component (18.7 percent rather than 19.2 percent as proposed). However, the cost share weight for the office rent component of the PE GPCI will be 12.2 percent (current and for CY 2011) rather than 8.4 percent (as proposed), and the medical equipment, supplies, and other miscellaneous expenses component will be 12.8 percent (current and for CY 2011) rather than 19.9 percent (as proposed). Moreover, the cost share weight for the malpractice GPCI will be 3.9 percent (current and for CY 2011) rather than 4.3 percent (as proposed).

Additionally, we will review the complete findings and recommendations from the Institute of Medicine's study of geographic adjustment factors for physician payment, the Secretary's Medicare Geographic Payment Summit, and the MEI technical advisory panel, and continue to study the issues as required by section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the ACA). We will once again consider the GPCIs for CY 2012 in the context of our annual PFS rulemaking beginning in CY 2011 based on the information available at that time.

We are using the 2006 through 2008 panels from the BLS OES data for updating the work GPCIs and the employee compensation component of the PE GPCIs. We are also using the 2010 apartment rental data produced by HUD at the 50th percentile as a proxy for the relative cost difference in physicians' office rents and 2006 and 2007 malpractice premium data for determining the malpractice GPCIs.

As required by section 1848(e)(1)(H)(ii) and (iii) of the Act (as added by section 3102(b) of the ACA), the CY 2011 GPCIs reflect only one-half of the relative cost differences for the employee compensation and rent portions of the PE GPCI, and the "hold harmless" provision ensures that no locality receives a payment reduction resulting from the limited recognition of PE cost differences. For CY 2011, the "hold harmless" provision was applied by selecting the *greater* of the CY 2011 transitional PE GPCI value calculated with the limited recognition of cost differences or the CY 2011 transitional

PE GPCI value calculated with full recognition of cost differences.

In accordance with section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the ACA), and consistent with the final FY 2011 hospital IPPS (75 FR 5160 through 5161), we applied a 1.0 PE GPCI floor for services furnished in frontier States. The frontier States are the following: Montana; Wyoming; North Dakota; Nevada; and South Dakota. As we indicated above in this section, section 1848(e)(1)(E) of the Act (as amended by section 3102(a) of the ACA) extended the 1.0 work GPCI floor only through December 31, 2010. Therefore, the CY 2011 physician work GPICs and summarized GAFs do not reflect the 1.0 work floor. However, the permanent 1.5 work GPCI floor for Alaska (as established by section 134(b) of the MIPPA) will remain in effect for CY 2011.

We are finalizing the CY 2011 GPICs shown in Addendum E. The GPICs have been budget neutralized to ensure that nationwide, total RVUs are not impacted by changes in locality GPICs. The 1.0 PE GPCI floor for frontier States and the PE GPCI "hold harmless" provision were applied to the budget neutralized GPICs.

Typically when we complete a review and update of the GPICs, the values shown represent the first year of the 2-year GPCI update transition. Although the CY 2011 GPICs have been set on that basis, we note that we will be assessing the results of the various studies regarding the GPICs and cost share weights (once they are completed), and exploring the use of the full ACS data. Based on these assessments, we may make additional proposals that would further modify the GPICs for CY 2012, which would result in changes to the CY 2012 GPICs shown in Addendum E to this final rule with comment period. Therefore, the final CY 2011 GPICs may not reflect a true mid-point "phase-in" to the updated GPICs, although, as noted above, they have been set for CY 2011 on that basis. The CY 2011 updated GAFs and GPICs may be found in Addenda D and E of this final rule with comment period.

3. Payment Localities

The current PFS locality structure was developed and implemented in 1997. There are currently 89 localities; 34 localities are Statewide areas. There are 52 localities in the other 18 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto

Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494).

As we have previously noted in the CYs 2008 and 2009 proposed rules (72 FR 38139 and 73 FR 38513), any changes to the locality configuration must be made in a budget neutral manner within a State and can lead to significant redistributions in payments. For many years, we have not considered making changes to localities without the support of a State medical association in order to demonstrate consensus for the change among the professionals whose payments would be affected (with some increasing and some decreasing). However, we have recognized that, over time, changes in demographics or local economic conditions may lead us to conduct a more comprehensive examination of existing payment localities.

For the past several years, we have been involved in discussions with physician groups and their representatives about recent shifts in relative demographics and economic conditions, most notably within the current California payment locality structure. We explained in the CY 2008 PFS final rule with comment period that we intended to conduct a thorough analysis of potential approaches to reconfiguring localities and would address this issue again in future rulemaking. For more information, we refer readers to the CY 2008 PFS proposed rule (72 FR 38139) and subsequent final rule with comment period (72 FR 66245).

As a follow-up to the CY 2008 PFS final rule with comment period, we contracted with Acumen to conduct a preliminary study of several options for revising the payment localities on a nationwide basis. The contractor's interim report was posted on the CMS Web site on August 21, 2008, and we requested comments from the public. The report entitled, "Review of Alternative GPCI Payment Locality Structures," remains accessible from the CMS PFS Web page under the heading "Interim Study of Alternative Payment Localities under the PFS." The report may also be accessed directly from the following link: http://www.cms.hhs.gov/PhysicianFeeSched/10_Interim_Study.asp#TopOfPage.

We accepted public comments on the interim report through November 3, 2008. The alternative locality configurations discussed in the report

are described briefly below in this section.

Option 1: CMS Core-Based Statistical Area (CBSA) Payment Locality Configuration

This option uses the Office of Management and Budget (OMB's) Metropolitan Statistical Area (MSA) designations for the payment locality configuration. MSAs would be considered as urban CBSAs. Micropolitan Areas (as defined by OMB) and rural areas would be considered as non-urban (rest of State) CBSAs. This approach would be consistent with the IPPS pre-reclassification CBSA assignments and with the geographic payment adjustments used in other Medicare payment systems. This option would increase the number of PFS localities from 89 to 439.

Option 2: Separate High-Cost Counties from Existing Localities (Separate Counties)

Under this approach, higher cost counties are removed from their existing locality structure and they would each be placed into their own locality. This option would increase the number of PFS localities from 89 to 214, using a 5 percent GAF differential to separate high-cost counties.

Option 3: Separate MSAs from Statewide Localities (Separate-MSAs)

This option begins with statewide localities and creates separate localities for higher cost MSAs (rather than removing higher cost counties from their existing locality as described in Option 2). This option would increase the number of PFS localities from 89 to 130, using a 5 percent GAF differential to separate high-cost MSAs.

Option 4: Group Counties Within a State Into Locality Tiers Based on Costs (Statewide Tiers)

This option creates tiers of counties (within each State) that may or may not be contiguous but share similar practice costs. This option would increase the number of PFS localities from 89 to 140, using a 5 percent GAF differential to group similar counties into statewide tiers.

As discussed in Acumen's interim report, all four studied alternative locality configurations would increase the number of localities and separate higher cost areas from rural "rest of state" areas. As a result, payments to urban areas would increase, while rural areas would see a decrease in payment because they would no longer be grouped with higher cost "urbanized" areas. A number of public commenters

on the draft report expressed support for Option 3 (separate MSAs from Statewide localities) because the commenters believed this alternative would improve payment accuracy over the current locality configuration and could mitigate possible payment reductions to rural areas as compared to Option 1 (CMS CBSAs). Therefore, Acumen is conducting a more in-depth analysis of the dollar impacts that would result from the application of Option 3. For a detailed discussion of the public comments on the contractor's interim locality study report, we refer readers to the CY 2010 PFS proposed rule (74 FR 33534) and subsequent final rule with comment period (74 FR 61757).

We note that the discussion of PFS payment localities and our preliminary study of alternative payment locality configurations in the CY 2011 PFS proposed rule was intended for informational purposes only. We did not make any proposals regarding the PFS locality configurations for CY 2011 and, therefore, public comments on the PFS locality configurations are not within scope of the CY 2011 PFS proposed rule. We thank the commenters for sharing their views and suggestions; however, we are not summarizing or responding to 'out of scope' comments in this final rule with comment period.

E. PFS Update for CY 2010: Rebasing and Revising of the Medicare Economic Index (MEI)

1. Background

The Medicare Economic Index (MEI) was originally required by section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. We continued to use the MEI as part of the statutory update formula (specified under section 1848 of the Act) when the physician fee schedule was implemented in 1992 (56 FR 59511).

Beginning July 1, 1975, and continuing through today, the MEI has served these purposes by reflecting the weighted-average annual price change for various inputs needed to furnish physicians' services. As such, the index is necessarily a fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. The MEI is comprised of two broad categories: (1) Physician's

own time; and (2) physician's practice expense (PE).

The MEI was first published on June 16, 1975 (40 FR 25446), and became effective for services furnished beginning July 1, 1975. The original MEI had a base period of 1971. The structure of the original MEI remained essentially unchanged from its original until the CY 1993 final rule (57 FR 55896) in which we finalized a comprehensive rebasing and revision process with a 1989 base year. The new index was based in part on the recommendations of a Congressionally-mandated meeting of experts held in March 1987. The MEI was again rebased in the CY 1999 final rule (63 FR 58845), which moved the cost structure of the index from a 1989 base to a 1996 base. The methodology for the productivity adjustment was revised in the CY 2003 final rule (67 FR 80019) to reflect the percentage change in the 10-year moving average of economy-wide private nonfarm business multifactor productivity (previously the index was adjusted by a measure of labor productivity). The current form of the MEI was detailed in the CY 2004 PFS final rule (68 FR 63239) which updated the cost structure of the index from a base year of 1996 to 2000.

We proposed to rebase and revise the MEI and incorporate it into the CY 2011 PFS update. The terms "rebasing" and "revising", while often used interchangeably, actually denote different activities. Rebasing refers to moving the base year for the structure of costs of an input price index, while revising relates to other types of changes such as changing data sources, cost categories, or price proxies used in the price index. As is always the case with a rebasing and revising exercise, we have used the most recently available, relevant, and appropriate information to develop the proposed MEI cost category weights and price proxies. In the following sections of this final rule with comment period, we detail our proposals and respond to comments regarding the updated cost weights for the MEI expense categories, our rationale for selecting the price proxies in the MEI, and the results of the rebasing and revising of the MEI.

2. Use of More Current Data

The MEI was last rebased and revised in 2003 in the CY 2004 PFS final rule with comment period (68 FR 63239). The current base year for the MEI is 2000, which means that the cost weights in the index reflect physicians' expenses in 2000. However, we believe it is desirable to periodically rebase and revise the index so that the expense shares and their associated price proxies

reflect more current conditions. For the CY 2011 PFS update, we are finalizing the proposal to rebase and revise the MEI to reflect appropriate physicians' expenses in 2006.

Compared to the 2000-based MEI, we proposed to make several changes to the MEI cost structure. First, we proposed to exclude the Pharmaceutical cost category as pharmaceuticals are neither paid for under the PFS nor are they included in the definition of "physicians' services" for purposes of calculating the physician update via the SGR system (for more details see the CY 2010 PFS final rule with comment period (74 FR 61961 through 61962)). We also proposed to exclude the expenses associated with separately billable supplies since these items are not paid for under the PFS. Our primary data source, the 2006 Physician Practice Information Survey (PPIS), collected data on these costs enabling us to accurately remove them from the index. In addition, we proposed to include nine new cost categories that disaggregate the costs under the broader Office Expenses cost category. The 2000-based MEI did not break these expenses into individual cost categories. As a result of comments received, which are described more fully below in this section, we are modifying this proposal to instead include ten detailed cost categories. As indicated in the CY 2011 PFS proposed rule, we proposed to continue to adjust the MEI for economy-wide multifactor productivity based on changes in the 10-year moving average of private nonfarm business multifactor productivity. After considering the comments received, we are finalizing our proposal to continue to adjust the MEI for economy-wide multifactor productivity based on changes in the 10-year moving average of private nonfarm business multifactor productivity.

3. Rebasing and Revising Expense Categories in the MEI

The MEI is used in conjunction with the SGR system to update the PFS and represents the price component of that update. The proposed expense categories in the index, along with their respective weights, are primarily derived from data collected in the 2006 AMA PPIS for self-employed physicians and selected self-employed non-medical doctor specialties. As noted, in addition to data on medical doctors, we included data from several non-medical doctor specialties in the MEI cost weight calculations (including optometrists, oral surgeons, podiatrists, and chiropractors) consistent with the definition of the term "physician" in section 1861(r) of the Act. In summary,

the term "physician" when used in connection with the performance of functions or actions an individual is legally authorized to perform means the following: (1) A doctor of medicine or osteopathy; (2) a doctor of dental surgery or of dental medicine; (3) a doctor of podiatric medicine; (4) a doctor of optometry; or (5) a chiropractor. For a complete definition, please see section 1861(r) of the Act. We weighted the expense data from the above-referenced specialties with the self-employed physician expense data using physician counts by specialty, the same methodology used in the AMA PPIS.

The AMA PPIS data were used to determine the expenditure weights in the MEI for all of the major cost categories including total expenses, physicians' earnings, physicians' benefits, employed physician payroll,

nonphysician compensation, office expenses, professional liability insurance (PLI), medical equipment, medical supplies, and other professional expenses. We are finalizing our proposal to further disaggregate both non-physician compensation and office expenses into subcategories reflecting more detailed expenses. We used several data sources for further disaggregation of expenses including: data from the 2002 Bureau of Economic Analysis (BEA) Benchmark Input-Output table (I/O), the 2006 Bureau of the Census Current Population Survey (CPS), the 2006 Bureau of Labor Statistics (BLS) Occupational Employment Survey (OES), the 2006 Employment Cost for Employee Compensation Survey (ECEC), and the 2006 Internal Revenue Service (IRS) Statistics of Income (SOI) data. The development of each of the cost

categories using these sources is described in detail below.

a. Developing the Weights for Use in the MEI

Developing a rebased and revised MEI requires selecting a base year and determining the appropriate expense categories. We proposed to rebase the MEI to CY 2006. We choose CY 2006 as the base year as: (1) this is the most recent year for which comprehensive physician expense data are available; and (2) we believe these data represent an accurate proxy for the physician expense distribution in CY 2011.

Table 27 lists the set of mutually exclusive and exhaustive cost categories that make up the final rebased and revised MEI, including the addition of the All Other Products category we are adopting in response to public comments.

TABLE 27—FINAL 2006 MEI COST CATEGORIES, WEIGHTS, AND PRICE PROXIES COMPARED TO THE 2000 MEI COST CATEGORIES AND WEIGHTS

Cost category	Final 2006-cost weights (1,2)	2000 Cost weights	2006 Price proxies
Total	100.00	100.000	
Physician's Compensation (Own Time) ⁽³⁾	48.266	52.466	
Wages and Salaries	43.880	42.730	AHE Total Nonfarm Private for Production & Nonsupervisory Employees. ⁽⁵⁾
Benefits ^{(3),(4)}	4.386	9.735	ECI-Benefits Total Nonfarm Private. ⁽⁶⁾
Physician's Practice Expense	51.734	47.534	
Nonphysician Employee Compensation	19.153	18.654	
Nonphysician Employee Wages and Salaries	13.752	13.809	
Prof/Tech Wages	6.006	5.887	ECI-Wages/Salaries: Private Professional & Technical.
Managerial Wages	1.446	3.333	ECI-Wages/Salaries: Private Managerial.
Clerical Wages	4.466	3.892	ECI-Wages/Salaries: Private Clerical.
Services Wages	1.834	0.696	ECI-Wages/Salaries: Private Service.
Nonphysician Employee Benefits ⁽⁴⁾	5.401	4.845	ECI-Ben: Private Blend.
Office Expenses	20.035	12.209	
Utilities	1.266		CPI Fuel & Utilities. ⁽⁷⁾
Chemicals	0.723		PPI for Other Basic Organic Chemical Manufacturing. ⁽⁸⁾
Paper	0.657		PPI for Converted Paper.
Rubber & Plastics	0.598		PPI for Rubber and Plastics.
Telephone	1.501		CPI for Telephone Services.
Postage	0.898		CPI for Postage.
All Other Services	3.582		ECI Compensation Services Occupations.
All Other Products	0.500		CPI-U All Items Less Food and Energy.
Fixed Capital	8.957		CPI for Owner's Equivalent Rent.
Moveable Capital	1.353		PPI for Machinery and Equipment.
PLI	4.295	3.865	CMS-Prof. Liab. Phys. Premiums.
Medical Equipment	1.978	2.055	PPI-Medical Instruments & Equip.
Pharmaceuticals and Medical Materials and Supplies	1.760	4.320	
Pharmaceuticals		2.309	
Medical Materials and Supplies	1.760	2.011	PPI Surg. Appliances and Supplies/CPI(U) Med Supplies.

TABLE 27—FINAL 2006 MEI COST CATEGORIES, WEIGHTS, AND PRICE PROXIES COMPARED TO THE 2000 MEI COST CATEGORIES AND WEIGHTS—Continued

Cost category	Final 2006-cost weights (1,2)	2000 Cost weights	2006 Price proxies
Other Professional Expenses	4.513	CPI-U All Items Less Food and Energy.
Other Expenses	6.433	

- (1) Due to rounding, weights may not sum to 100.000 percent.
- (2) Sources: 2006 Physician Practice Information Survey (PPIS), Center for Health Policy Research, American Medical Association; 2006 Employment Cost for Employee Compensation, U.S. Department of Labor, Bureau of Labor Statistics; 2006 Occupational Employment Statistics (OES), BLS; U.S. Department of Commerce, Bureau of Economic Analysis 2002 Benchmark Input Output Tables, and U.S. Department of Commerce, Bureau of the Census, 2006 Current Population Survey.
- (3) Includes employed physician payroll.
- (4) Includes paid leave.
- (5) Average Hourly Earnings (AHE)
- (6) Employment Cost Index (ECI)
- (7) Consumer Price Index (CPI)
- (8) Producer Price Index (PPI)

The development of each of the cost categories in the final 2006 MEI is described, in detail, as follows.

b. Physician's Own Time

The component of the MEI that reflects the physician's own time is represented by the net income portion of business receipts. The proposed 2006 cost weight associated with the physician's own time (otherwise referred to as the Physician Compensation cost weight) is based on 2006 AMA PPIS data for mean physician net income (physician compensation) for self-employed physicians and for the selected self-employed specialties referenced previously in this rule.

We proposed to continue to add employed physician compensation to self-employed physician compensation in order to calculate an aggregate Physician Compensation cost weight. By including the compensation of employed physicians in the Physician Compensation expense category, these expenses will be adjusted by the appropriate price proxies for a physician's own time. The proposed 2006 Physician Compensation cost weight is 48.266 percent as compared to a 52.466 percent share in the 2000-based MEI. We split the Physician Compensation component into two subcategories: Wages & Salaries; and Benefits. For self-employed physician's compensation, the ratios for Wages & Salaries and Benefits were calculated using data from the PPIS. Self-employed physician wages & salaries accounted

for 92.2 percent of physician compensation while physician benefits accounted for the remaining 7.8 percent. For employed physician payroll, the distribution for wages & salaries and benefits for 2006 was 85.8 percent and 14.2 percent, respectively. This ratio was determined by calculating a weighted average of available SOI data for partnerships, corporations, and S-corporations specific to physicians and outpatient care centers. Based on these methods, the proposed 2006 Physician Wages & Salaries cost weight was 43.880 percent and the proposed 2006 Physician Benefits cost weight was 4.386 percent.

c. Physician's Practice Expenses

To determine the remaining individual Practice Expenses cost weights, we used mean expense data from the 2006 PPIS survey expressed as a percentage of total expenses. The detailed explanations for the derivation of the individual weights under Practice Expenses are listed below.

(1) Nonphysician Employee Compensation

The cost weight for Nonphysician Employee Compensation was developed using the 2006 AMA PPIS mean expenses for these costs. We further divided this cost share into Wages & Salaries and Benefits using 2006 BLS Employer Costs for Employee Compensation (ECEC) data for the Health Care and Social Assistance (private industry) category. Although this survey does not contain data only

for offices of physicians, data are available to help determine the shares associated with wages & salaries and benefits for private industry health care and social assistance services (which include offices of physicians, hospitals, nursing homes, and offices of dentists). We believe these data provide a reasonable estimate of the split between wages and benefits for employees in physicians' offices. Data for 2006 in the ECEC for Health Care and Social Assistance indicate that wages and benefits are 71.8 percent and 28.2 percent of compensation, respectively. The 2000-based MEI included a wage and benefit split of 74.0 percent and 26.0 percent of compensation.

We proposed to use 2006 Current Population Survey (CPS) data and 2006 BLS Occupational Employment Statistics (OES) data to develop cost weights for wages for nonphysician occupational groups. These are the same data sources that were used in the 2000-based MEI. We determined total annual earnings for offices of physicians using employment data from the CPS and mean annual earnings from the OES. To arrive at a distribution for these separate categories, we determined annual earnings for each of the four categories (which are Professional & Technical workers, Managers, Clerical workers, and Service workers), using the Standard Occupational Classification (SOC) system. We then determined the overall share of the total for each. The resulting proposed distribution, as well as the distribution from the 2000-based MEI, are presented in Table 28.

TABLE 28—PERCENT DISTRIBUTION OF NONPHYSICIAN PAYROLL EXPENSE BY OCCUPATIONAL GROUP: 2006 AND 2000

BLS Occupational Group	2006 Expenditure shares	2000 Expenditure shares
Total	100.000	100.000

TABLE 28—PERCENT DISTRIBUTION OF NONPHYSICIAN PAYROLL EXPENSE BY OCCUPATIONAL GROUP: 2006 AND 2000—Continued

BLS Occupational Group	2006 Expenditure shares	2000 Expenditure shares
Professional & Technical Workers	43.671	42.635
Managers	10.517	24.138
Clerical Workers	32.477	28.187
Service Workers	13.336	5.040

Values may not sum to 100 due to rounding.

The decrease in the Managers expenditure share is directly related to a decrease in the total number of employees in Management occupations in physicians' offices, in particular, "Medical and health service managers." The decrease in expenditure share may also be due, in part, to the methods used in this rebasing. That is, for the 2006-based MEI, we are using data limited to "Offices of physicians." In the 2000-based version of the index, the only data that were available to inform these estimates were inclusive of physician offices and clinics ("Offices of physicians and clinics"). An examination of 2006 CPS and OES data comparing "Outpatient care centers" to "Offices of physicians" indicates that there is a higher share of management occupations in the "Outpatient care centers" than in "Offices of physicians".

The increase in the Service Workers expenditures share is attributable to a substantive increase in the number of employees in service occupations, particularly, "Medical assistants and other health care support occupations".

(2) Office Expenses

The aggregate Office Expenses cost weight was derived using the 2006 AMA PPIS and was calculated as the mean office expenses expressed as a percentage of mean total expenses. This calculation resulted in a 20.035 percent share of total costs in 2006 compared to a 12.209 percent share in the 2000-based index. The Office Expenses cost weight used in the 2000-based MEI was based on the AMA 1997 Socioeconomic Monitoring System (SMS) survey, which defined office expenses as rent, mortgage interest, depreciation on medical buildings, utilities, and telephones. The AMA expanded the office expense question in the 2006 PPIS survey to include additional expenses, described in more detail below in this section.

As a result, and in order to provide for a higher level of precision in assigning appropriate price proxies to underlying costs, we proposed to further disaggregate the Office Expenses cost category into 9 detailed cost categories

using the BEA 2002—Benchmark I/O data for Offices of Physicians, Dentists, and Other Health Practitioners (North American Industrial Classification System (NAICS) 621A00). In response to comments, and as described more fully below, we are finalizing those nine categories, as well as adding a tenth detailed cost category.

The proposed Office Expenses cost categories and associated cost weights were developed by matching the BEA I/O data as closely as possible to the 2006 AMA PPIS survey, which defined office expenses as "office (non-medical) equipment and office (nonmedical) supplies, as well as rent, mortgage, interest, maintenance, refrigeration, storage, security, janitorial, depreciation on medical buildings used in your practice, utilities, or other office computer systems (including information management systems/electronic medical record systems) and telephone." In most instances, the proposed underlying detailed cost categories and associated cost weights were chosen to be consistent with the NAICS 3-digit classification. BEA I/O expense data is published on a NAICS-basis. Some of the proposed underlying detailed cost categories such as All Other Services include various 3-digit NAICS codes for service related industries. Similar methods are used in the other legislatively-required market baskets developed by CMS. After we categorized the BEA I/O data, we calculated the relative share for each category as a percentage of the total office expenses categories within the I/O data. We then aged the 2002 weights forward to 2006 to derive the 2006 detailed Office Expense cost weights as a percent of total Office Expenses. The methodology we used to age the data forward was to apply the annual price changes from each respective price proxy to the appropriate cost categories. We repeated this practice for each year of the interval from 2002 to 2006. We then applied the resulting 2006 distributions to the aggregate 2006 AMA Office Expenses weight of 20.035 percent to yield the detailed 2006 Office

Expenses' weights as a percent of total expenses.

In response to public comments that are detailed in the subsequent sections of this rule, we conducted an additional review of the BEA I/O data used to disaggregate the Office Expense cost category, comparing the I/O's detailed categories with the questions on the AMA PPIS survey. This review led to small revisions to the underlying Office Expense cost weights and resulted in the inclusion of one additional cost weight in that category: All Other Products. These products, which were previously assumed to be captured in the Other Professional Expenses category (as measured by the AMA PPIS survey), include a variety of miscellaneous products, such as miscellaneous wood and building products, that we believe respondents included in Office Expenses as maintenance expense. Table 2Z provides the revised MEI weights.

We believe the introduction of these new, more detailed categories for the 2006-based index allow for an increased level of precision while maintaining appropriate levels of aggregation in the index. The individual price proxies are described in more detail in section I.E.4 of this final rule.

The following is a description of the types of expenses included in each of the detailed Office Expense cost categories.

- **Utilities:** The Utilities cost weight includes expenses classified in the fuel, oil and gas, water and sewage, and electricity industries. These types of industries are classified in NAICS and include NAICS 2211 (Electric power generation, transmission, and distribution), 2212 (Natural gas distribution), and 2213 (Water, sewage, and other systems). The cost weight for utilities is 1.266 percent.

- **Chemicals:** The Chemicals cost weight includes expenses classified in the NAICS 325 (Chemical manufacturing), excluding pharmaceuticals and biologicals. This would include, but is not limited to, expenses such as soap and cleaning compounds, as well as photocopier

toners and laser printer toners. The cost weight for chemicals is 0.723 percent.

- **Paper:** The Paper cost weight includes expenses classified in NAICS 322 (paper manufacturing) and NAICS 323 (printing and related support activities). This would include expenses associated with items such as paper, paperboard, sanitary paper products, and printing. The cost weight for paper is 0.657 percent.

- **Rubber and Plastics:** The Rubber and Plastics cost weight includes expenses classified in NAICS 326 (Plastics and Rubber Products Manufacturing). This would include, but is not limited to expenses associated with plastic bags, plastic trash cans, and plastic plumbing fixtures. The cost weight for Rubber and Plastics is 0.598 percent.

- **Telephone:** The Telephone cost weight includes expenses classified in NAICS 517 (Telecommunications) and NAICS 518 (Internet service providers), and NAICS 515 (Cable and other subscription programming). Telephone service, which is one component of the Telecommunications expenses, accounts for the majority of the expenditures in this cost category. The cost weight for Telephone services is 1.501 percent.

- **Postage:** The Postage cost weight includes expenses classified in NAICS 491 (Postal services) and NAICS 492 (Courier services). The cost weight for Postage is 0.898 percent.

- **All Other Services:** The All Other Services cost weight includes other service expenses including, but not limited to, nonresidential maintenance and repair, machinery repair, janitorial, and security services. This cost weight does not include expenses associated with professional services such as accounting, billing, legal, and marketing which are included in the Other Professional Expenses cost weight derived using the AMA PPIS survey. The cost weight for All Other Services is 3.582 percent.

- **All Other Products:** The All Other Products cost weight, which we are adding based upon our further review in response to public comments, includes other miscellaneous expenses, including but not limited to, a variety of miscellaneous building products (such as wood and concrete). The cost weight for All Other Products is 0.500 percent.

- **Fixed Capital:** The Fixed Capital cost weight includes expenses for building leases, mortgage interest, and depreciation on medical buildings. The cost weight for Fixed Capital is 8.957 percent.

- **Moveable Capital:** The Moveable Capital cost weight includes expenses

and depreciation costs for non-medical equipment including but not limited to, computer equipment and software and the rental and leasing of industrial machinery equipment. The cost weight for Moveable Capital is 1.353 percent.

(3) Professional Liability Insurance (PLI) Expense

The proposed weight for PLI expense was derived from the 2006 AMA survey and was calculated as the mean PLI expense expressed as a percentage of mean total expenses. This calculation resulted in a 4.295-percent share of total costs in 2006 compared to a 3.865-percent share in the 2000-based index. The increase in the weight for PLI reflects the current prices of premiums, as well as an update to the level of coverage purchased by physicians in 2006 compared to 2000.

(4) Medical Equipment Expenses

The proposed weight for Medical Equipment was calculated using the 2006 AMA PPIS mean expense data expressed as a percentage of mean total expenses. This calculation resulted in a 1.978-percent share of total costs in 2006 compared to a 2.055-percent share in the 2000-based index. By definition, this category includes the expenses related to depreciation, maintenance contracts, and the leases or rental of medical equipment used in diagnosis or treatment of patients. The category would also include the tax-deductible portion of the purchase price or replacement value of medical equipment, if not leased.

(5) Medical Supplies Expenses

The proposed weight for Medical Supplies was calculated using the 2006 AMA PPIS mean expense data expressed as a percentage of mean total expenses. This calculation resulted in a 1.760-percent share of total costs in 2006 compared to a 2.011-percent share in the 2000-based index. By definition, this category includes the expenses related to medical supplies such as sterile gloves, needles, bandages, specimen containers, and catheters. Additionally, we proposed to exclude the expenses related to separately billable supplies as these expenses are not paid for under the PFS. The Medical Supply cost category does not include expenses related to drugs.

(6) Other Professional Expenses

The proposed weight for Other Professional expenses was calculated using the 2006 AMA PPIS mean expense data expressed as a percentage of mean total expenses. This calculation resulted in a 4.513-percent share of total

costs in 2006. By definition, this category includes the expenses related to tax-deductible expenses for any other professional expenses not reported in another category from the PPIS. These expenses would include fees related to legal, marketing, accounting, billing, office management services, professional association memberships, maintenance of certification or licensure, journals and continuing education, professional car upkeep and depreciation, and any other general expenses or other professional expenses not reported elsewhere on the PPIS.

In summary, we are finalizing the proposed 2006-based MEI cost categories and respective cost weights for all categories except for the underlying detailed Office Expense cost categories and cost weights. In response to public comments, we reexamined the BEA I/O data and compared it again with the specific types of costs sought by the AMA PPIS survey question on Office Expenses. Although we are finalizing the proposed Office Expense cost weight of 20.035 percent, our re-evaluation resulted in slight changes to the underlying detail of the Office Expense cost categories and cost weights. Specifically, we are finalizing the nine proposed detailed cost categories and adding one additional detailed cost category, All Other Products. The final detailed cost categories and cost weights for the underlying Office Expense cost categories are shown in Table 27.

Table 29 shows a comparison of the proposed MEI Office Expense cost categories and weights to the final MEI Office Expense cost categories and weights. In addition to adding the subcategory All Other Products, the final Office Expenses' category weights were updated in response to public comments to reflect the removal of automobile-related expenses, which were in effect being double-counted, from the Movable Capital category. Further examination of the AMA's PPIS questions showed that automobile costs, such as those associated with leasing and depreciation, were captured in the question related to other professional expenses and are, thus accounted for in Other Professional Expenses (with a final cost weight of 4.513 percent). Notably, that cost weight is not impacted as, again, those costs were captured there in the survey.

TABLE 29—COMPARISON OF PROPOSED OFFICE EXPENSE COST CATEGORIES AND COST WEIGHTS TO THE FINAL OFFICE EXPENSE COST CATEGORIES AND COST WEIGHTS

Cost categories	2006 Final weight (%)	2006 Proposed weight (%)
Office Expenses	20.035	20.035
Utilities	1.266	1.139
Chemicals	0.723	0.679
Paper	0.657	0.616
Rubber & Plastics	0.598	0.563
Telephone	1.501	1.415
Postage	0.898	0.661
All Other Services	3.582	4.718
All Other Products	0.500
Fixed Capital	8.957	8.410
Moveable Capital	1.353	1.834

4. Selection of Price Proxies for Use in the MEI

After the 2006 cost weights for the rebased and revised MEI were developed, we reviewed all of the price proxies to evaluate their appropriateness. As was the case in the development of the 2000-based MEI (68 FR 63239), most of the proxy measures we considered are based on BLS data and are grouped into one of the following five categories:

- **Producer Price Indices (PPIs):** PPIs measure price changes for goods sold in markets other than retail markets. These fixed-weight indexes are a measure of price change at the intermediate or final stage of production. They are the preferred proxies for physician purchases as these prices appropriately reflect the product's first commercial transaction.

- **Consumer Price Indices (CPIs):** CPIs measure changes in the prices of final goods and services bought by consumers. Like the PPIs, they are fixed-weight indexes. Since they may not represent the price changes faced by producers, CPIs are used if there are no appropriate PPIs or if the particular expenditure category is likely to contain purchases made at the final point of sale.

- **Average Hourly Earnings (AHEs):** AHEs are available for production and nonsupervisory workers for specific industries, as well as for the nonfarm business economy. They are calculated by dividing gross payrolls for wages & salaries by total hours. The series reflects shifts in employment mix and, thus, is representative of actual changes in hourly earnings for industries or for the nonfarm business economy.

- **ECIs for Wages & Salaries:** These ECIs measure the rate of change in employee wage rates per hour worked. These fixed-weight indexes are not affected by employment shifts among industries or occupations and thus, measure only the pure rate of change in wages.

- **ECIs for Employee Benefits:** These ECIs measure the rate of change in employer costs of employee benefits, such as the employer's share of Social Security taxes, pension and other retirement plans, insurance benefits (life, health, disability, and accident), and paid leave. Like ECIs for wages & salaries, the ECIs for employee benefits are not affected by employment shifts among industries or occupations.

When choosing wage and price proxies for each expense category, we evaluate the strengths and weaknesses of each proxy variable using the following four criteria:

- **Relevance:** The price proxy should appropriately represent price changes for specific goods or services within the expense category. Relevance may encompass judgments about relative efficiency of the market generating the price and wage increases.

- **Reliability:** If the potential proxy demonstrates a high sampling variability, or inexplicable erratic patterns over time, its viability as an appropriate price proxy is greatly diminished. Notably, low sampling variability can conflict with relevance—since the more specifically a price variable is defined (in terms of service, commodity, or geographic area), the higher the possibility of high sampling variability. A well-established time series is also preferred.

- **Timeliness of actual published data:** For greater granularity and the need to be as timely as possible, we prefer monthly and quarterly data to annual data.

- **Public availability:** For transparency, we prefer to use data sources that are publicly available.

The BLS price proxy categories previously described meet the criteria of relevance, reliability, timeliness, and public availability. Below we discuss the price and wage proxies for the rebased and revised MEI (as shown in Table E4), along with a summary of the public comments we received on our proposals and our responses to those comments.

a. Cost (Expense) Categories in the MEI

(1) Physician's Own Time (Physician Compensation)

For the revised and rebased MEI, we proposed to continue to use the AHE for

production and non-supervisory employees for the private nonfarm economy as the proxy for the Physician Wages & Salaries component (BLS series code: CEU0500000008).

The AHE for the private nonfarm economy reflects general earnings including the impacts of supply, demand, and economy-wide productivity for the average worker in the economy. As such, use of this proxy is consistent with the original intent of the Congress for the change in the MEI to follow reflect changes in expenses of practice and general earnings levels.¹ The current 2000-based MEI uses the ECI for Total Benefits (BLS series code: CIU20300000000001) for total private industry as the price proxy for Physician Benefits. We proposed to continue using the same proxy for the 2006-based MEI and received no public comment on this particular aspect of the index. This means that both the wage and benefit proxies for physician earnings are derived from the private nonfarm business sector and are computed on a per-hour basis.

(2) Nonphysician Employee Compensation

For the 2006-based MEI, we proposed to use the same ECI private series for each occupational group as in the 2000-based MEI. In particular, we proposed to use the ECI for Professional and Technical Workers, the ECI for Managerial Services, the ECI for Administrative Support Services, and the ECI for Service Occupations.

As described in the CY 2008 PFS proposed rule (72 FR 38190), as a result of the discontinuation of the White Collar Benefit ECI for private workers, we proposed to continue to use a composite ECI benefit index. We are continuing to use the composite ECI for non-physician employees in the proposed rebased and revised MEI; however, we proposed to rebase the weights within that blend in order to reflect the more recent 2006 data. Table 30 lists the four ECI series and corresponding weights used to construct the 2006 composite benefit index.

¹ U.S. Senate, Committee on Finance, *Social Security Amendments of 1972*. "Report of the Committee on Finance United States Senate to Accompany H.R. 1," September 26, 1972, p. 191.

TABLE 30—CMS COMPOSITE PRICE INDEX FOR NONPHYSICIAN EMPLOYEE BENEFITS

ECI series	2006 weight (%)
Benefits, Private, Professional & Related	44
Benefits, Private, Management, Business, Financial	11
Benefits, Private, Office & Administrative Support	32
Benefits, Private, Service Occupations	13

(3) Utilities

For the 2006-based MEI, we proposed to use the CPI for Fuel and Utilities (BLS series code #CUUR0000SAH2) to measure the price growth of this cost category. This cost category was not broken out separately in the 2000-based MEI.

(4) Chemicals

For the 2006-based MEI, we proposed to use the PPI for Other Basic Organic Chemical Manufacturing (BLS series code #PCU32519–32519) to measure the price changes of this cost category. We are using this industry-based PPI because BEA's 2002 benchmark I/O data show that the majority of the office of physicians' chemical expenses are attributable to Other Basic Organic Chemical Manufacturing (NAICS 32519). This cost category was not broken out separately in the 2000-based MEI.

(5) Paper

For the 2006-based MEI, we proposed to use the PPI for Converted Paper and Paperboard (BLS series code #WPU0915) to measure the price growth of this cost category. This cost category was not broken out separately in the 2000-based MEI.

(6) Rubber and Plastics

For the 2006-based MEI, we proposed to use the PPI for Rubber and Plastic Products (BLS series code #WPU07) to measure the price growth of this cost category. This cost category was not broken out separately in the 2000-based MEI.

(7) Telephone

For the 2006-based MEI, we proposed to use the CPI for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category. This cost category was not broken out separately in the 2000-based MEI.

(8) Postage

For the 2006-based MEI, we proposed to use the CPI for Postage (BLS series code #CUUR0000SEEC01) to measure the price growth of this cost category. This cost category was not broken out separately in the 2000-based MEI.

(9) All Other Services

For the 2006-based MEI, we proposed to use the ECI for Compensation for Service Occupations (private industry) (BLS series code #CIU20100003000001) to measure the price growth of this cost category. This cost category was not broken out separately in the 2000-based MEI.

(10) All Other Products

As noted previously, we are adding this category in this final rule with comment period in response to public comments. This category includes a variety of miscellaneous expenses such as miscellaneous building products; thus, we will use the CPI-U for All Items Less Food and Energy as a proxy for price changes. This cost category was not broken out separately in the 2000-based MEI.

(11) Fixed Capital

For the 2006-based MEI, we proposed to use the CPI for Owner's Equivalent Rent (BLS series code #CUUS0000SEHC) to measure the price growth of this cost category. This price index represents about 50 percent of the CPI for Housing, which was used in the 2000-based MEI to proxy total Office Expenses.

(12) Moveable Capital

For the 2006-based MEI, we proposed to use the PPI for Machinery and Equipment (series code #WPU11) to measure the price growth of this cost category. This cost category was not broken out separately in the 2000-based MEI.

(13) Professional Liability Insurance (PLI)

Each year, we solicit PLI premium data for physicians from a sample of commercial carriers. This information is not collected through a survey form, but instead is requested directly from, and provided by (on a voluntary basis), several national commercial carriers. As we require for our other price proxies, the professional liability price proxy is intended to reflect the pure price change associated with this particular cost category. Thus, it does not include changes in the mix or level of liability coverage. To accomplish this result, we obtain premium information from a sample of commercial carriers for a

fixed level of coverage, currently \$1 million per occurrence and a \$3 million annual limit. This information is collected for every State by physician specialty and risk class. Finally, the State-level, physician-specialty data are aggregated by effective premium date to compute a national total, using counts of physicians by State and specialty as provided in the AMA publication, *Physician Characteristics and Distribution in the U.S.*

The resulting data provide a quarterly time series, indexed to a base year consistent with the MEI, and reflect the national trend in the average professional liability premium for a given level of coverage, generally \$1 million/\$3 million of claims-made mature policies. From this series, quarterly and annual percent changes in PLI are estimated for inclusion in the MEI.

The most comprehensive data on professional liability costs are held by the State insurance commissioners, but these data are available only with a substantial time lag and hence, the data currently incorporated into the MEI are much timelier. We believe that, given the limited data available on professional liability premiums, the information and methodology described above produces an adequate proxy of the PLI price trends facing physicians.

(14) Medical Equipment

The Medical Equipment cost category includes depreciation, leases, and rent on medical equipment. We proposed to use the PPI for Medical Instruments and Equipment (BLS series code: WPU156201) as the price proxy for this category, consistent with the price proxy used in the 2000-based MEI and other CMS input price indexes.

(15) Medical Materials and Supplies

As was used in the 2000-based MEI, we proposed to use a blended index comprised of a 50/50 blend of the PPI Surgical Appliances (BLS series code: WPU156301) and the CPI-U for Medical Equipment and Supplies (BLS series code: CUUR0000SEMG). We believe physicians purchase the types of supplies contained within these proxies, including such items as bandages, dressings, catheters, intravenous (I.V.) equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we proposed to combine the two aforementioned indexes to reflect those modes of purchase.

(16) Other Professional Expenses

This category includes the residual subcategory of other professional expenses such as accounting services, legal services, office management services, continuing education, professional association memberships, journals, professional car expenses, and other general expenses and other professional expenses not captured elsewhere. Given this heterogeneous mix of goods and services, we are finalizing our proposal to use the CPI-U for All Items Less Food and Energy. In summary, we are finalizing the proposed 2006-based MEI price proxies with one modification. Since an additional cost category, All Other Products, was added to the office expense disaggregation, we are also finalizing the decision to use the CPI for All Items Less Food and Energy as the price proxy for that category.

(b) Productivity Adjustment to the MEI

The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for those changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business multifactor productivity that were applied to the entire index. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by changes in the 10-year moving average of economy-wide private nonfarm business labor productivity.

We proposed to continue to use the current method for adjusting the full MEI for multifactor productivity in the rebased and revised MEI, and are finalizing that proposal.

As described in the CY 2003 PFS final rule, we believe this adjustment is appropriate because it explicitly reflects the productivity gains associated with all inputs (both labor and non-labor). We believe that using the 10-year moving average percent change in private nonfarm business multifactor productivity is appropriate for deriving a stable measure that helps alleviate the influence that a peak (or a trough) of a business cycle may have on the measure. The adjustment will be based on the latest available historical e

private nonfarm business multifactor productivity data as measured and published by BLS.

5. Results of Rebasing

Table 31 illustrates the results of updating the MEI cost weights for Physician Compensation, Practice Expenses (excluding PLI), and PLI from a 2000-based cost distribution to a 2006-based cost distribution, including all the proposed and finalized revisions as specified in this final rule.

TABLE 31—PERCENT DISTRIBUTION OF SELECTED PHYSICIAN EXPENSES USED TO CALIBRATE RVUS: CYS 2006 AND 2000

	CY 2006 weight (%)	CY 2000 weight (%)
Physician Compensation (Own Time)	48.266	52.466
Practice Expenses (less PLI)	47.439	43.669
PLI	4.295	3.865

The rebased and revised MEI has several differences as compared to the 2000-based MEI; these changes have been discussed in detail in prior sections of this rule. Table E8 shows the average calendar year percent change for CY 2004 to CY 2011 for both the 2000- and 2006-based MEIs. The 2006-based MEI annual percent changes differ from the 2000-based MEI annual percent changes by 0.0 to 0.8 percentage point. For CYS 2007 through 2011, the annual percent change in the rebased and revised MEI was within 0.3 percentage point of the percent change in the 2000-based MEI. In the earlier years, there were larger differences between the annual percent change in the rebased and revised MEI and the 2000-based MEI. The majority of these differences can be attributed to the lower benefit cost weight, as measured by the 2006 AMA data, and the exclusion of the Pharmaceuticals cost category. The remaining differences are attributable to the higher cost weight for PLI, as measured by the 2006 AMA data.

TABLE 32—ANNUAL PERCENT CHANGES IN THE 2000-BASED AND REVISED 2006-BASED MEI

Update year (A)	Final 2006-based MEI	Current 2000-based MEI
CY 2004	2.3	2.6
CY 2005	1.8	2.6
CY 2006	1.8	2.4
CY 2007	1.6	1.9
CY 2008	1.9	1.8
CY 2009	1.6	1.6
CY 2010	1.5	1.2
CY 2011(B)	0.4	0.3
Average Change for CYS 2004-2011	1.6	1.8

(A) Update year based on historical data through the second quarter of the prior calendar year. For example, the 2010 update is based on historical data through the second quarter 2009.

(B) Based on historical data through the 2nd quarter 2010.

As shown in Table 33, the percent change of the rebased and revised MEI for the CY 2011 PFS final rule is an increase of 0.4 percent, one tenth of a percentage point higher than the 2000-based MEI for the same period. The proposed rule included an estimated increase of 0.3 percent for 2011 based on projected data from IHS Global Insight, Inc. The 0.4 percent increase was calculated based on historical data through the second quarter of 2010, including revised data from the BLS on the 10-year moving average of BLS private nonfarm business multifactor productivity published on October 6, 2010 (<http://www.bls.gov/news.release/pdf/prod3.pdf>). The 0.1 percentage point difference in the MEI update factor from the 0.3-percent estimate indicated in the proposed rule to our current figure of 0.4 percent is primarily related to the incorporation of more recent historical data for private nonfarm business multifactor productivity.

TABLE 33—ANNUAL PERCENT CHANGE IN THE 2000-BASED AND REVISED 2006-BASED MEI FOR CY 2011

	2006-based MEI	2000-based MEI
CY 2011	0.4	0.3

TABLE 34—ANNUAL PERCENT CHANGE IN THE REVISED AND REBASED MEI CY 2011, ALL CATEGORIES¹

Cost categories	2006 weight ² (%)	CY 2011 percent change
MEI Total, productivity adjusted	100.000	0.4
Productivity: 10-year moving average of MFP	N/A	1.2
MEI Total, without productivity adjustment	100.000	1.6
Physician Compensation (Own Time) ³	48.266	2.4
Wages and Salaries	43.880	2.5
Benefits	4.386	1.7
Physician's Practice Expenses	51.734	0.7
Nonphysician Employee Compensation	19.153	1.5
Nonphysician Employee Wages	13.752	1.4
Prof/Tech Wages	6.006	1.2
Managenal Wages	1.446	1.2
Clerical Wages	4.466	1.7
Services Wages	1.834	1.7
Nonphysician Employee Benefits	5.401	1.6
Other Practice Expenses	26.308	0.1
Office Expenses	20.035	0.6
Utilities	1.266	-3.1
Chemicals	0.723	-2.5
Paper	0.657	-0.3
Rubber & Plastics	0.598	-0.3
Telephone	1.501	0.8
Postage	0.898	4.7
All Other Services	3.582	1.8
All Other Products	0.500	1.4
Fixed Capital	8.957	0.6
Moveable Capital	1.353	0.1
PLI ⁴	4.295	-2.9
Medical Equipment	1.978	0.5
Medical Materials and Supplies	1.760	0.4
Other Professional Expenses	4.513	1.4

¹The estimates are based upon the latest available Bureau of Labor Statistics data on the 10-year moving average of BLS private nonfarm business multifactor productivity published on October 6, 2010 (<http://www.bls.gov/news.release/pdf/prod3.pdf>).

²The weights shown for the MEI components are the 2006 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2006. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2006 weight. The sum of these products (weights multiplied by the price index levels) yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

³The measures of Productivity, Average Hourly Earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics (BLS) Web site at <http://stats.bls.gov>.

⁴Derived from a CMS survey of several major commercial insurers.

⁵Productivity is factored into the MEI as a subtraction from the total index growth rate; therefore, no explicit weight exists for productivity in the MEI.

6. Medicare Economic Index Technical Advisory Panel

In the CY 2011 PFS proposed rule, we notified the public of our intent to convene a Medicare Economic Index Technical Advisory Panel (MEI TAP) to study all aspects of the MEI including its cost categories, their associated cost weights and price proxies, and the adjustment of the index by an economy-wide measure of multi-factor productivity. We will be convening the MEI TAP. More details regarding this issue can be found in the next section of this rule.

7. Summary of Comments and the Associated Responses

a. Timing of Rebasing and Revising the MEI

Comment: Many commenters support the rebasing and revising of the MEI using CY 2006 as a base year and the

incorporation of practice cost changes reflected in the 2006 AMA PPIS. Many of these commenters also indicated their support for the upcoming MEI technical advisory panel, but stressed that CMS should not delay moving forward with rebasing and revising the MEI for CY 2011. Several people wrote that they believe that the rebasing, along with the addition of new product categories, will result in a more accurate distribution of expenses among physician compensation, practice expense, and professional liability. The commenters believe that the proposal to rebase to 2006 will make the MEI more representative of current conditions in the health care marketplace and, in particular, more reflective of the higher burden of practice expenses in relation to physician compensation in modern physician practices. The commenters agree that the use of more current data

and the expansion of the categories used in determining the MEI update are a technical improvement over the 2000-based MEI and urge CMS to proceed accordingly.

Response: We agree with the commenters that the 2006-based MEI reflects a more current estimate of the cost distribution associated with furnishing physicians' services. Therefore we are finalizing our proposals (with minor modifications described above) to rebase and revise the MEI, and are proceeding with implementation of the 2006-based MEI for CY 2011.

Comment: Many commenters indicated CMS should postpone implementation of the rebased and revised MEI until the MEI technical advisory panel can conduct a comprehensive review of all aspects of the index. These commenters believe that it is premature to finalize proposals

that will significantly change the MEI prior to receiving recommendations from the technical advisory panel and therefore strongly support convening the technical advisory panel first and rebasing and revising the MEI afterwards.

Response: We agree with the commenters that the MEI technical advisory panel should move forward (discussed in more detail below). However, we do not find any compelling technical reason to postpone finalizing the proposed changes to the index. We believe rebasing and revising the index for CY 2011 to reapportion the work, practice expense, and malpractice weights will allow the MEI to appropriately reflect more recent data. For these reasons we disagree with the commenters that support delaying the rebasing of the MEI until the technical panel has had a chance to convene and make further recommendations. Should we concur with recommendations from the technical advisory panel that would result in technical improvements to the MEI, we would propose any changes in a future rulemaking exercise.

Comment: One commenter questioned the need for changes in the MEI in 2011, particularly since there is no statutory timeframe for these changes and the most recent changes in practice expenses from the PPIS survey are in the first year of a 4-year phase-in.

Response: The current MEI reflects the physician practice cost structure for 2000. Based on both our own analysis and supporting public comments, it is evident that this cost structure has changed from 2000 to 2006.

Accordingly, we believe it is technically appropriate to update to a more recent base year for use in CY 2011.

Comment: A commenter suggested that when rebasing is done in the future, CMS should propose phasing in the changes, perhaps over 2 years, in order to mitigate negative consequences.

Response: We do not believe it would be appropriate to phase in changes to the MEI associated with rebasing and revising the index. These periodic efforts are done to ensure that the MEI is reflecting the latest available information and echoes current cost distributions associated with furnishing physicians' services. Our approach is consistent across all of the Medicare market baskets in this regard and is likewise consistent with how technical improvements are incorporated into other published price indexes, such as the CPI or PPI.

Comment: Some commenters asked CMS to delay rebasing the MEI until the summit on geographic practice costs

and the IOM studies have been completed.

Response: We believe that it is technically appropriate to update the MEI to reflect the more current cost structure as determined by using the 2006 AMA PPIS data. We note that the MEI is constructed independent of the GPCIs. While the GPCI weights have historically been linked to the MEI cost weights, we do not believe it would be appropriate to postpone rebasing the MEI in anticipation of the summit's or the IOM's findings.

b. PPIS Data

Comment: Many commenters stated they, like CMS, are unaware of another more robust or more current source of available data on physician practice costs than the PPIS. Other commenters noted that CMS and the AMA have supported using PPIS data to update the practice expense per hour (PE/HR) calculations beginning in CY 2010. The commenters believe that if the data were sufficient to adjust PE/HR, then they are sufficient to update the MEI. Other commenters indicate they support periodic updates to the index, recognizing the difficulties associated with updating the MEI's cost categories and weights on an annual basis.

Response: We agree with the commenters that the PPIS is the most up-to-date and comprehensive data source available on physician practice costs. We also believe that the estimates derived from the PPIS are current, valid, and appropriate for use in rebasing and revising the MEI. Likewise, we concur that a variety of data-related issues would make updating the MEI on an annual basis difficult and believe that periodic revisions such as the one we are adopting in this final rule with comment period are more appropriate.

Comment: A few commenters expressed general concerns over using data from the PPIS. One commenter specifically notes that the MEI changes are allegedly being proposed to reflect changes in medical practice based on research using PE data. The commenter has reviewed some of the research, including the research process and questioned the research data itself. Their concerns over the raw data source include issues related to sample design, sample geographic distribution, and sample size sufficiency. They questioned the choice of the data collection firm used by AMA.

Response: We conducted an extensive review of the PPIS data and continue to believe it appropriately reflects the cost distributions of physicians. We note that we rely upon the physician community to complete the AMA surveys as

accurately as possible since unlike other provider types (such as hospitals and skilled nursing facilities) physicians are not required to submit annual Medicare cost report data.

Comment: Some commenters indicated that CMS did not make clear why the rebased MEI would be based on PPIS data from 2006. Several expressed concerns that the use of 4-year old data is questionable as data this old would not reflect physician expenses in 2011 (and that more up-to-date data on physician costs is surely available).

Response: As stated in the CY 2011 PFS proposed rule (75 FR 40088), we chose to rebase the MEI to 2006 in order to incorporate the 2006 AMA PPIS data. We believe the 2006 AMA PPIS data is the most up-to-date, complete, statistically valid data source available. We welcome any recommendations for more up-to-date data sources available on physician expenses. We would also note that the 2006 data from the PPIS are used to provide the cost structure that is used in the MEI. The increase in the CY 2011 MEI ultimately reflects the input price inflation, adjusted for productivity, that physicians face based on a 2006 distribution of costs. It does not, nor is it intended to, reflect physician input cost levels for 2011.

Comment: Some commenters noted that in the interest of transparency, CMS should publish on its Web site all data from the PPIS that were used in rebasing the MEI.

Response: We understand the commenter's request for transparency. Unfortunately, we are unable to publish the detailed micro level data from the AMA PPIS survey as it is proprietary information. We would suggest the commenter contact the AMA with their request.

c. Office Expenses

Comment: Several commenters appreciated the intent of the new subcategories found in Office Expenses to include more medical office-specific data and believe it will improve the index.

Response: We agree with the commenters and believe that having greater detail under the Office Expense cost category in the MEI provides a technical improvement.

Comment: Several commenters questioned the CMS proposal to create detailed categories under the broader Office Expense cost category. Some of the commenters had specific concerns about the particular subcategories. Examples included the following:

- The Chemicals and Rubber & Plastics categories (all derived from the BEA) might not be relevant (or

meaningful) to today's physicians' practice.

- Computers, computer expenses, billing, and scheduling technology and electronic medical records are high-cost, non-optional office expenses for medical practices that are not adequately captured and would represent more appropriate categories.

- CMS references data on the Office Expenses' components derived from the BEA, but the agency provided no rationale to justify the changes in Office Expenses, nor did it provide a detailed accounting methodology or solicit advice on new inputs to the index.

Response: We proposed to disaggregate the Office Expense cost category into more detailed cost categories as a result of a change to the question in the 2006 AMA PPIS survey that captured these types of costs. In addition, in rulemaking for the CY 2008 Physician Fee Schedule, we received a comment from the industry about our use of the CPI for Housing to proxy Office Expenses (72 FR 66376). At that time, we notified the public of our intent to explore the feasibility of breaking the Office Expenses category into more descriptive cost categories during the next rebasing.

In order to appropriately represent the information collected by the PPIS and to increase the level of precision of our price proxies, we proposed to disaggregate the Office Expense cost category and its associated weight into more detailed components and to proxy those costs with the most technically appropriate price proxies. Moreover, we believe it would be technically inappropriate to proxy the Office Expense cost category, which now includes a much broader range of expenses, by one price proxy, namely the CPI for Housing. For these reasons, we developed our proposals and solicited public comments.

We disagree with the commenters' assertion that the Chemicals and Rubber & Plastics categories are not relevant to today's physician practice (and note that

the commenters did not provide additional information or data to support the claim that the proposed categories are not relevant). The information we relied on came directly from the BEAs' Benchmark I/O files for Offices of Physicians, Dentists, and Other Health Practitioners. The Chemicals cost category includes expenses for items such as soaps and cleaning compounds, as well as photocopier toners and laser printer toners. The Rubber and Plastics category includes expenses for items such as plastic plumbing fixtures, plastic bags, and plastic trash cans. Although we will continue to explore further additional disaggregation of expenses, we believe that the aforementioned costs are associated with, and relevant to, furnishing physicians' services.

As indicated previously, and in response to the comment, we conducted an additional review of the BEA I/O data used to disaggregate the Office Expense cost category, comparing the detailed underlying expenses with the questions on the AMA PPIS survey. This review led us to make small revisions to the underlying Office Expense cost weights, including the addition of another cost weight for the new subcategory, All Other Products. These products were initially assumed to be captured in Other Professional Expenses as measured by the AMA PPIS survey, but were determined to have been reported as Office Expenses. All Other Products would include a variety of miscellaneous products such as miscellaneous wood and apparel products. Table E4 provides the revised MEI weights. Also, as part of this additional analysis on the Office Expense categories, we determined that automobile-related expenses were captured in the PPIS question associated with Other Professional Expenses (and that its associated weight reflected respondents including those costs when answering that question). As a result, we removed automobile-related NAICS-

based industry spending from the BEA I/O data that was being used to distribute expenses across the various Office Expense subcategories. As this spending was included in the Movable Capital subcategory for the proposed rule, the weight associated with that subcategory will be 1.353 rather than the 1.834 we proposed.

We disagree with the commenters' statements that the MEI does not adequately capture high-level or high-cost technology expenses (and briefly note that Movable Capital includes only non-medical movable equipment). The Office Expense cost weight (20.035 percent) was calculated using the 2006 PPIS data, which specifically requested health information technology equipment and other nonmedical office equipment to be included in the Office Expense category as follows:

Provide [your] share (dollar amount) of the specialty or department level's share (dollar amount) of the practice's total (dollar amount) for 2006 office expenses, including office (non-medical) equipment and office (non-medical) supplies, as well as rent, mortgage interest, maintenance, refrigeration, storage, security, janitorial, depreciation on medical buildings used in your practice, utilities, or other office computer systems (including information management systems/ electronic medical record systems) and telephone.

Given that the expenses related to information management systems and electronic medical record systems were included as "office expenses" in the 2006 PPIS, the 20.035 percent weight would include these costs. Unfortunately, given the data limitations, it remains difficult to determine a percentage associated specifically with computer equipment, computer-related depreciation, and computer-related leasing. For this rebasing, the costs we classified as Moveable Capital are comprised of the expenses paid by Office of Physicians industry to the following industries based on NAICS classification:

33329A	Other industrial machinery manufacturing.
33331A	Vending, commercial, industrial, and office machinery manufacturing.
333414	Heating equipment, except warm air furnaces.
333415	Air conditioning, refrigeration, and warm air heating equipment manufacturing.
33399A	Other general purpose machinery manufacturing.
33411A	Computer terminals and other computer peripheral equipment manufacturing.
334210	Telephone apparatus manufacturing.
334220	Broadcast and wireless communications equipment.
334290	Other communications equipment manufacturing.
334300	Audio and video equipment manufacturing.
334418	Printed circuit assembly (electronic assembly) manufacturing.
334613	Magnetic and optical recording media manufacturing.
335120	Lighting fixture manufacturing.
337110	Wood kitchen cabinet and countertop manufacturing.
337215	Showcase, partition, shelving, and locker manufacturing.
532400	Commercial and industrial machinery and equipment rental and leasing.

We believe technology-related expense are captured in the MEI and that the PPI for Machinery and Equipment is an appropriate price proxy to estimate price changes. However, we will actively monitor the data moving forward to ensure these types of expenses are adequately reflected in the MEI.

Finally, we would note that the descriptions of the methodologies used to construct the subcategories under Office Expenses were both detailed and consistent with those provided in the recent proposed rules relating to the rebasing of other CMS market baskets. However, in response to the comment we hope the additional information provided here is helpful.

Comment: One commenter found it most problematic that the CMS proposal related to Office Expenses would reduce the weight of rent within physician practice expenses. Currently, rent comprises 12.2 percent of the practice expense GPCI. Under the proposed rule, rent would be reduced to 8.4 percent. The commenter also noted that their attempt to validate the proposal, using BEA 2002 Benchmark I/O use files for NAICS 621A00 as described in the proposed rule were not successful.

Response: We proposed to disaggregate the Office Expense cost weight in the 2006-based MEI in order to recognize and take advantage of the expansion of the AMA PPIS survey question to include additional expenses not included in the 2000-based survey. Consistent with the methodology used for other CMS market baskets, we relied upon the BEA I/O data to disaggregate the Office Expense cost category, which we described in the proposed rule. This methodology required a series of calculations including classifying costs as office expenses consistent with AMA PPIS survey. As noted elsewhere, and based on public comment, we have refined our methodology, as well as added additional detail in this final rule which we believe will be helpful in validating our estimates. The new methodology has resulted in a cost weight of 8.957 percent for Fixed Capital. Comments related to weights specifically associated with the PE GPICs are found in section II.D. of this final rule with comment period.

Comment: A commenter stated that it appeared that utility costs have been included twice in the MEI calculation. The HUD data used by CMS as a source for the rent data includes utilities. However, utilities have been included a second time as a new component of the "Office Expense" category of "Other Practice Expenses" and it does not appear that the "Fixed Capital" (rent)

component has been scaled down as a result. This error should be corrected, a new proposed rule published, and a new comment period opened.

Response: We disagree with the commenter's assertions that utilities expenses in the MEI are double counted. The Utilities cost weight in the MEI was derived using the BEA I/O data for NAICS 621A (Offices of Physicians, Offices of Dentist, and Offices of Other Practitioners). The BEA I/O data provide information regarding physicians' purchases from other industries. Expenses classified in the Utilities cost weight, such as NAICS 22110 (Electric power generation, transmission, and distribution), were not included in the Fixed Capital cost weight; therefore, we did not include utility costs twice in the MEI calculation. The HUD data referenced by the commenter is used in conjunction with the GPCI rent update and is independent of the development of the cost weight for Utilities in the MEI.

d. Purpose of the MEI

Comment: Several commenters requested that CMS address the problem that the "market basket" of inputs, whose prices are measured in the MEI, is outdated and, despite periodic rebasing, has not been comprehensively revised since it was originally developed in 1973. They indicated that the MEI does not reflect the inputs involved in 21st century medical practice and claim that the costs associated with complying with an array of government-imposed regulatory requirements, including increasing staffing levels, costs related to Medicare prescription drug plans and formulary compliance, compliance with rules governing referrals and interactions with other providers, and others, are not accounted for in the index. They also indicate that the MEI has not been adjusted for modern practice costs such as computers, copiers, and new medical technology.

Response: We disagree with the commenters' statement that the MEI only measures changes in specific types of practice costs that existed in 1973. Since 1973, the MEI has been rebased four times. For each of those updates, the MEI methodology and data sources were thoroughly reviewed and evaluated to ensure that the index accurately reflected the cost distributions encountered by physicians. The revisions have included changes to the structure of the index, the price proxies used, the data sources used to develop the weights, the productivity adjustment, and, as proposed in the CY 2011 PFS proposed

rule, disaggregating categories within the Office Expenses category into more detail.

We also note that the MEI is a price index, not a cost index. Changes in physician costs are a function of changes in prices and changes in quantities. Examples of changes in quantities include purchasing more moveable equipment (such as health information technology), hiring additional office staff, or changing the mix of staff. The MEI was established in accordance with section 1842(b)(3) of the Act, which states the growth of prevailing charge levels is to be limited to growth in an "appropriate economic index". The relevant Senate Finance Committee report² provides slightly more detail on such an index, stating that:

[I]t is necessary to move in the direction of an approach to reasonable charge reimbursement that ties recognition of fee increases to appropriate economic indexes so that the program will not merely recognize whatever increases in charges are established in a locality but would limit recognition of charge increases to rates that economic data indicate would be fair to all concerned and follow rather than lead any inflationary trends.

Thus, in accordance with Congressional intent that the index reflect and follow inflationary trends, and since its inception in 1973, the MEI has been constructed as a fixed-weight price index that measures the inflationary trends of goods and services associated with furnishing physicians' services. The data sources that are used to construct the weights have been updated regularly to include the modern inputs required by physicians in running their respective practices. The MEI then appropriately apportions the various costs into their respective categories and calculates the associated weights. It is this distribution of costs, and not the level of costs, that the MEI appropriately incorporates. Based on this distribution, the MEI measures the weighted input price inflation, adjusted by productivity, faced by physicians. The MEI is then incorporated into the SGR formula to derive the final PFS update. Having an accurate and contemporary distribution of input costs is critical to producing an accurate measure of price inflation and is the major reason we are moving forward to rebase and revise the MEI for CY 2011.

Finally, to date, we have not received any proposals from the public on how the MEI should be revised and still meet

² U.S. Senate, Committee on Finance, *Social Security Amendments of 1972*. Report of the Committee on Finance United States Senate to Accompany H.R. 1. September 26, 1972, p. 190.

its statutory requirements. We will continue to evaluate the validity and relevance of the index to ensure that it meets statutory requirements while adequately reflecting the evolution of the expense distribution associated with furnishing physicians' services.

Comment: A commenter asserted that the time gap between the two surveys, the PPIs and the SMS, may not be directly comparable, but a comparison of the two indicates that medical practice costs increased 79 percent from 2000 to 2006. However, the MEI only increased 18 percent from 2000 to 2006. The commenter notes that every other available measure of physician expense growth shows faster growth than the MEI.

Response: The MEI is strictly a fixed-weight price index expressly designed to measure the change in price of a fixed basket of goods. Changes in physician costs are a function of changes in prices and changes in quantities. As other commenters have noted to CMS, and CMS agrees, cost increases are only reflected in the MEI's weights to the extent the relative cost of an input changes over time. Comparing the MEI (reflecting price changes) to other cost metrics (that reflect both price changes, as well as changes in volume and mix) is inappropriate given the MEI's definition and purpose.

Comment: A commenter noted that the proposed revisions to the MEI do not do anything to improve the adequacy of the MEI. The commenter also noted that in the proposed rule, CMS estimated the 2011 MEI at just 0.3 percent, and the addition of the new components that CMS has proposed based on BEA data does nothing to increase it.

Response: The rebased and revised MEI is intended to more accurately reflect the cost structure of furnishing physicians' services, as well as measure the input price inflation encountered by physicians. Accordingly, we disagree with the commenter and believe that the 2006-based MEI offers numerous technical improvements. These improvements include updating the base year to reflect more current cost distributions, updating price proxies, and adding more detailed cost categories.

Comment: A commenter stated that the MEI is used to annually update medical practice costs in the SGR calculation. Virtually all physician groups signed on to a January 2009 letter arguing that the MEI's price inputs as currently structured do not accurately reflect current medical practice costs. No action has been taken to remedy the situation.

Response: We disagree with the commenter's claim the MEI annually updates the medical practice cost in the SGR. The purpose of the MEI in the SGR is to measure price increases related to the furnishing of physician services. It is not intended to measure cost increases, but rather to reflect the cost structure associated with furnishing physicians' services, and then subsequently measure the weighted price increases associated with that cost structure. We would also like to note that the MEI is currently part of the statutorily prescribed formula for physician payment updates and that revisions to the MEI are adopted through the notice and comment rulemaking process.

e. Technical Panel

Comment: Many commenters expressed their support for the convening of a Medicare Economic Index Technical Advisory Panel (MEI TAP).

Response: We agree that the MEI TAP should be convened and will be moving forward accordingly. This process includes announcing the panel's creation through an official CMS communication such as a **Federal Register** announcement. This announcement will provide details on the expected number of panel members, provide an opportunity for the public to nominate members, and inform the public of the objectives and scope of the panel's activities.

We will be asking this group of independent experts to evaluate only technical aspects of the MEI, including the index's inputs, input weights, price-measurement proxies, and the productivity adjustment.

Any formal recommendations made by the MEI TAP will be carefully considered by CMS. Suggested modifications that we believe would result in technical improvements to the MEI would appear in subsequent PFS proposed rules and be subject to public comment and the overall rulemaking process.

Comment: Several commenters provided many suggestions on technical issues that they believe should be considered by the technical advisory panel. The commenters generally requested that the panel perform a thorough review of all aspects and elements of the MEI.

Response: We appreciate the constructive comments on potential topics for the MEI technical advisory panel, which will be asked to fully evaluate the index. As noted above, the panel will be evaluating all technical aspects of the MEI including the cost

categories, their associated weights and price proxies, and the productivity adjustment.

Comment: A commenter stated that any recommendations that are made by the panel should be published with an opportunity for comment before they are finalized.

Response: Any substantive recommendations from the technical advisory panel that CMS believes will result in technical improvements to the MEI will be subject to the rulemaking process, including giving the opportunity to the public to review and comment.

Comment: Some commenters request that CMS reach out to the medical community to ensure that the panel's work is accurate and complete. Others indicated that pending the recommendations of the technical advisory panel, CMS should: (1) Include physicians and other stakeholders in the MEI revision process, so that the impact of any recommended changes can be studied prior to implementation; and (2) clearly state their rationale for proposed changes.

Response: As mentioned previously, we will be reaching out to the public for suggestions as to the composition of an independent expert panel that will assist us in ensuring that the MEI is constructed accurately and completely, and fulfills its purpose to appropriately reflect the inflationary pressures faced by physicians in furnishing services. CMS will also present to the public any future proposed revisions to the MEI through notice and comment rulemaking, during which we will clearly state the rationale for any proposed changes and consider public comment before finalizing changes to the index.

Comment: One commenter believes that one of the possible options for resolving the SGR problem involves replacing the SGR update formula with the MEI. The commenter noted that input from the MEI technical panel should better position the MEI as a viable alternative to the SGR update formula.

Response: We welcome any technical comments the public has on the composition of the MEI, including the inputs, input weights, price-measurement proxies, and productivity adjustment. Any recommendations from the MEI TAP will be evaluated and considered for possible future rulemaking. However, we note that replacement of, or adjustments to, the SGR is outside the scope of the MEI TAP.

f. Other

Comment: Several commenters agreed with CMS' proposal to remove pharmaceuticals and separately billable medical supplies, since these are not paid under the PFS. Even though this change lessens the weight given to the practice expense component of the index, it made sense to the commenters given the separate line-item payments for these goods. Further, incident-to drugs are now paid based on average sales price (ASP) and, since last-year's changes, are no longer a factor in the SGR formula and the determination of the PFS conversion factor.

Response: We agree with the commenters on the appropriateness of removing drugs and separately billable supplies from the MEI since they are not paid under the PFS and are no longer included as costs in the SGR formula.

Comment: A commenter disagreed with the continued use of the AHE wage data for the total nonfarm business economy as a price proxy for physician income rather than using BLS data specific to all professional and technical workers.

Response: We disagree with the commenter's suggestion. We believe that the use of the average hourly earnings data for the total nonfarm business economy, which captures skill mix shifts in the labor force, is the most appropriate index for use as the price proxy for physician income in the MEI. The AHE for the nonfarm business economy reflects general earnings including the impacts of supply, demand, and economy-wide productivity for the average worker in the economy. Its use is consistent with the Congress's original intent that the index be based on changes in expenses of practice and general earnings levels.³ It is also consistent with our use of the BLS private nonfarm business multifactor productivity measure to adjust the index as economy-wide wage increases reflect economy-wide productivity increases. Therefore, we are finalizing our proposal to continue to use average hourly earnings for the total private nonfarm economy as a price proxy for physician income in the 2006-based MEI.

Comment: A commenter stated that although CMS has expanded the designation of the data underlying some of the GPCI and MEI constructs over the designations of previous years, the descriptions used are sometimes either inconsistent or contradictory. For

example, CMS noted that "for the proposed sixth GPCI update, we used the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data as a replacement for the 2000 Census data." (75 FR 40083). In contrast, CMS used "2006 Occupational Employment Statistics (OES), BLS" for the proposed 2006 MEI expense weights. (75 FR 40089, note (2)). The commenter believes it is impossible to discern from the proposed rule whether inconsistent data sets were used or whether there is simply a misprint.

Response: Because the MEI and GPCIs serve different purposes and are not interdependent, we may use data from different years and, in some instances, different sources. Both the MEI and the GPCI use the OES. However, because the MEI is based to 2006 it is appropriate to use the 2006 BLS Occupational Employment Statistics data to disaggregate the nonphysician wages cost weight into more detailed occupational cost weights.

For the proposed sixth GPCI update, CMS proposed to use OES data for 2006 through 2008. The rationale for choosing this data for the proposed GPCI update was provided in the CY 2011 PFS proposed rule (75 FR 40084).

8. Adjustments to the RVU Shares To Match the Proposed Rebased MEI Weights

As described in the previous section, CMS proposed to rebase the MEI for CY 2011 based on the most current data and establish new weights for physician work, PE, and malpractice under the MEI. As stated in the previous section, the MEI was rebased to a CY 1996 base year beginning with the CY 1999 MEI (63 FR 58845), and to a CY 2000 base year beginning with the CY 2004 MEI (68 FR 63239). For both the CY 1999 and CY 2004 rebasing, we made adjustments to ensure that estimates of aggregate PFS payments for work, PE, and malpractice were in proportion to the weights for these categories in the rebased MEI (63 FR 58829 and 69 FR 1095).

Consistent with past practice when the MEI has been rebased, we proposed to make adjustments to ensure that estimates of aggregate CY 2011 PFS payments for work, PE, and malpractice are in proportion to the weights for these categories in the rebased CY 2011 MEI.

As explained in the CY 2011 PFS proposed rule (75 FR 40095), to match the proportions for work, PE, and malpractice in the rebased CY 2011 MEI would necessitate increasing the proportion of aggregate CY 2011 PFS

payments for PE and malpractice and decreasing the proportion for work. This could be accomplished by applying adjustments directly to the work, PE, and malpractice RVUs. However, as stated in the proposed rule (75 FR 40095), we are cognizant of the public comments made during prior rulemaking on issues related to scaling the work RVUs. Many commenters have indicated a preference for the work RVUs to remain stable over time and for any necessary adjustments that would otherwise be made broadly to the work RVUs to be accomplished in an alternative manner. For example, in past 5-Year Reviews of the work RVUs, many commenters cited stability in the work RVUs, among other reasons, in their requests that any required budget neutrality adjustments not be made directly to the work RVUs. Given these prior comments, for CY 2011, we proposed to make the necessary MEI rebasing adjustments without adjusting the work RVUs. Instead, we proposed to increase the PE RVUs and the malpractice RVUs. Furthermore, as noted in the proposed rule (75 FR 40096), section 1848(c)(2)(B)(ii)(II) of the Act requires that changes to RVUs cannot cause the amount of expenditures for a year to differ by more than \$20 million from what expenditures would have been in the absence of the changes. Therefore, as required by section 1848(c)(2)(B)(ii) of the Act, we proposed to make an adjustment to the CY 2011 conversion factor to ensure that the adjustments to the PE RVUs and the malpractice RVUs would not cause an increase in CY 2011 PFS expenditures.

Comment: A number of commenters expressed support for the use of the most current and accurate data as inputs to "formulas used by the Agency, whether the formula for the SGR, for practice expense inputs, malpractice expense inputs, or in this case to calculating the Medicare Economic Index." These commenters supported the proposal to rebase and revise the MEI using the AMA PPIS data and the corresponding adjustments to the work, PE, and MP RVUs. Some commenters noted particularly that since the AMA PPIS has been deemed appropriate for the purpose of the PE RVU update process begun in CY 2010, using this same data source to inform the MEI costs and weights in CY 2011 is also appropriate because it will ensure that all of the major cost-based components of the fee schedule methodology will now be tied to cost data collected in the same year (2006). Furthermore, a number of commenters supported the

³ U.S. Senate, Committee on Finance, *Social Security Amendments of 1972*, "Report of the Committee on Finance United States Senate to Accompany H.R. 1," September 26, 1972, p. 191.

proposed policy to adjust the RVU shares on the basis that the changes appear to have a modest positive impact on many of the services that were negatively affected by the implementation of the AMA PPIS data in CY 2010. These services were typically ones that are more heavily weighted to PE than work. In contrast, numerous commenters expressed dissatisfaction with the proposed policy on the premise that it "penalizes health care work that is not technology-intensive," that is, services that are typically more heavily weighted to physician work than PE, "when in fact it is the technology-intensive health expenses that are actually driving up costs." A few of these commenters suggested that CMS insulate certain services that are work-intensive from the effects of the MEI rebasing.

Response: We believe that using the most current and accurate data whenever practicable to update the PFS is a key principle for the payment system. We agree with the commenters that using the AMA PPIS data to rebase and revise the MEI in CY 2011 promotes consistency within the PFS. In using the AMA PPIS information to rebase and revise the MEI, the result is that the most current data drive the work RVU share down compared to the PE RVU and malpractice RVU shares. Since the PFS is both resource-based, relative, and budget neutral, if the data show that physicians' resources (that is, costs) have shifted proportionately more to PE and malpractice, the proportion for work must come down. We have tried to accommodate the preferences of previous commenters to preserve the stability of work RVUs by proposing to make the necessary MEI rebasing adjustments without adjusting the work RVUs. However, given the PFS budget neutrality requirement, we cannot implement some commenters' suggestion to insulate certain services that are work-intensive from the effects of the MEI rebasing without violating the inherent relativity of the system. That is, in order to insulate certain services from the effects of the MEI rebasing while adjusting the RVU shares to match the proportions for work, PE, and malpractice in the rebased MEI in a budget neutral manner as discussed previously, the individual work RVUs for those certain services would need to be increased. However, if we were to increase the work RVUs for those certain services, the services would no longer be appropriately valued relative to the other services under the PFS.

Comment: Of the many commenters who supported CMS' proposal to adjust the RVU shares to match the

proportions for work, PE, and malpractice in the rebased CY 2011 MEI, the vast majority also favored adjusting the RVU shares upward for PE and malpractice while making a corresponding adjustment to the conversion factor for budget neutrality without modifying the RVUs for work. These commenters stated that stability in the work RVUs was desirable. However, some commenters also expressed concern that CMS proposed an additional downward adjustment to the conversion factor when, under current law, the effect of the SGR update formula in December of 2010 and CY 2011 would reduce PFS payments significantly. These commenters generally opposed the MEI rebasing and the adjustment to the RVUs to match the MEI weights; however, if CMS were to proceed with the policy, the commenters suggested that, at the very least the adjustments be phased in over 2 or 4 years. A few commenters suggested replacing the SGR update formula entirely with the MEI.

Response: We are sympathetic to the commenters' concern that an additional downward adjustment to the conversion factor on top of the negative effect of the statutory SGR-based update is inopportune. However, as we explained in the proposed rule (75 FR 40095) and discussed previously in this section, rather than applying adjustments directly to the work, PE, and malpractice RVUs in order to match the rebased MEI weights for those categories, we believe that it is appropriate for the work RVUs to remain stable over time. The only way we can make the adjustments without affecting the work RVUs is to also make an adjustment to the conversion factor. We note that we did not receive a public comment suggesting that we make the downward adjustment to the work RVUs instead of the conversion factor in order to meet the requirements of section 1848(c)(2)(B)(ii) of the Act for budget neutrality. In response to the commenters that suggested replacing the SGR update with the MEI, we assume the commenters are making a general suggestion for a change in the current law, which is outside the purview of CMS.

Comment: Many commenters addressed CMS' proposal to convene a technical advisory panel to review all aspects of the MEI. In light of this proposal, the majority of commenters urged CMS to delay implementation of the MEI rebasing and any other MEI changes, including the proposed adjustment to the RVU shares, until the advice of the technical advisory panel is reviewed by CMS and recommendations

for change, if any, are considered. Additionally, while the commenters generally supported convening an MEI technical advisory panel, some commenters, including MedPAC, advised that CMS should go ahead and implement the rebased and revised MEI and the proposed adjustment to the RVU shares in CY 2011. These commenters noted that if the recommendations of the advisory panel indicated that the MEI should be adjusted, CMS could propose future changes accordingly.

Response: We acknowledge the overwhelming support from commenters for the MEI technical advisory panel and refer readers to section II.E.6 of this final rule with comment period for a more detailed discussion of our plans to convene the panel. We note that a more detailed summary of the public comments and our responses is included in that section.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to make MEI rebasing adjustments to the PFS work and PE RVUs and to adjust the conversion factor to maintain budget neutrality. In light of the substantial support in general for us to make adjustments to match the proportions of the work, PE, and malpractice RVU shares to the categories in the revised and rebased CY 2011 MEI and our decision, as described in section II.E.5 of this final rule, to proceed with rebasing the MEI for CY 2011, we are finalizing our proposal to adjust the RVU shares for CY 2011 to align the RVU shares with the rebased MEI weights. Specifically, we will not be making an adjustment directly to the work RVUs. Instead, we are increasing the PE RVUs by an adjustment factor of 1.181 and the malpractice RVUs by an adjustment factor of 1.358. The RVUs in Addendum B to this final rule with comment period reflect the application of these adjustment factors. We note that an application of the 1.358 adjustment factor to the malpractice RVUs for services with malpractice RVUs of 0.01 will, due to rounding, result in malpractice RVUs of 0.01.

Furthermore, section 1848(c)(2)(B)(ii)(II) of the Act requires that changes to RVUs cannot cause the amount of expenditures for a year to differ by more than \$20 million from what expenditures would have been in the absence of the changes. Therefore, as required by section 1848(c)(2)(B)(ii) of the Act, we are making an adjustment of 0.9181 to the CY 2011 conversion factor to ensure that the 1.181 adjustment to the PE RVUs and the 1.358 adjustment to

to the malpractice RVUs do not cause an increase in CY 2011 PFS expenditures.

F. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

1. Medicare Sustainable Growth Rate (SGR)

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with CY 2001) is equal to the product of the following four factors:

- (1) The estimated change in fees for physicians' services;
- (2) The estimated change in the average number of Medicare fee-for-service beneficiaries;
- (3) The estimated projected growth in real GDP per capita; and
- (4) The estimated change in expenditures due to changes in statute or regulations.

In general, section 1848(f)(3) of the Act requires us to publish SGRs for 3 different time periods, no later than November 1 of each year, using the best data available as of September 1 of each year. Under section 1848(f)(3)(C)(i) of the Act, the SGR is estimated and subsequently revised twice (beginning with the FY and CY 2000 SGRs) based on later data. (The Act also provides for adjustments to be made to the SGRs for FY 1998 and FY 1999. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs.) Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the preliminary estimate. In this final rule with comment, we are making our preliminary estimate of the CY 2011 SGR, a revision to the CY 2010 SGR, and our final revision to the CY 2009 SGR.

2. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute

indicates that "the term physicians' services includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee."

We published a definition of physicians' services for use in the SGR in the November 1, 2001 **Federal Register** (66 FR 55316). We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. As discussed in the CY 2010 PFS final rule with comment period (74 FR 61961), the statute provides the Secretary with clear discretion to decide whether physician-administered drugs should be included or excluded from the definition of "physicians' services." Accordingly, we removed physician-administered drugs from the definition of "physicians' services" in section 1848(f)(4)(A) of the Act for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years. Furthermore, in order to effectuate fully the Secretary's policy decision to remove drugs from the definition of "physicians' services," we removed physician-administered drugs from the calculation of allowed and actual expenditures for all prior years.

Additionally, payment was made under the PFS for several new benefit categories in CY 2010 including pulmonary rehabilitation (PR), cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR), and kidney disease education (KDE) services. We note further that section 101 of the MIPPA added a new benefit category for "additional preventive services" effective January 1, 2009. Although we neglected to identify and add these additional benefit categories when describing the scope of physicians' services for purposes of the SGR in course of rulemaking for CY 2010 and CY 2009, respectively, we did include payments for these services in calculating target and actual PFS expenditures beginning in CY 2009 for additional preventive services and beginning in CY 2010 for PR, CR, ICR, and KDE services.

Section 4103 of the ACA added a new benefit category for "personalized prevention plan services" (which include the annual wellness visit). Payment for these services will be made under the PFS, and payments for these services will be included in calculating target and actual PFS expenditures, beginning January 1, 2011.

Thus, for purposes of determining allowed expenditures, actual expenditures for all years, and SGRs beginning with CY 2010 and for all subsequent years, we are specifying that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified) or the equivalent services processed by the Medicare Administrative Contractors (MACs):

- Physicians' services.
- Services and supplies furnished incident to physicians' services, except for the expenditures for drugs and biologicals which are not usually self-administered by the patient.
- Outpatient physical therapy services and outpatient occupational therapy services.
- Services of PAs, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, clinical social workers, NPs, and certified nurse specialists.
- Screening tests for prostate cancer, colorectal cancer, and glaucoma.
- Screening mammography, screening pap smears, and screening pelvic exams.
- Diabetes outpatient self-management training (DSMT) services.
- MNT services.
- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).
- X-ray, radium, and radioactive isotope therapy.
- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.
- Bone mass measurements.
- An initial preventive physical exam.
- Cardiovascular screening blood tests.
- Diabetes screening tests.
- Telehealth services.
- Physician work and resources to establish and document the need for a power mobility device.
- Additional preventive services.
- Pulmonary rehabilitation.
- Cardiac rehabilitation.
- Intensive cardiac rehabilitation.
- Kidney disease education services.
- Personalized prevention plan services.

3. Preliminary Estimate of the SGR for 2011

Our preliminary estimate of the CY 2011 SGR is -13.4 percent. We first estimated the CY 2011 SGR in March

2010, and we made the estimate available to the MedPAC and on our Web site. Table 35 shows the March 2010 estimate and our current estimates

of the factors included in the CY 2011 SGR. The majority of the difference between the March estimate and our current estimate of the CY 2011 SGR is

explained by adjustments to reflect several intervening legislative changes that occurred after our March estimate was prepared.

TABLE 35—CY 2011 SGR CALCULATION

Statutory factors	March estimate	Current estimate
Fees	0.2 percent (1.002)	0.2 percent (1.002)
Enrollment	3.1 percent (1.031)	2.4 percent (1.024)
Real Per Capita GDP	0.8 percent (1.008)	0.7 percent (1.007)
Law and Regulation	-4.4 percent (0.956)	-16.2 percent (0.838)
Total	-0.4 percent (0.996)	-13.4 percent (0.866)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.002 \times 1.024 \times 1.007 \times 0.838 = 0.866$). A more detailed explanation of each figure is provided in section II.F.6.a. of this final rule with comment period.

4. Revised Sustainable Growth Rate for CY 2010

Our current estimate of the CY 2010 SGR is 8.3 percent. Table 36 shows our preliminary estimate of the CY 2010

SGR that was published in the CY 2010 PFS final rule with comment period (74 FR 61965) and our current estimate. The majority of the difference between the preliminary estimate and our current estimate of the CY 2010 SGR is

explained by adjustments to reflect several intervening legislative changes that have occurred since publication of the CY 2010 final rule with comment period.

TABLE 36—CY 2010 SGR CALCULATION

Statutory factors	Estimate from CY 2010 final rule	Current estimate
Fees	0.9 percent (1.009)	0.9 percent (1.009)
Enrollment	1.2 percent (1.012)	1.6 percent (1.016)
Real Per Capita GDP	0.7 percent (1.007)	0.7 percent (1.007)
Law and Regulation	-11.3 percent (0.887)	4.9 percent (1.049)
Total	-8.8 percent (0.912)	8.3 percent (1.083)

Note: A more detailed explanation of each figure is provided in section II.F.6.b. of this final rule with comment period.

5. Final Sustainable Growth Rate for CY 2009

The SGR for CY 2009 is 6.4 percent. Table 37 shows our preliminary

estimate of the CY 2009 SGR from the CY 2009 PFS final rule with comment period (73 FR 69904), our revised estimate from the CY 2010 PFS final

rule with comment period (74 FR 61966), and the final figures determined using the best available data as of September 1, 2010.

TABLE 37—CY 2009 SGR CALCULATION

Statutory factors	Estimate from CY 2009 final rule	Estimate from CY 2010 final rule	Final
Fees	2.1 percent (1.021)	1.8 percent (1.018)	1.8 percent (1.018)
Enrollment	-0.2 percent (0.998)	-0.8 percent (0.992)	-0.6 percent (0.994)
Real Per Capita GDP	1.2 percent (1.012)	0.9 percent (1.009)	1.0 percent (1.010)
Law and Regulation	4.2 percent (1.042)	4.1 percent (1.041)	4.1 percent (1.041)
Total	7.4 percent (1.074)	6.1 percent (1.061)	6.4 percent (1.064)

Note: A more detailed explanation of each figure is provided in section II.F.6.b. of this final rule with comment period.

6. Calculation of CYs 2011, 2010, and 2009 Sustainable Growth Rates

a. Detail on the CY 2011 SGR

All of the figures used to determine the CY 2011 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent PFS updates.

(1) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2011

This factor is calculated as a weighted-average of the CY 2011 changes in fees for the different types of services included in the definition of physicians' services for the SGR. Medical and other health services paid using the PFS are estimated to account for approximately 89.4 percent of total allowed charges included in the SGR in CY 2011 and are updated using the MEI.

The MEI for CY 2011 is 0.4 percent. Diagnostic laboratory tests are estimated to represent approximately 10.6 percent of Medicare allowed charges included in the SGR for CY 2011. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI-U), which is 1.1 percent for CY 2011. However, section 3401 of the AGA reduces the CPI-U update applied to clinical laboratory tests by a productivity adjustment, but does not allow this adjustment to cause the

update to be negative. The applicable productivity adjustment for CY 2011 is 1.2 percent. Adjusting the CPI-U update by the productivity adjustment results in a -0.1 percent (1.1 percent-1.2 percent) update for CY 2011. However, since section 3401 of the ACA does not allow the productivity adjustment to result in a negative CLFS update, the result is that the CLFS update for CY 2011 is 0.0 percent. Additionally,

section 3401 of the ACA reduces the update applied to clinical laboratory tests by 1.75 percent for CYs 2011 through 2015. Therefore, for CY 2011, diagnostic laboratory tests will receive an update of -1.75 percent. Additionally, as discussed in the CY 2010 PFS final rule with comment period (74 FR 61961), we removed physician-administered drugs from the definition of "physicians' services" in

section 1848(f)(4)(A) of the Act for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years. Therefore, drugs represent 0.0 percent of Medicare allowed charges included in the SGR in CY 2011.

Table 38 shows the weighted-average of the MEI and laboratory price changes for CY 2010.

TABLE 38—WEIGHTED-AVERAGE OF THE MEI AND LABORATORY PRICE CHANGES FOR CY 2011

	Weight	Update
Physician	0.894	0.4
Laboratory	0.106	-1.8
Weighted-average	1.000	0.2

We estimate that the weighted-average increase in fees for physicians' services in CY 2011, under the SGR (before applying any legislative adjustments) will be 0.2 percent.

(2) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2010 to CY 2011

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from CY 2010 to CY 2011. Services provided to Medicare Advantage (MA) plan

enrollees are outside the scope of the SGR and are excluded from this estimate. We estimate that the average number of Medicare Part B fee-for-service enrollees will increase by 2.4 percent from CY 2010 to CY 2011. Table 39 illustrates how this figure was determined.

TABLE 39—AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2010 TO CY 2011
[Excluding beneficiaries enrolled in MA plans]

	2010	2011
Overall	43.932 million	45.010 million
Medicare Advantage (MA)	11.683 million	11.998 million
Net	32.249 million	33.012 million
Percent Increase		2.4 percent

An important factor affecting fee-for-service enrollment is beneficiary enrollment in MA plans. Because it is difficult to estimate the size of the MA enrollee population before the start of a CY, at this time we do not know how actual enrollment in MA plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for CY 2011 becomes known.

(3) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in 2011

We estimate that the growth in real GDP per capita from CY 2010 to CY 2011 will be 0.7 percent (based on the 10-year average GDP over the 10 years of 2002 through 2011). Our past experience indicates that there have also been changes in estimates of real per capita GDP growth made before the year begins and the actual change in GDP computed after the year is complete. Thus, it is possible that this figure will change as actual information on

economic performance becomes available to us in CY 2011.

(4) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2011 Compared With CY 2010

The statutory and regulatory provisions that will affect expenditures in CY 2011 relative to CY 2010 are estimated to have an impact on expenditures of -16.2 percent. These include the Department of Defense Appropriations Act (DODAA), the Temporary Extension Act (TEA), and the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act (PACMBPRA) which provided for physician updates.

Furthermore, the ACA contained provisions regarding the policy on equipment utilization for imaging services, the multiple procedure payment reduction policy for imaging services, and the annual wellness visit providing personalized prevention plan services.

b. Detail on the CY 2010 SGR

A more detailed discussion of our revised estimates of the four elements of the CY 2010 SGR follows.

(1) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2010

This factor was calculated as a weighted-average of the CY 2010 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2010.

We estimate that services paid using the PFS account for approximately 91.1 percent of total allowed charges included in the SGR in CY 2010. These services were updated using the CY 2010 MEI of 1.2 percent. We estimate that diagnostic laboratory tests represent approximately 8.9 percent of total allowed charges included in the SGR in CY 2010. Medicare payments for these tests are updated by the CPI-U, which is -1.4 percent for CY 2010. However, section 145 of the MIPPA, as modified

by section 3401 of the ACA, reduced the update applied to clinical laboratory tests by 0.5 percent for CY 2009 and CY 2010. Therefore, for CY 2010, diagnostic laboratory tests received an update of -1.9 percent. Since we removed

physician-administered drugs from the definition of "physicians' services" for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years,

drugs represent 0.0 percent of Medicare allowed charges included in the SGR in CY 2010.

Table 40 shows the weighted-average of the MEI, laboratory, and drug price changes for CY 2010.

TABLE 40—WEIGHTED-AVERAGE OF THE MEI, LABORATORY, AND DRUG PRICE CHANGES FOR CY 2010

	Weight	Update
Physician	0.911	1.2
Laboratory	0.089	-1.9
Drugs	0.000	0.0
Weighted-average	1.000	0.9

After considering the elements described in Table 40, we estimate that the weighted-average increase in fees for physicians' services in CY 2010 under the SGR (before applying any legislative adjustments) will be 0.9 percent. Our estimate of this factor in the CY 2010

PFS final rule with comment period was 0.9 percent (74 FR 61966).

(2) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2009 to CY 2010

We estimate that the average number of Medicare Part B fee-for-service

enrollees (excluding beneficiaries enrolled in Medicare Advantage plans) increased by 1.6 percent in CY 2010. Table 41 illustrates how we determined this figure.

TABLE 41—AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2009 TO CY 2010 [Excluding beneficiaries enrolled in MA plans]

	2009	2010
Overall	42.846 million	43.932 million
Medicare Advantage (MA)	11.098 million	11.683 million
Net	31.748 million	32.249 million
Percent Increase		1.6 percent

Our estimate of the 1.6 percent change in the number of fee-for-service enrollees, net of Medicare Advantage enrollment for CY 2010 compared to CY 2009, is a larger change than our original estimate of 1.2 percent in the CY 2010 PFS final rule with comment period (74 FR 61967). While our current projection based on data from 8 months of CY 2010 differs from our original estimate of 1.2 percent when we had no actual data, it is still possible that our final estimate of this figure will be different once we have complete information on CY 2010 fee-for-service enrollment.

(3) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2010

We estimate that the growth in real GDP per capita will be 0.7 percent for CY 2010 (based on the 10-year average GDP over the 10 years of CY 2001 through CY 2010). Our past experience indicates that there have also been differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is possible that this figure will change further as complete actual information on CY 2010

economic performance becomes available to us in CY 2011.

(4) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2010 Compared With CY 2009

The statutory and regulatory provisions that will affect expenditures in CY 2010 relative to CY 2009 are estimated to have an impact on expenditures of 4.9 percent. These include the DODAA, TEA, and PACMBPRA which provided for physician updates. Also included are the MIPPA provisions regarding the physician update, Physician Quality Reporting Initiative (PQRI) and e-prescribing bonuses, the work GPCIs, and payment provisions related to certain pathology services. Additionally, the ACA contained provisions regarding the work GPCIs, the policy on equipment utilization for imaging services, coverage of preventive services, and a physician enrollment requirement.

c. Detail on the CY 2009 SGR

A more detailed discussion of our final revised estimates of the four elements of the CY 2009 SGR follows.

(1) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2009

This factor was calculated as a weighted-average of the CY 2009 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2009. As we stated in the CY 2010 PFS final rule with comment period (74 FR 61965), although we removed drugs from the calculation of allowed and actual expenditures under sections 1848(d)(3)(C) and 1848(d)(4) of the Act retrospectively to the 1996/1997 base year, we determined that we were only authorized to remove drugs from the calculation of the SGR beginning with CY 2010. Therefore, we did not remove drugs from the SGR calculations for previous years, including CY 2009. Consistent with this determination, the revisions to our estimate of the CY 2009 SGR will be limited to revisions to reflect later data available as of September 1, 2010, that were not available when we published our previous estimates.

Services paid using the PFS accounted for approximately 82.3 percent of total Medicare-allowed charges included in the SGR for CY

2009 and are updated using the MEI. The MEI for CY 2009 was 1.6 percent. Diagnostic laboratory tests represented approximately 8.0 percent of total CY 2009 Medicare allowed charges included in the SGR and were updated by the CPI-U, which was 5.0 percent for CY 2009. However, section 145 of the

MIPPA, as modified by section 3401 of the ACA, reduced the update applied to clinical laboratory tests by 0.5 percent for CYs 2009 and 2010. Therefore, for CY 2009, diagnostic laboratory tests received an update of 4.5 percent. Drugs represented approximately 9.7 percent of total Medicare-allowed charges

included in the SGR for CY 2009. We estimate a weighted-average change in fees for drugs included in the SGR of 1.6 percent for CY 2009. Table 42 shows the weighted-average of the MEI, laboratory, and drug price changes for CY 2009.

TABLE 42—WEIGHTED-AVERAGE OF THE MEI, LABORATORY, AND DRUG PRICE CHANGES FOR CY 2009

	Weight	Update
Physician	0.823	1.6
Laboratory	0.080	4.5
Drugs	0.097	1.6
Weighted-average	1.000	1.8

After considering the elements described in Table 42, we estimate that the weighted-average increase in fees for physicians' services in CY 2009 under the SGR (before applying any legislative adjustments) was 1.8 percent. This

figure is a final one based on complete data for CY 2009.

(2) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2008 to CY 2009

We estimate the change in the number of fee-for-service enrollees (excluding

beneficiaries enrolled in MA plans) from CY 2009 to CY 2010 was -0.6 percent. Our calculation of this factor is based on complete data from CY 2009. Table 43 illustrates the calculation of this factor.

TABLE 43—AVERAGE NUMBER OF MEDICARE PART B FROM CY 2008 TO CY 2009
[Excluding beneficiaries enrolled in MA plans]

	2008*	2009
Overall	41.958 million	42.846 million
Medicare Advantage (MA)	10.008 million	11.098 million
Net	31.950 million	31.748 million
Percent Change		-0.6 percent

(3) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2009

We estimate that the growth in real per capita GDP was 1.0 percent in CY 2009 (based on the 10-year average GDP over the 10 years of CY 2000 through CY 2009). This figure is a final one based on complete data for CY 2009.

(4) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2009 Compared With CY 2008

Our final estimate for the net impact on expenditures from the statutory and regulatory provisions that affect expenditures in CY 2009 relative to CY 2008 is 4.1 percent. These include the DRA provision regarding payments for imaging services, the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173) (MMSEA) provision regarding the PQRI bonuses payable in CY 2009, and the MIPPA provisions regarding the physician update, mental health services, and the change in application of budget neutrality to the CF.

G. The Update Adjustment Factor (UAF)

Section 1848(d) of the Act provides that the PFS update is equal to the product of the MEI and the UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as "allowed expenditures") equal. As discussed previously, allowed expenditures are equal to actual expenditures in a base period updated each year by the SGR. The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act.

1. Calculation Under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with CY 2001 is equal to the sum of the following—

- *Prior Year Adjustment Component.* An amount determined by—
 - + Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the

- amount of the actual expenditures for those services for that year;
 - + Dividing that difference by the amount of the actual expenditures for those services for that year; and
 - + Multiplying that quotient by 0.75.
 - *Cumulative Adjustment Component.* An amount determined by—
 - + Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;
 - + Dividing that difference by actual expenditures for those services for the prior year as increased by the SGR for the year for which the UAF is to be determined; and
 - + Multiplying that quotient by 0.33.
- Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. As discussed previously, section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (CY 2011 in this case), the current

CY (that is, CY 2010) and the preceding CY (that is, CY 2009) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures for

a year generally are estimated initially and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the second revision to CY 2009 allowed

expenditures in this final rule with comment).

Table 44 shows the historical SGRs corresponding to each period through CY 2011.

TABLE 44—ANNUAL AND CUMULATIVE ALLOWED AND ACTUAL EXPENDITURES FOR PHYSICIANS' SERVICES FROM APRIL 1, 1996 THROUGH THE END OF THE CURRENT CALENDAR YEAR

Period	Annual allowed expenditures (\$ in billions)	Annual actual expenditures (\$ in billions)	Cumulative allowed expenditures (\$ in billions)	Cumulative actual expenditures (\$ in billions)	FY/CY SGR (%)
4/1/96-3/31/97	¹ \$46.8	\$46.8	\$46.8	\$46.8	N/A
4/1/97-3/31/98	48.3	47.0	95.2	93.9	FY 1998=3.2
4/1/98-3/31/99	50.4	47.8	145.6	141.7	FY 1999=4.2
1/1/99-3/31/99	12.7	12.4	⁽²⁾	141:7	FY 1999=4.2
4/1/99-12/31/99	40.3	37.0	⁽³⁾	178.8	FY 2000=6.9
1/1/99-12/31/99	53.0	49.5	185.8	178.8	FY 1999/2000
1/1/00-12/31/00	56.8	54.1	242.7	232.9	CY 2000=7.3
1/1/01-12/31/01	59.4	61.2	302.1	294.2	CY 2001=4.5
1/1/02-12/31/02	64.3	64.6	366.4	358.7	CY 2002=8.3
1/1/03-12/31/03	69.0	70.2	435.4	429.0	CY 2003=7.3
1/1/04-12/31/04	73.6	78.3	509.0	507.2	CY 2004=6.6
1/1/05-12/31/05	76.7	83.5	585.7	590.7	CY 2005=4.2
1/1/06-12/31/06	77.8	84.6	663.5	675.3	CY 2006=1.5
1/1/07-12/31/07	80.5	84.5	744.0	759.8	CY 2007=3.5
1/1/08-12/31/08	84.2	86.7	828.2	846.4	CY 2008=4.5
1/1/09-12/31/09	89.6	90.6	917.8	937.0	CY 2009=6.4
1/1/10-12/31/10	97.0	92.9	1,014.7	1,029.9	CY 2010=8.3
1/1/11-12/31/11	84.0	NA	1,098.7	NA	CY 2011= -13.4

⁽¹⁾ Allowed expenditures in the first year (April 1, 1996–March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our Web site at the following address: <http://www.cms.hhs.gov/SustainableGRatesConFact/>. We expect to update the web site with the most current information later this month.

⁽²⁾ Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.

⁽³⁾ Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

Consistent with section 1848(d)(4)(E) of the Act, Table 44 includes our second revision of allowed expenditures for CY 2009, a recalculation of allowed expenditures for CY 2010, and our initial estimate of allowed expenditures for CY 2011. To determine the UAF for CY 2011, the statute requires that we

use allowed and actual expenditures from April 1, 1996 through December 31, 2010 and the CY 2011 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making revisions to the CY 2010 and CY 2011 SGRs and CY 2010 and CY 2011 allowed expenditures. Because we have

incomplete actual expenditure data for CY 2010, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the UAF for future years.

We are using figures from Table 44 in the following statutory formula:

$$UAF_{11} = \frac{Target_{10} - Actual_{10}}{Actual_{10}} \times 0.75 + \frac{Target_{4/96-12/10} - Actual_{4/96-12/10}}{Actual_{10} \times SGR_{11}} \times 0.33$$

UAF₁₁ = Update Adjustment Factor for CY 2011 = -2.9 percent
 Target₁₀ = Allowed Expenditures for CY 2010 = \$97.0 billion

Actual₁₀ = Estimated Actual Expenditures for CY 2010 = \$92.9 billion
 Target_{4/96-12/10} = Allowed Expenditures from 4/1/1996-12/31/2010 = \$1,014.7 billion

Actual_{4/96-12/10} = Estimated Actual Expenditures from 4/1/1996-12/31/2010 = \$1,029.9 billion
 SGR₁₁ = -13.4 percent (0.866)

$$\frac{\$97.0 - \$92.9}{\$92.9} \times 0.75 + \frac{\$1,014.7 - \$1,029.9}{\$92.9 \times 0.866} \times 0.33 = -2.9\%$$

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than -0.07 or

greater than 0.03. Since -0.029 is between -0.07 and 0.03, the UAF for CY 2010 will be -0.029.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1.0 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding

1.0 to -0.029 makes the UAF equal to 0.971.

H. Physician and Anesthesia Fee Schedule Conversion Factors for CY 2011

The CY 2011 PFS CF is \$25.5217. The CY 2011 national average anesthesia CF is \$15.8085.

1. Physician Fee Schedule Update and Conversion Factor

a. CY 2011 PFS Update

The formula for calculating the PFS update is set forth in section 1848(d)(4)(A) of the Act. In general, the PFS update is determined by multiplying the CF for the previous year by the percentage increase in the MEI times the UAF, which is calculated as specified under section 1848(d)(4)(B) of the Act.

b. CY 2011 PFS Conversion Factor

Generally, the PFS CF for a year is calculated in accordance with section 1848(d)(1)(A) of the Act by multiplying the previous year's CF by the PFS update.

We note section 101 of the MIEA-TRHCA provided a 1-year increase in the CY 2008 CF and specified that the CF for CY 2009 must be computed as if the 1-year increase had never applied. Section 101 of the MMSEA provided a 6-month increase in the CY 2009 CF, from January 1, 2009, through June 30, 2009, and specified that the CF for the

remaining portion of CY 2009 and the CFs for CY 2010 and subsequent years must be computed as if the 6-month increase had never applied. Section 131 of the MIPPA extended the increase in the CY 2009 CF that applied during the first half of the year to the entire year, provided for a 1.1 percent increase to the CY 2010 CF, and specified that the CFs for CY 2011 and subsequent years must be computed as if the increases for CYs 2008, 2009, and 2010 had never applied. Section 1011(a) of the DODAA and section 5 of the TEA specified a zero percent update for CY 2010, effective January 1, 2010 through May 31, 2010. Subsequently, section 101(a)(2) of the PACMBPRA provided for a 2.2 percent update to the CF, effective from June 1, 2010 to November 30, 2010. Therefore, under current law, the CF in effect in December 2010 is \$28.3868.

In addition, when calculating the PFS CF for a year, section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ more than \$20 million from what it would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. We estimate that CY 2011 RVU changes would result in a decrease in Medicare physician expenditures of more than \$20 million. Accordingly, we are increasing the CF by 1.0045 to offset this estimated

decrease in Medicare physician expenditures due to the CY 2011 RVU changes. Furthermore, as discussed in section II.E.6 of this final rule with comment period, we are decreasing the CF by 0.9181 in order to offset the increase in Medicare physician payments due to the CY 2011 rescaling of the RVUs so that the proportions of total payments for the work, PE, and malpractice RVUs match the proportions in the final revised and rebased MEI for CY 2011. Accordingly, we calculate the CY 2011 PFS CF to be \$25.5217. This final rule with comment period announces a reduction to payment rates for physicians' services in CY 2011 under the SGR formula: These payment rates are currently scheduled to be reduced under the SGR system on December 1, 2010, and then again on January 1, 2011. The total reduction in MPFS rates between November 2010 and January 2011 under the SGR system will be 24.9 percent. By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of Congress. While Congress has provided temporary relief from these reductions every year since 2003, a long-term solution is critical. We are committed to permanently reforming the Medicare payment formula.

We illustrate the calculation of the CY 2011 PFS CF in Table 45.

TABLE 45—CALCULATION OF THE CY 2011 PFS CF

December 2010 Conversion Factor		\$28.3868
CY 2011 Medicare Economic Index	0.4 percent (1.0040)	
CY 2011 Update Adjustment Factor	-2.9 percent (0.9710)	
CY 2011 RVU Budget Neutrality Adjustment	0.5 percent (1.0045)	
CY 2011 Rescaling to Match MEI Weights Budget Neutrality Adjustment	-8.2 percent (0.9181)	
CY 2011 Conversion Factor		\$25.5217

We note payment for services under the PFS will be calculated as follows:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU malpractice} \times \text{GPCI malpractice})] \times \text{CF}$$

2. Anesthesia Conversion Factor

We calculate the anesthesia CF as indicated in Table 45. Anesthesia services do not have RVUs like other PFS services. Therefore, we account for any necessary RVU adjustments through an adjustment to the anesthesia CF to simulate changes to RVUs. More specifically, if there is an adjustment to

the work, PE, or malpractice RVUs, these adjustments are applied to the respective shares of the anesthesia CF as these shares are proxies for the work, PE, and malpractice RVUs for anesthesia services. Furthermore, as discussed in section II.E.6 of this final rule with comment period, we are rescaling the RVUs so that the proportions of total payments for the work, PE, and malpractice RVUs match the proportions in the final revised and rebased MEI for CY 2011. Accordingly, we are adjusting the anesthesia CF to reflect the RVUs adjustments being

made to all other physician fee schedule services to match the revised and rebased MEI weights.

As explained previously, in order to calculate the CY 2011 PFS CF, the statute requires us to calculate the CFs for CYs 2009, 2010, and 2011 as if the various legislative changes to the CFs for those years had not occurred. Accordingly, under current law, the anesthesia CF in effect in December 2010 is \$16.6058. We illustrate the calculation of the CY 2011 anesthesia CF in Table 46.

TABLE 46—CALCULATION OF THE CY 2011 ANESTHESIA CONVERSION FACTOR

December 2010 Anesthesia Conversion Factor		\$16.6058
CY 2011 Medicare Economic Index	0.4 percent (1.0040)	

TABLE 46—CALCULATION OF THE CY 2011 ANESTHESIA CONVERSION FACTOR—Continued

CY 2011 Update Adjustment Factor	-2.9 percent (0.9710)	
CY 2011 Anesthesia Adjustment	-2.3 percent (0.97651)	
CY 2011 Anesthesia Conversion Factor		\$15.8085

III. Code-Specific Issues for the PFS

A. Therapy Services

1. Outpatient Therapy Caps for CY 2011

Section 1833(g) of the Act applies an annual, per beneficiary combined cap on expenses incurred for outpatient physical therapy and speech-language pathology services under Medicare Part B. A similar separate cap for outpatient occupational therapy services under Medicare Part B also applies. The caps apply to expenses incurred for therapy services furnished in outpatient settings, other than in an outpatient hospital setting which is described under section 1833(a)(8)(B) of the Act. The caps were in effect during 1999, from September 1, 2003 through December 7, 2003, and continuously beginning January 1, 2006. The caps are a permanent provision, that is, there is no end date specified in the statute for therapy caps. Beginning January 1, 2006, the DRA provided for exceptions to the therapy caps until December 31, 2006. The exceptions process for therapy caps has been extended through December 31, 2009 pursuant to three subsequent amendments (in MEIA-TRHCA, MMSEA, and MIPPA).

Section 1833(g)(5) of the Act (as amended by section 3103 of the ACA) extended the exceptions process for therapy caps through December 31, 2010. The annual change in the therapy cap is computed by multiplying the cap amount for CY 2010, which is \$1,860, by the MEI for CY 2011, and rounding to the nearest \$10. This amount is added to the CY 2010 cap to obtain the CY 2011 cap. Since the MEI for CY 2011 is 0.4 percent, the therapy cap amount for CY 2011 is \$1870.

The agency's authority to provide for exceptions to therapy caps (independent of the outpatient hospital exception) will expire on December 31, 2010, unless the Congress acts to extend it. If the current exceptions process expires, the caps will be applicable in accordance with the statute, except for services furnished and billed by outpatient hospital departments.

Comment: The commenters unanimously requested repeal of the therapy caps, while characterizing caps as arbitrary and medically unfounded and the combination of cap amounts for PT and SLP services as groundless. A number of commenters argued that

therapy caps restrict provision of medically necessary services to beneficiaries. Several commenters reported that patients are discharged for care prior to recovery due to payment restrictions and this leads to increased medical costs for Medicare.

Response: Therapy caps are mandated by statute. We have no authority to repeal the caps, or to restructure the grouping of therapy disciplines to which the caps apply. However, we understand the concerns of the commenters, and we are actively exploring alternatives to therapy caps to inform the discussions about approaches to identify and pay for those therapy services that are necessary for patients to attain the best outcomes with the most efficient use of resources.

2. Alternatives to Therapy Caps

a. Background

In section 4541 of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA), the Congress enacted the financial limitations on outpatient therapy services (the "therapy caps" discussed above for physical therapy, occupational therapy, and speech-language pathology). At the same time, the Congress requested that the Secretary submit a Report to Congress that included recommendations on the establishment of a revised coverage policy for outpatient physical therapy services and outpatient occupational therapy services under the statute. The Balanced Budget Refinement Act of 1999 (Pub. L. 106-113) (BBRA) placed the first of a series of moratoria on implementation of the limits. In addition, it required focused medical review of claims and revised the report requirements in section 4541(d)(2) of the BBA to request a report that included recommendations on the following: (A) The establishment of a mechanism for assuring appropriate utilization of outpatient physical therapy services, outpatient occupational therapy services, and speech-language pathology services; and (B) the establishment of an alternative payment policy for such services based on classification of individuals by diagnostic category, functional status, prior use of services (in both inpatient and outpatient settings), and such other criteria as the Secretary determines appropriate, in place of the limits. In

1999, therapy services were not defined, but services documented as therapy were billed and reported when furnished by a variety of individuals in many different settings. These services were not identified in a way that would allow analysis of utilization or development of alternative payment policies. Since that time, we have clarified the definition of therapy services and applied the qualifications of therapists consistently to outpatient settings, which have facilitated analysis of therapy services.

We have studied therapy services with the assistance of a number of contractors over the past 11 years. Reports of these projects are available on the CMS Web site at <http://www.cms.gov/TherapyServices/>. On November 9, 2004, we delivered the Report to Congress, Number 137953, "Medicare Financial Limitations on Outpatient Therapy Services" that referenced two utilization analyses. We periodically updated the utilization analyses and posted other contracted reports on the CMS web site in order to further respond to the requirements of the BBRA. Subsequent reports highlighted the expected effects of limiting services in various ways and presented plans to collect data about patient condition using available tools. The general belief was that if patient condition could be reliably described, that approach would ensure appropriate payment for appropriately utilized services.

Over the past decade, significant progress has been made in identifying the outpatient therapy services that are billed to Medicare, the demographics of the beneficiaries who utilize those services, the types of services, the HCPCS codes used to bill the services, the allowed and paid amounts of the services, and the settings, geographic locations, and provider or supplier types where services are furnished.

Some of the information that is necessary to ensure appropriate utilization and develop objective and equitable payment alternatives to therapy caps based on patient condition has proven difficult to develop. The influence of prior use of inpatient services on outpatient use of therapy services was not accessible due to systems issues and differences in the policies, billing, and reporting practices for inpatient and outpatient therapy

services. The weakness of the ICD-9-CM diagnostic codes in describing the condition of the rehabilitation patient obscured analyses of claims to assess the need for therapy services. The primary diagnosis on the claim is a poor predictor for the type and duration of therapy services required, which complicates assignment of patient cohorts for analysis. Although changes to the guidance in the Medicare Benefit Policy Manual (Pub. 100-02) on documentation of therapy services in 2005 improved the consistency of records and facilitated chart review, it became increasingly obvious that neither claims analysis nor chart review could serve as a reliable and valid method to determine a patient's need for services or to form the basis for equitable payment. We concluded that in order to develop alternative payment approaches to the therapy caps, we needed a method to identify patients with similar risk-adjusted conditions (cohorts) and then we would identify the therapy services that are necessary for the patients to attain the best outcomes with the most efficient use of resources.

While we studied therapy utilization, a number of proprietary tools were developed by researchers in the professional community to assess the outcomes of therapy. Some tool sponsors collected sufficient information to predict with good reliability the amount or length of treatment that would result in the best expected outcomes. We encouraged the use of these proprietary tools in manual instructions, but proprietary tools do not serve our purposes because modification of proprietary tools may only be done by the tool sponsor. There now are some versions of the tools in the public domain and they are being utilized widely to identify patient conditions and, by some insurers, to pay for efficient and effective treatment. Examples of such tools include the National Outcomes Measurement System (NOMS) by the American Speech-Language Hearing Association and Patient Inquiry by Focus On Therapeutic Outcomes, Inc. (FOTO).

In 2006, Focus on Therapeutic Outcomes, Inc. delivered to CMS a report titled, "Pay for Performance for Physical Therapy and Occupational Therapy," which is also available on the CMS Web site at <http://www.cms.gov/TherapyServices>. The purpose of this project was to simulate a pay-for-performance implementation, designed to align financial incentives with the achievement of better clinical outcomes from services that were delivered efficiently. The project, funded by HHS/

CMS Grant 18-P-93066/9-01, demonstrated the predictive validity of the risk-adjusted pay-for-performance model and the feasibility of reducing payments without affecting services to beneficiaries who need them.

b. Current Activities

The Tax Relief and Health Care Act of 2006 (TRIICA) extended the therapy cap exceptions process through December 31, 2007 and provided funds used for two CMS projects related to developing alternative payment approaches for therapy services that are based on beneficiary needs. A 5-year project titled, "Development of Outpatient Therapy Alternatives" (DOTPA), awarded to RTI International, was initiated in order to develop a comprehensive and uniform therapy-related data collection instrument, assess its feasibility, and determine the subset of the measures that we could routinely and reliably collect in support of payment alternatives. While DOTPA will identify measurement items relevant to payment, the project will not deliver a standardized measurement tool. We may either develop a tool or allow other tools to be used for payment purposes when they include those items that identify the following: (1) Beneficiary need; and (2) outcomes (that is effectiveness of therapy services). In addition to therapy caps, the DOTPA project considers our interest in value-based purchasing by identifying components of value, including beneficiary need and the effectiveness of the therapy services. The DOTPA project reports are available on the contractor's Web site at <http://optherapy.rti.org/>. The data collection design and instrument development have been completed, and a Paperwork Reduction Act (PRA) package was submitted for approval of the data collection forms by the Office of Management and Budget (OMB). The **Federal Register** notice for the second round of public comment on this package was published on April 23, 2010 (75 FR 21296). The PRA package has been approved; the contractor is recruiting potential participants in the data collection, developing training materials for participants, and updating the project web site. We did not seek public comments on the DOTPA project in the proposed rule.

The TRCHA also funded the 2-year project contracted to Computer Sciences Corporation (CSC) entitled "Short Term Alternatives for Therapy Services" (STATS). STATS has provided recommendations regarding alternative payment approaches to therapy caps that could be considered before completion of the DOTPA project. The

STATS project draws upon the analytical and clinical expertise of contractors and stakeholders to consider policies, measurement tools, and claims data that are currently available to provide further information about patient condition and the outcomes of therapy services. The final report, received September 13, 2010, included recommended actions we could take within 2 or 3 calendar years to replace the current cap limits on therapy services with a policy that pays appropriately for necessary therapy services.

c. Potential Short-Term Approaches to Therapy Caps

On June 30, 2009, we received a draft of the CSC report titled "STATS Outpatient Therapy Practice Guidelines," a summary of expert workgroup discussions, and several short-term payment alternatives for consideration. CSC discussed options based on the assumption that short-term policy changes should facilitate the development of adequate function and/or outcomes reporting tools. In the longterm, CSC recommended that payment be based on function or quality measurements that adequately perform risk adjustment for episode-based payment purposes.

Based on the draft report, additional stakeholder input, and subsequent communications with the contractor, in the CY 2011 PFS proposed rule (75 FR 40097 through 40099) we discussed several potential alternatives to the therapy caps that could lead to more appropriate payment for medically necessary and effective therapy services that are furnished efficiently. We solicited public comments on the proposed rule regarding all aspects of these alternatives, including the potential associated benefits or problems, clinical concerns, practitioner administrative burden, consistency with other Medicare and private payer payment policies, and claims processing considerations. We did not propose either short-term or long-term payment alternatives to the therapy caps. However, we referred readers to section II.C.4.(c) of the proposed rule for our CY 2011 proposal to expand the MPPR policy to "always therapy" services furnished in a single session in order to pay more appropriately for therapy services, taking into consideration the expected efficiencies when services are furnished together. While we did not propose the adoption of an MPPR policy for therapy services specifically as an alternative to the therapy caps, we acknowledged that by paying more appropriately for combinations of

therapy services that are commonly furnished in a single session, practitioners would be able to furnish more medically necessary therapy services to a given beneficiary before surpassing the caps. We noted that the proposed MPPR policy would have the potential to reduce the number of beneficiaries impacted by the therapy caps in a given year.

Comment: Many commenters stated that use of the financial cap on therapy services as a rationale for the proposed MPPR was unacceptable and not a sound basis for such a significant policy proposal. Quite a few commenters contrasted the cap alternatives research with the MPPR which, in the commenters' opinion, did not reflect a similar level of analysis. Instead of implementing the proposed MPPR, a large majority of the commenters urged CMS to place a high priority in resources and funding for research to identify alternatives to the cap that would ensure patients receive medically necessary therapy services.

While the commenters agreed that more therapy could be furnished to a beneficiary before surpassing the caps if the payments were reduced, the commenters believe that other, more serious access problems would result from arbitrary payment reductions under an MPPR. Many commenters were concerned that the proposed MPPR policy might restrict access to therapy services for patients with more severe problems, especially neurological problems and complex medical conditions. Less payment, explained the commenters, would force therapists to spend less time with patients, incentivize cutting corners, and encourage greater fraud and abuse. The commenters argued that the shortage of therapists, particularly physical therapists, would be exacerbated and access to therapy services would be severely jeopardized.

Response: We appreciate the effort and resources contributed by stakeholders to the discussion and development of alternatives to therapy caps. We look forward to the continued cooperation of stakeholders as we continue our work in this area over the coming years. We refer readers to section II.C.4.(c) of this final rule with comment period for a detailed discussion of the public comments and our responses regarding the proposed therapy MPPR.

The three specific short-term options that we discussed in the CY 2011 PFS proposed rule would not have required statutory changes when CSC originally delivered them. In CY 2011, some would require extension of the therapy

cap exceptions process. Some would require moderate reporting changes that would yield more detailed information about patient function and progress to inform future payment approaches and facilitate the medical review of services above the therapy caps at the present time. Others require new coding and bundled per-session payment that would be a first step toward episode-based payment. They are not necessarily independent of each other.

Under each of these alternatives, administrative simplification with respect to current policies, such as HCPCS code edits and "ICD-9-CM to HCPCS code" crosswalk edits that serve to limit utilization without regard to the patient's clinical presentation, could be pursued in the context of these options.

The first option would modify the current therapy caps exceptions process to capture additional clinical information regarding therapy patient severity and complexity in order to facilitate medical review. This approach would complement the DOTPA project, which is identifying items to measure patient condition and outcomes. We believe the first option may have the greatest potential for rapid implementation that could yield useful information in the short-term. In the CY 2011 PFS proposed rule (75 FR 40097), we indicated that we were especially interested in detailed public comments on this option that could inform a potential proposal to adopt such an alternative through future rulemaking. The second option would involve introducing additional claims edits regarding medical necessity, in order to reduce overutilization. The third option would be to adopt a per-session bundled payment that would vary based on patient characteristics and the complexity of evaluation and treatment services furnished in the session. Each option would require significant provider and contractor education, and all would necessitate major claims processing systems changes. Moreover, some of the options may affect beneficiaries by changing the type or amount of services covered by Medicare or the beneficiary's cost sharing obligations.

Comment: Many commenters agreed that a long term solution to the therapy caps is desirable. Generally, the commenters supported an evidence-based payment system grounded in accurate, comprehensive analysis of the clinical characteristics of the wide range of therapy patients in diverse settings and the concept of bundled payment for episodes of care based on clinical characteristics of patients. Many commenters urged CMS to place a high

priority in resources and funding for research to identify alternatives to the cap that would ensure patients receive medically necessary therapy services. The commenters asserted that such research would be a key factor in identifying clinically appropriate ways to control spending. Those who commented on this issue commended CMS for proposing alternatives that reflect in-depth analytical work, expressing appreciation to CMS and its contractor for the opportunity to participate on task forces and pledging continued assistance in trials of alternatives. The commenters also commend CMS for recommending better clinical information be included in payment decisions.

MedPAC and some other commenters supported all three alternatives as reasonable steps consistent with the end goals of value for purchases based on the care needs of beneficiaries. Many commenters supported the first option or the third option, and very few supported the second option. Regardless of the alternative chosen, commenters consistently recommended further study and analysis, with a national demonstration or pilot project to test any alternative prior to implementation.

Response: We continue to believe that the advice and assistance of stakeholders, including clinicians and practice administrators, are essential to the development of policies that are appropriate, realistic, and effective in allowing necessary therapy care while limiting overutilization. We appreciate the time and effort provided by the dedicated professionals involved in the STATS workgroups and DOTPA technical advisory panels.

Comment: A commenter suggested that diagnoses cannot be used to predict medical necessity. The same commenter argued that if the patient were assessed using self-reported functional status measures that are risk-adjusted using many variables, it would be possible to predict outcomes, identify ineffective treatment, and reduce gaming without relying on clinician-generated estimates known to be biased and fraught with poor reliability and validity.

Several other commenters stated that clinicians' judgment is essential to accurate outcomes assessment, and these commenters provided examples of clinical judgments believed essential to appropriate care planning.

Response: None of the alternatives discussed in the proposed rule would require a measurement tool scored by either a clinician or the patient. We note the disagreement among the commenters on this point.

Comment: While generally supportive of the development of alternatives to therapy caps, many commenters expressed concern that there were insufficient data and details of the options discussed in the proposed rule to develop a rational payment system based on the options at this time. Several commenters suggested that sophisticated multivariate statistical methods with a long list of clinically appropriate risk-adjustment variables would be required. Another commenter recommended using risk-adjustment models built on large aggregate datasets to develop efficiency and effectiveness projections on which payments could be based.

Response: We agree that the alternatives presented were not fully developed and that statistically sound methods of evaluation of the fully developed alternatives would be appropriate. We made no specific proposal to adopt an alternative beginning in CY 2011, but instead presented three potential options in order to gather additional public input on the overall concepts and the details to inform our future developmental work in this area. We will continue to review and consider all the information provided to us and acknowledge that, in the context of any future proposal, we would need to provide further detail as part of notice and comment rulemaking in order for the public to provide meaningful comment prior to the adoption of changes to therapy payment.

Comment: Many commenters complained that therapy payments have decreased relative to inflation over the past 10 years. The commenters described the practitioner's struggle to provide appropriate care and noted their fear of alternatives that could result in fewer resources with which to treat beneficiaries. Some commenters stated that Medicaid payments also decreased, leaving them with less flexibility to provide covered services to Medicare beneficiaries. Several commenters warned that those who bill therapy services will find "creative" ways to manage patients in the future, leading to reduced quality of care, or that therapists will be laid off, leading to access problems for beneficiaries.

Some commenters recommended that CMS take time to consider the potential alternatives to therapy caps from all angles related to cost, including the costs of different health outcomes. Several commenters reported that outpatient physical therapy saves Medicare spending by preventing more expensive procedures and surgeries.

Response: Achieving appropriate payment for quality services that quickly lead to good health outcomes is among the major goals of our payment policy. It is also our goal to limit overutilization of services, and to discourage the provision of services that are not medically reasonable and necessary or represent an abuse of Medicare funds. To that end, we will continue to develop policies aimed at paying for those therapy services that meet patients' needs. The clear challenge is to identify those needs and the services required.

Comment: One commenter was concerned that underlying therapy utilization data are flawed due to inconsistent coverage and payment policies that also negatively affect good clinical practice by restricting the therapist's clinical judgment. The commenter provided detailed examples to illustrate inconsistencies in forms and billing rules between Part A and B providers and suppliers which in the aggregate, the commenter argued, impede CMS' ability to analyze claims data for comparison purposes. Differences due to National Correct Coding Initiative (NCCI) and Medically Unlikely Edit (MUE) policies and most particularly local coverage determinations (LCDs) were also identified by the commenter as creating significant variations among contractors. The commenter was particularly concerned about requirements for specific ICD-9-CM and CPT code combinations, which limit therapy diagnoses or require specific diagnoses as primary.

Response: We develop national and local policies and guidelines as needed to interpret statutory requirements and to limit, whenever possible, abusive behaviors while encouraging high quality care and good outcomes for beneficiaries. Since no one method is entirely effective in curbing incorrect or fraudulent billing practices, a number of approaches have been adopted. We attempt to coordinate these policies and we recognize that it is sometimes difficult for providers and suppliers to stay informed about changes, especially when they treat beneficiaries whose services are impacted by different payment policies. We will continue to work cooperatively with interested stakeholders, as we did with the STATS project, to identify and resolve concerns or conflicts regarding our policies. We intend that any claims data collected in a pilot study would be unencumbered by conflicts that have been identified.

Comment: Many commenters stated that the options are identified as alternatives to the cap exceptions

process, which expires December 31, 2010.

Response: The short-term alternatives discussed are potential alternatives to the therapy caps, and while it may be possible to implement some as modifications to the exceptions process, we recognize that Congress would have to act to extend the authority for a therapy cap exceptions process or to otherwise provide for certain alternatives to therapy caps.

Option (1): Revise therapy caps exceptions process by requiring the reporting of new patient function-related Level II HCPCS codes and severity modifiers.

This option would require that clinicians submit beneficiary function-related nonpayable HCPCS codes to replace the -KX modifier (Specific required documentation on file). Codes would not be submitted on every claim, but at episode onset and at periodic intervals (for example, progress report intervals of 12 sessions or 30 days—whichever is less). Codes would be submitted for all patients in order for the claims to be paid and not only those claims approaching or surpassing the therapy caps. The current -KX modifier is not useful to identify claims exceeding therapy caps, because it is used for services both before and after the caps are exceeded, and it must be used on the entire claim for facilities. New codes also would not identify claims above the cap, but they would perform the same function as the current -KX modifier to signal that documentation in the medical record supported medical necessity that should lead to an exception to the therapy caps. The codes would also provide more information for medical review.

Six Level II HCPCS G-codes representing functions addressed in the plan of care and 5 (or 7) modifiers representing severity/complexity would be utilized to report information on the claim. Examples of six new function-related G-codes:

- GXXXU—Impairments to body functions and/or structures—current.
- GXXXV—Impairments to body functions and/or structures—goal.
- GXXXW—Activity limitations and/or participation restrictions—current.
- GXXXX—Activity limitations and/or participation restrictions—goal.
- GXXXY—Environmental barriers—current.
- GXXXZ—Environmental barriers—goal.

Two potential severity/complexity scales have been suggested that would require the adoption of 5 or 7 new severity modifiers, respectively. Under one scenario, modifiers based on the

International Classification of Function would identify severity as follows:

- None (0 to 4 percent).
- MILD (5 to 24 percent).
- MODERATE (25 to 49 percent).
- SEVERE (50 to 95 percent).
- COMPLETE (96 to 100 percent).

Alternatively, a proportional severity/complexity scale would use 7 modifiers to describe impairments, limitations, or barriers—

- 0 percent;
- 1 to 19 percent;
- 20 to 39 percent;
- 40 to 59 percent;
- 50 to 79 percent;
- 80 to 99 percent;
- 100 percent.

Implementation of this general approach might require 6 months to 2 years to modify claims processing for the current therapy caps and exceptions processing of claims, and to develop, pilot test, and refine coding before applying the approach nationally. While therapists initially would need to learn the new codes and update their billing systems, ultimately their reporting burden might be reduced because the -KX modifier would not be required on each claim line for patients with expenditures approaching or exceeding the therapy caps. This option could potentially result in a small reduction in outpatient therapy expenditures due to increased Medicare contractor scrutiny of episodes where functional severity scores did not change over time, or to other atypical reporting patterns associated with the new codes.

In the longterm, these codes and modifiers could be mapped to reliable and validated measurement tools (either currently available tools in the public domain or newly developed tools from items on the DOTPA instrument or the Continuity Assessment Record and Evaluation (CARE) tool). If statistically robust patient condition information were collected from claims data, it may be possible to develop Medicare payment approaches for outpatient therapy services that could pay appropriately and similarly for efficient and effective services furnished to beneficiaries with similar conditions who have good potential to benefit from the services furnished. At a minimum, the new codes could allow contractors to more easily identify and limit the claims for beneficiaries who show no improvement over reasonable periods of time.

Comment: Most commenters supported the concept of Option (1) although often not without concerns about the details of implementation. The commenters generally endorsed the concept of describing patients' goals in

terms of activity participation and environmental barriers, in addition to impairments based on the World Health Organization's (WHO's) International Classification of Functioning, Disability and Health (ICF). Some supported Option (1) as the best of the three options as it could begin providing a national overview of functional status and severity of patients which would be essential if CMS were to pursue future episode-based payment. The majority of commenters agreed with the concept of developing an infrastructure to work toward payment reform based on episodes of care, patient characteristics, functional status, rehabilitation complexity, severity, and outcomes. Many commenters supported Option (1) as the first step in a plan to move toward Option (3) that would introduce per-session codes to bundle payment, as described in detail below, and ultimately episode-based payments, although a few suggested the severity codes could be used, after adequate testing and definition, to inform appropriate payment. Some commenters recommended developing Option (1) and suggested that further development should include: definition of terms (including the ICD-10 diagnosis codes in 2013), input from therapists, field testing, and data analysis to ensure that payment appropriately reflects patient complexity and risk before application of the codes to individual therapy disciplines.

The commenters in favor of this option supported the use of ICF language in descriptions, but consistently preferred a 7-point rating scale for severity over the 5-point scale based on the ICF. Several commenters also noted that sufficient training would be required for contractors and providers of service under this option.

Response: We appreciate the perspectives of the commenters who see Option (1) as a first step in the process of exploring alternatives to the therapy caps that could move toward payment based on the needs of beneficiaries.

Comment: Many commenters opposed this option as burdensome, easy to "game," and lacking the potential for saving money. The commenters in opposition to the option claimed it could require a great deal of research to establish, validate and value codes, and then pilot test, refine, establish inter-therapist reliability, and modify the claims processing process, which could take 2 years. Instead, the same commenters recommended the use of valid and reliable measurement tools currently in the public domain and in use by clinicians. One commenter requested that CMS not use clinician-graded single

item assessment scales of patient severity or complexity, unless such methodology possessed published reliability and validity on the selection and grading processes because there are more psychometrically sound published scales available that include a risk-adjustment process to predict treatment success and number of visits and are less vulnerable to gaming. If scales were used, several commenters recommended that they must be sensitive and cardinal so each change would represent an equal increment.

Response: We recognize that Option (1) is not yet fully developed and would require further study. As we consider this option further, we will also assess the feasibility of using currently available validated measurement scales in the public domain. The issues of "gaming" and savings remain of interest in relationship to this and the other options.

Comment: Several commenters voiced serious concerns about the concept of using function-related codes and severity modifiers on the claim to monitor patient improvement. The commenters were alarmed that contractors would deny services when improvement was insufficiently demonstrated, or when the beneficiary's goal was to prevent deterioration of function. Several commenters were concerned that a contractor's attention to function and severity modifiers might cause the contractor to unduly limit the therapy sessions a patient needed to maintain or increase functionality.

A few commenters interpreted the statute to require only that a service be medically necessary to treat the underlying illness or condition, and not to require that the service lead to improvement. According to the commenters, a service required to maintain current function is medically necessary but the focus on identifying improvement would prevent those patients with progressive diseases from receiving therapy to prevent further decline in function when there is little probability of meeting an undefined improvement standard. A few commenters provided citations of court cases that rejected Medicare policies and practices that denied therapy services based on arbitrary rules of thumb without consideration of the patient's individual condition. Therefore, the same commenters recommended that CMS omit reference to improvement standards in any proposal related to Option (1).

Response: The policies for Medicare Part B outpatient therapy services require payment for therapy services that require the skills of a therapist. In

contrast, "Unskilled services are palliative procedures that are repetitive or reinforce previously learned skills, or maintain function after a maintenance program has been developed * * *. services related to activities for the general good and welfare of patients, for example, general exercises to promote overall fitness and flexibility and activities to provide diversion or general motivation, do not constitute therapy services for Medicare purposes" (Medicare Benefit Policy Manual, Pub. 100-02, chapter 15, section 220.2.A.). We note that when the goal of therapy is to halt degeneration of function due to disease, therapy is not palliative or related to general welfare, but may be an active treatment with measurable outcomes. For that reason, we do not anticipate that function-related codes and severity modifiers would be used exclusively as a proxy for the determination of medical necessity.

The Medicare policy goes on to state, " * * * services must be necessary for the establishment of a safe and effective maintenance program required in connection with a specific disease state. In the case of a progressive degenerative disease, service may be intermittently necessary to determine the need for assistive equipment and/or establish a program to maximize function * * *." (Pub. L. 100-02, chapter 15, section 220.2.A.). Further details concerning maintenance therapy and examples of covered services to patients with degenerative neurological diseases are found in Pub. 100-02, chapter 15, section 220.2.D.

Option (2): Enhance existing therapy caps exceptions process by applying medical necessity edits when per-beneficiary expenditures reach a predetermined value.

The existing automatic process for exceptions, and the revised exceptions process described in Option (1) above, pay practitioners indefinitely for services if they attest on the claim by appending a specific modifier to therapy HCPCS codes that the services being furnished are medically necessary and that supporting documentation is included in the medical record. Unless the local contractor uses claims edits or does post-payment review, these processes do not identify or limit unusually high annual per-beneficiary utilization. High utilization is not limited to beneficiaries with multiple or complex conditions. We would use existing therapy utilization data to develop annual per-beneficiary medical necessity payment edits, such as limits to the number of services per-session, per-episode, or per-diagnostic grouping, for exceptions to the therapy caps which

would be set at benchmark payment levels that only a small percentage of beneficiaries would surpass in a single year. Once these levels were reached, additional claims would be denied and practitioners would need to appeal those denials if they wished to challenge Medicare's nonpayment.

This alternative would require 1 to 2 years to implement as an expansion of existing policy, and its effects would be anticipated by analysis of the current utilization of therapy services. Additional practitioner burden would be incurred in the small number of cases exceeding the per beneficiary expenditure edits if the practitioner chose to appeal the medical necessity denial.

Comment: Few commenters preferred Option (2) over the other two. In addition, the commenters stated that they were familiar with this approach because other insurers use a similar system of edits, so the adoption of Option (2) for Medicare patients would not represent an additional administrative burden. The commenters who favored this option reported that it would be the easiest for CMS to implement and would be the only option likely to save money in the very short-term. Some commenters who favored this option would still prefer the use of existing measurement tools to gather data about therapy services. One commenter pointed out that limits per-diagnosis should be based on reasonable data that reflect good patient outcomes.

Most of the commenters who supported Option (2) also noted that this option could influence therapy utilization and possibly outcomes, creating flawed data that were not representative of needed services. The commenters were concerned that future payment policy decisions might later be based on those flawed data.

Response: We agree that Option (2) has the benefit of being relatively easy to implement and we appreciate the perspective of some commenters on the low anticipated burden. We also recognize that a database of limited services would not be appropriate to use for estimating the full cost of medically necessary services.

Comment: Some commenters took a neutral position on this option, finding that it could be part of a viable alternative to therapy caps but only after considerable study and development. MedPAC noted that Option (2) would implement more meaningful therapy caps in the interim, while longer-term solutions were being developed and tested. At the same time, MedPAC supported CMS' efforts to identify medically unnecessary care and to

implement payment systems that ensure that the program obtains value for its purchases. Other commenters were concerned that the benchmark levels for edits be realistic and not arbitrary. The commenters requested that CMS consider a method to deal with outliers without forcing denials and appeals.

Response: Option (2) could be used in combination with other options. We recognize the description we provided was not specific about the edit levels and that further deliberation would be appropriate before edits could be implemented.

Comment: The majority of commenters opposed Option (2). Although some commenters agreed the edits for medically unlikely services are useful and appropriate, they expressed concerns about this approach because edits can often be arbitrary, are not based on patient needs, and may improperly limit necessary services. Some commenters asserted that individuals with degenerative conditions may require shorter sessions over longer periods of time to address functional loss and slow deterioration and to maximize health outcomes. The commenters also opposed edits that would fail to address the affects of cognitive impairment on treatment. Several commenters cited the existing ICD-9-CPT code crosswalks, LCDs, NCCI edits, and MUEs as examples of similar edits that commenters often found to be clinically inappropriate. The commenters argued that current edits and policies based on unsupported information led to denials and appeals that were costly to therapists and CMS. The commenters urged CMS to avoid edits that lack clinical relevance or a scientific basis and create anomalies in claims data.

Response: Option (2) was developed with input from therapy professionals based on their review of therapy utilization data. If this option were to be implemented, we would, at a minimum, review the advice and recommendations of stakeholders, along with any available utilization data to inform our decisions regarding the edit levels.

Comment: A few commenters criticized Option (2) as scientifically flawed. One commenter reported that use of a combined effectiveness (that is, functional status change) and efficiency (that is, number of treatment visits) algorithm in a value-based payment process is one of the few methods where one could determine if the patient needs more or less treatment to reach optimal risk-adjusted gains in functional status. The same commenter referenced numerous research efforts that have analyzed functional status outcomes in

rehabilitation using sophisticated risk-adjustment methods and requested that CMS use these as a basis for a new payment policy.

Other commenters asserted that currently available utilization data are inadequate to develop predetermined edit values, citing studies of therapy utilization under contract to CMS and studies performed by industry that demonstrate why ICD-9 coding, lack of function/severity data, and lack of a definition for "episode" are problematic.

Response: Current therapy utilization data reveal that one percent of beneficiaries who receive services incur costs that proportionately far exceed those of the other 99 percent of beneficiaries. However, we are also aware that without some knowledge of the condition of the beneficiary, it is impossible to determine which, if any, of those services were medically necessary. While it would be desirable to analyze more detailed utilization data that include patient function/severity outcomes for setting edit values, those data are not available to us in the short-term. We believe that the existing limited utilization data, albeit not fully descriptive of patients, could inform potential future edit values for therapy services.

Comment: If CMS plans to move forward with edits, many commenters strongly requested that professional organizations be consulted to determine whether such edits are clinically appropriate and realistic. Some commenters specifically urged CMS to await the results of the DOTPA pilot in the hope of capturing meaningful clinical differences between patients before applying edits. Before such edits could reliably be applied to payment, other commenters recommended that CMS design, test, and evaluate additional data on functional status and barriers to participation. Many commenters indicated that more data are needed; especially thresholds based on episodes, condition groupings, and similar criteria that could trigger medical review, but not support denial. To that end, some commenters stated that it might be possible to support this approach under Option (2), but after Option (1) was implemented.

Response: We understand the commitment of stakeholders to the development of alternatives to the therapy caps based on clinically appropriate policies. We will consider the potential benefit of Option (1) to develop data on which to base the edits

required under Option (2) as we further contemplate alternatives to the therapy caps.

Comment: A few commenters opposed Option (2) edits because the edits would virtually eliminate the exceptions process mandated by law and replace it with denial of claims at a predetermined value, which may be inconsistent with the statutory requirement for an exceptions process. The same commenters stated that there would be no basis for edits until Option (1) was implemented to provide more detailed claims-based information. Several commenters reported research showing 10 percent of Part B patients in nursing facilities have highly complex problems, with multidisciplinary needs, and inconsistent patterns of therapy service use. The commenters were concerned that denials would interfere with treatment of these complex patients with special needs.

Response: Option (2) would require an existing exception to the therapy caps, which would be enhanced to allow limited billing and payment for medically necessary services that exceed the caps. The option could not be used if the exceptions process were not extended. However, the Deficit Reduction Act of 2005 that established exceptions to the caps for medically necessary therapy services also required implementation of clinically appropriate code edits in order to identify and eliminate improper payments for therapy services. CMS currently applies NCCI and MUE edits to therapy services that fail to meet a reasonable assumption of medical necessity. We view implementation of Option (2) as consistent with our current authority to create edits to control inappropriate billings.

Benchmark levels for Option (2) would be based on existing therapy utilization data and limits would be set at levels that a high percentage of beneficiaries would not exceed. While it may be helpful to have more data related to patient condition as described in Option (1) before implementing Option (2), we do not consider such information vital to the development of limits that affect a very small percentage of beneficiaries whose service payments would so far exceed average payments that they would be likely to include inappropriate billings and would be unlikely to interfere with the delivery of medically necessary services.

Comment: If the option of implementing edits were pursued,

several commenters indicated that the edits should be variable based on clinical criteria, result in medical review instead of denials, and reflect issues of multidisciplinary care, care coordination, and clinical issues.

Response: If Option (2) were to be further developed, we would consider the commenters' suggestions prior to finalizing a plan for implementation, along with any new information available from additional research studies, OIG reports, or other sources.

Option (3): Introduce per-session "Evaluation/Assessment and Intervention" (E&I) codes to bundle payment for groups of current therapy HCPCS codes into a single per-session payment.

As discussed in section II.C.4.(c) of this final rule with comment period, multiple therapy services are often furnished in a single session, and we proposed to expand the MPPR policy to "always therapy" services in CY 2011 in order to take into consideration the efficiencies that occur when multiple services (the typical therapy scenario) are furnished in one session to a beneficiary. Furthermore, we note that section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) regarding potentially misvalued codes under the PFS specifies that the Secretary may make appropriate coding changes, which may include consolidation of individual services into bundled codes for payment under the PFS, as part of her review and adjustment of the relative values for services identified as potentially misvalued.

This option would require that practitioners submit a single new Level II HCPCS code to represent all the therapy services currently reported and paid separately for an outpatient therapy session. Payment for the HCPCS code would be based on patient characteristics (as identified through prior CMS contractor analyses) and the complexity of the evaluation/assessment and intervention services furnished during the session. The new coding requirements would not necessarily disrupt the current exceptions process or the revised exceptions process described in Option (1) above. Approximately 12 E&I codes would be needed for each discipline, taking into consideration the basic algorithm shown in Table 47.

TABLE 47—EVALUATION/ASSESSMENT & INTERVENTION LEVEL II HCPCS CODES

Intervention level		Evaluation/assessment complexity		
		Minimal	Moderate	Significant
	None	E&I Code #1	E&I Code #2	E&I Code #3.
	Minimal	E&I Code #4	E&I Code #5	E&I Code #6.
	Moderate	E&I Code #7	E&I Code #8	E&I Code #9.
	Significant	E&I Code #10 ...	E&I Code #11 ...	E&I Code #12.

We would need to develop and test operational definitions for each E&I code so that practitioners would be able to properly report services and appropriate relative values could be established for each per-session code. We believe that a pilot study might reveal that the different practice patterns for the three therapy professions (physical therapy, occupational therapy, and speech-language pathology) could necessitate separate relative value determinations for each E&I code by type of therapy service furnished. As a result, up to 36 total new Level II HCPCS codes could be needed (12 per discipline).

We anticipate that the definitions of E&I codes 1 through 3 and 7 through 12 would describe services that may only be furnished by a "clinician" (therapist, physician, or non-physician practitioner). E&I codes 1 through 3 would be reported for sessions that consisted only of evaluations. In addition, the definitions of E&I codes 4 through 6 would describe services that could be furnished by or under the permissible supervision of all qualified outpatient therapy professionals. Based upon historical therapy utilization patterns, the vast majority of E&I codes submitted would likely fall in the 4 through 9 code range. We would expect the RVUs under the PFS for all E&I codes to take into consideration the efficiencies when multiple services (those that would be currently reported under multiple CPT codes) are furnished.

This option would require 2 to 4 years to add new codes and conduct a short-term pilot study to refine coding and value the 12 new HCPCS codes (or 36 if they are specific to each therapy discipline). There would be significant initial practitioner administrative burden to learn new codes and update billing systems. However, ultimately, with elimination of the practitioner's reporting of 76 different codes and many of the associated claims processing edits, the administrative burden of reporting therapy services to Medicare would be minimized.

This bundled approach to reporting and payment could result in more

appropriate valuation of therapy services that reflects efficiencies when individually reported services are furnished in the same session. As a result, it could lead to reduced therapy expenditures, as well as a reduction in the number of beneficiaries affected by the therapy caps in a given year.

Comment: The vast majority of commenters concurred that provider payments should be influenced by underlying beneficiary characteristics. Most commenters agreed that following research and development, an episode-based payment alternative would be the most feasible payment model for outpatient therapy services in the longterm, and some recommended it be developed in a performance-based model. The commenters generally supported this option as a foundation to those goals, but recommended expert therapist input into the process and further study to determine how such an approach might affect different therapy types and settings. Several commenters noted that it would be critical to ensure clear nomenclature, the availability of an appropriate reporting methodology, and adequate payment for these codes that reflects the resources used to provide these services.

To assure appropriate payment for needed services, the commenters agreed that the outcomes resulting from provider interventions must be incorporated in payment models. The commenters believe that experience gained in a transparent development process could be carried over into future payment system reform. Therefore, the majority of commenters who supported Option (3) also requested that there be a transparent process of development and testing in which expert therapists from various settings were included. Many also argued that Option (3) should be developed only after Option (1) had been implemented and function and severity data had been collected to inform the development of Option (3).

Response: We appreciate the support of commenters for Option (3) and their interest in moving toward long-term goals by implementing short-term approaches as an incremental step. We agree that the information presented in

the proposed rule was limited regarding Option (3) and that further study would be necessary before a bundled per-session payment approach could be implemented. We will consider the commenters' recommendations to develop an episode-based payment alternative in the future.

Comment: The concept of moving toward per-session codes that would be based on the severity of the patient and intensity of therapist clinical judgment and work involved in the provision of the therapy service was welcomed by many commenters. Those commenters who encouraged CMS to use this option to reduce the administrative burden of counting minutes and eliminate NCCI edits and MUEs anticipated corresponding improvement in the effective and efficient delivery of clinical interventions. The commenters urged CMS to ensure compliance of policies related to Option (3) with other payment policies, such as the delivery of medically necessary care driven by the development of an appropriate functional goal-based plan of care.

Response: While a per-session payment methodology could result in modification of current policies regarding counting treatment time, it would not necessarily result in deleting claims edits. If we were to adopt such a methodology, we would assess the current claims processing edits and determine whether they continued to be appropriate and/or implement new edits to address potential issues under the revised payment approach.

Comment: Some commenters suggested a modified definition of severity. The commenters recommended two separate severity tables of "severity or complexity," one for evaluation and the other for intervention. For each table separately, severity/complexity of clinical presentation would be rated as low, moderate, or high. In all cases, the commenters believe CMS should identify the factors to be used to determine severity for both evaluations and interventions. The commenters urged that CMS defer to professional standards of practice and state law with respect to the provision of services in each category. Other commenters

recommended modifiers for complex patients and comprehensive multidisciplinary rehabilitation settings to facilitate application of special policies for those circumstances.

Response: The tables presented in the proposed rule were illustrative of the potential Level II per-session HCPCS codes, and these codes would require further development prior to implementation. We appreciate the commenters' suggestions and will consider them as we weigh this option.

Comment: Some commenters who supported the general premise of Option (3) and some commenters who opposed it were not optimistic that per-session payment could be developed in a reliable and valid manner in the short term.

Response: This alternative was developed as a short-term action that would start the process toward bundled payments for therapy episodes. The work completed by expert therapist advisors to the STATS workgroups laid a foundation that could facilitate development of the initial per-session HCPCS codes, which could reasonably be based on utilization data that demonstrated which services were historically billed together most of the time. We have analyzed data regarding common therapy code combinations. While a per-session payment approach could have a significant impact on payment for therapy services, we would not expect that developing and valuing per-session E&I codes would be a particularly lengthy or complex process. We note that over the past several years, the CPT Editorial Panel has bundled multiple services into a single code numerous times in different medical specialty areas and the AMA RUC has then valued the new comprehensive service by taking into account the expected efficiencies in the physician work and/or practice expense.

Comment: Rather than consign the code definition and valuation processes integral to Option (3) to the CPT Editorial Panel and AMC RUC processes, which have little transparency, several commenters recommended that CMS develop Level II HCPCS codes for this purpose and allow for continued stakeholder input as to their valuation. Some commenters expressed appreciation for being included in the STATS process and suggested it as a model for future transparency in developing payment policies.

Response: We appreciate the confidence stakeholders expressed regarding our capacity to develop HCPCS codes and values using a transparent process that includes input

from stakeholders. If we were to move toward per-session payment in the future, we would need to consider the most appropriate approach to the development and valuation of new codes to describe those services. In the meantime, we note that if the CPT Editorial Panel were to develop new codes for comprehensive therapy services, as they have developed new CY 2011 comprehensive codes for cardiac catheterization and lower extremity endovascular revascularization services that bundle services that are commonly furnished together, we would consider those therapy codes for adoption under the PFS and would value them if we recognized them for PFS payment.

Comment: Due to the nature of certain services when assessment and intervention are inseparable, some commenters asserted that interventions should not be included in this model but should be separately identified. The commenters provided the examples of active wound care management and prosthetic/orthotic management.

Response: The details of therapy E&I codes have not been proposed or finalized. We appreciate the perspective of the commenters and will keep it in mind if we were to pursue the creation of per-session therapy codes in the future.

Comment: While some commenters stated that Option (3) has the potential to simplify and increase consistency in coding for therapy services, several commenters who opposed this option and Option (1) mentioned that providers would learn to "game the system" and that all patients would be documented as severe on initial intake.

Response: We too are concerned about approaches where providers could learn to game the system. The commenters who criticized this option generally preferred the edits in Option (2).

Restriction on utilization of certain codes sometimes increases the risk of billing different codes, billing more of the same codes, or increasing patient visits, resulting in the same or greater cost to the Medicare program. The edits described in Option (2) would prevent high payments for individual beneficiaries, but might have little or no effect on the payments to providers or suppliers who increase the number of beneficiaries treated. Generally, we apply a number of different methods concurrently to reduce risk.

At times, it may be difficult to know whether the clinical judgment and objective measurements have been accurately reported or documented in the record and whether the service furnished is appropriately represented

by the billed HCPCS code. Providers focused on billing inappropriately may also document inappropriately. In the long term, we hope to incentivize honest and ethical providers and suppliers of services to furnish effective and efficient, high quality services. Possible fraudulent activity may be identified by aberrant billing patterns, and the new codes could facilitate the identification of such patterns.

Several commenters expanded on the options presented as alternatives to the therapy caps or recommended options of their own. A few presented their own analyses of utilization to support their recommendations.

Comment: Several commenters recommended incorporation of currently and publicly available validated tools to inform the collection of patient-specific information and move toward performance-based payment. A few commenters suggested that the study "Pay-for-Performance for Outpatient Physical Therapy and Occupational Therapy" that Focus On Therapeutic Outcomes (FOTO) completed in 2006 under Grant #18-P-93066-0-01 might be a good template from which to start a process to replace caps and ultimately develop a value-based purchasing process. The commenters suggested the FOTO predictive model could be used, after pilot testing, to develop a reimbursement process where care is based on need and payment is based on results.

Response: We recognize the importance of demonstrating the application of a value-based purchasing approach to physical and occupational therapy services. We posted the FOTO study on the CMS Web site at: <http://www.cms.gov/TherapyServices/downloads/P4PFinalReport06-01-06.pdf>.

We are aware that research continues on the functional status indicator and that other measurement tools are also available in the public domain. The STATS discussions resulted in some improvements in the feasibility of matching outcomes data to claims. However, there are a number of problems that would have to be resolved before any of the currently available versions of therapy outcomes tools could be incorporated into payment policy. The FOTO study did not address value-based purchasing for speech-language pathology services and there remain questions about applying the FOTO functional status indicator, or any self-reported measure, to certain cognitively impaired patients or to the Medicare population without further refinement.

As we continue to explore various options, we would be interested in the feasibility of using historical research, existing electronic input systems, and registry information to provide a conceptual framework for alternative payment systems.

Comment: Although CMS did not discuss the option of establishing therapy payments based on episodes in the discussion of short-term options, many commenters encouraged CMS to pursue that goal. Using data obtained from the severity/complexity codes described in Option (1), DOTPA, and other data initiatives, several commenters urged CMS to undertake research to develop a new episodic prospective payment system for Part B therapy services. Some commenters described the details of a plan to base therapy episode payment on groups based on patient clinical characteristics, considering mean episode costs, adjusting for high and low outliers or interrupted episodes, setting a default payment for unmapped episode groups, and also adjusting for local wage indices and providing an annual market basket payment rate update.

The opportunity for CMS to define sessions and episodes more clearly and the potential to support the overall goal of payment reform was eagerly anticipated by several commenters. The commenters applauded CMS for recognizing the potential opportunity to gather these data on episodes for payment of therapy services furnished in the institutional setting.

Episode-based payment was recommended as an alternative to the proposed therapy MPPR by numerous commenters. The commenters explained that the fundamental problem with fee-for-service payment is the incentive to over utilize therapy services in the outpatient setting and limit institutional providers from using resources flexibly. The commenters described analysis of a large database of Medicare beneficiaries as the basis for a methodology for grouping diagnosis codes to create episodes of care on which therapy payment would be based. The commenters noted that adjustment would be needed to payments for complex patients and readmissions. The same commenters supported episode payments for separate therapy disciplines based on a patient's medical diagnosis and goals. A critical goal for these commenters was to identify and account for differences in the conditions and needs of patients in skilled nursing facilities as opposed to other outpatient therapy settings.

Response: We did not discuss development of episode-based payments

as an option in the CY 2011 PFS proposed rule because we recognize that substantially more research would be necessary to define the episodes and determine what resources would be needed for different groups or categories of patients before the episodes could be incorporated into a payment system, particularly one that also addressed quality, efficiency, and good health outcomes. However, the absence of discussion in our proposed rule of an episode-based payment methodology as a short-term therapy cap alternatives option should not be interpreted as our reluctance to pursue the definition of episodes or the refinement of the concept of episode-based payments.

Comment: A number of commenters supported testing variables they believe to be important in making a clinical judgment concerning a patient's severity, including: general type of patient (orthopedic, neurological, medical, etc.); impairment (body part treated); intake functional status; patient age; symptom acuity; surgical history; payer; gender; level of fear-avoidance of physical activities; and number of comorbid conditions. Other commenters urged inclusion of clinical judgment of severity based on medical condition, physical impairments resulting from these conditions, patient function, and ability to participate in activities of daily living.

Response: As we progress in the analysis of payment alternatives to the therapy caps, we appreciate the information on variables believed to be critical by stakeholders who have conducted related research and/or furnished therapy services to a wide array of patients in different clinical settings. We welcome their expert contributions and collaboration with us on this important issue.

In conclusion, we emphasize that we continue to be committed to developing alternatives to the therapy caps that would provide appropriate payment for medically necessary and effective therapy services furnished to Medicare beneficiaries based on patient needs, rather than the current therapy caps which establish financial limitations on Medicare payment for therapy services in some outpatient settings regardless of medical necessity. The Congress has repeatedly intervened to allow exceptions to these caps for certain time periods, and the current exceptions are automatically processed based on a practitioner's attestation that medical necessity is documented in the chart for an individual patient. We believe that, ultimately, payment for therapy services should incentivize the most effective and efficient care, consistent with

Medicare's focus on value in its purchasing.

The STATS contractor has worked closely with a broad variety of clinicians, administrators, scientists, researchers, and other contractors to develop the three alternatives presented in this discussion in CY 2011 rulemaking for the PFS. We are grateful for all public comments on the proposed rule from interested stakeholders, including individual therapists from both facility and nonfacility outpatient settings paid under Medicare Part B.

We are committed to finding alternatives to the current therapy cap limitations on expenditures for outpatient therapy services that will ensure that beneficiaries continue to receive those medically necessary therapy services that maximize their health outcomes. We continue to dedicate our resources to identifying alternatives that would encourage the most efficient and cost-effective treatments. We believe motivated therapists, with attention to the most cost-effective practices, can incorporate practice efficiencies that benefit patients by achieving the best possible results at the lowest cost. Our STATS and DOTPA projects, which are currently engaged in data collection and analysis to inform short-term and long-term alternatives to the therapy caps, respectively, lay the foundation for future payment alternatives for outpatient therapy services. We are optimistic that the STATS project has identified short-term, feasible alternatives that may be tested in the future. The DOTPA project will create a tool and test its use to collect patient condition information that could then be applied to identify patient need for therapy services. Together, these projects may provide the basis for a long-term plan to reshape Medicare's payment policy for outpatient therapy services to align with the value-based purchasing principles that are now guiding principles of the Medicare program.

B. Diabetes Self-Management Training (DSMT) Services (HCPCS Codes G0108 and G0109)

1. Background

Section 1861(s)(2)(S) of the Act provides for coverage of DSMT in outpatient settings without limiting this coverage to hospital outpatient departments. DSMT services consist of educational and training services furnished to an individual with diabetes by a certified provider in an outpatient setting.

Section 1861(qq)(2)(A) of the Act stipulates that training must be

furnished by a "certified provider" which is a physician or other individual or entity that also provides other items or services for which payment may be made under Medicare. This program is intended to educate beneficiaries in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the skills for self-management. DSMT services are reported under HCPCS codes G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes) and G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes).

2. Payment for DSMT Services

In accordance with section 1848(j)(3), Medicare payment for outpatient DSMT services is made under the PFS as specified in § 414.1 through § 414.48. When we created HCPCS codes G0108 and G0109, the only direct costs included in the PE were registered nurse labor. Section 410.144(a)(4)(a) states that the DSMT team includes at least a registered dietitian and a certified diabetes educator. We initially did not establish work RVUs for DSMT services because we believed training would typically be performed by individuals other than a physician, such as a registered nurse (65 FR 83130). However, since that time, we have received requests from a number of stakeholders, including the American Association of Clinical Endocrinologists (AAACE), the American Association of Diabetes Educators (AADE), and the Juvenile Diabetes Research Foundation, to include physician work in valuing DSMT services that is similar to the physician work that has been included in medical nutrition therapy (MNT) services since CY 2007 and kidney disease education (KDE) services since CY 2010. The stakeholders argued that because physicians coordinate DSMT programs, provide patient instruction, and communicate with referring physicians, physician work should be included in the RVUs for DSMT services. The stakeholders also requested that we reconsider the direct PE inputs for DSMT services and include clinical labor for diabetes educators at a higher hourly rate instead of registered nurse labor. In addition, they stated that the supplies and equipment in the PE for DSMT services should be the same as for KDE services, with additional direct PE inputs for a

diabetes educator curriculum, data tracking software, and DSMT program accreditation.

For CY 2011, we proposed the following:

- To assign physician work RVUs to DSMT services that are comparable, as adjusted for the service times of the HCPCS codes, to the work RVUs for MNT services. The rationale for the proposed work RVUs for the DSMT HCPCS G-codes was based on the similarity of DSMT services to MNT services in the individual (CPT code 97803) and group (CPT code 97804) setting.
- That HCPCS G0108 for 30 minutes of individual DSMT services would be crosswalked to CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes) for purposes of assigning work RVUs, with the physician work RVUs for CPT code 97803 multiplied by two to account for the greater time associated with HCPCS code G0108 (that is, 30 minutes).
- That HCPCS G0109 for 30 minutes of group DSMT services would be crosswalked to CPT code 97804 (Medical nutrition therapy; group (2 or more individuals(s)), each 30 minutes) for purposes of assigning work RVUs.
- To modify the PE inputs for DSMT services to reflect the current equipment and supplies for the KDE HCPCS G-codes implemented in the CY 2010 PFS final rule with comment period (74 FR 61901) (that is, HCPCS codes G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour) and G0421 (Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour)), based on the similarity in the equipment and supplies necessary for DSMT and KDE services. We made adjustments to some of the equipment times for the 30 minute DSMT individual and group services as compared to the one hour individual and group KDE services.
- To include a diabetes educator curriculum and data tracking software in the PE inputs for DSMT services, while noting that we did not include the DSMT program accreditation costs because it is our general practice not to include these costs in the PE inputs.
- To utilize the same approach for clinical labor as we adopted for MNT services when we provided physician work RVUs for those services in CY 2007 (71 FR 69645), rather than changing the current labor type for DSMT services. Specifically, we removed all of the clinical labor from

the group DSMT code and most of the clinical labor from the individual DSMT code, given that we proposed work RVUs for both DSMT HCPCS codes for CY 2011.

In the CY 2011 PFS proposed rule (75 FR 40100), we stated our belief that these proposals would value DSMT services more consistently with other similar services that are paid under the PFS. As a result of our proposed CY 2011 changes, the proposed work RVUs for HCPCS codes G0108 and G0109 were 0.90 and 0.25, respectively. As described above, we also proposed to modify the direct PE inputs for these codes for CY 2011.

Comment: Numerous commenters specifically supported the establishment of work RVUs for the DSMT services based on the work RVUs of the similar MNT services, CPT codes 97803 for 15 minutes of individual MNT services and 97804 for 30 minutes of group MNT services. Some commenters explained that addition of work RVUs would lead to higher payment rates for DSMT services, resulting in a significant positive impact on diabetes education practices and increased patient access to care for DSMT services. Several commenters suggested that this change would appropriately recognize the active role many physicians contribute to ensuring that their patients have access to DSMT services and providing care coordination and communication with the multidisciplinary DSMT team members. One commenter concurred with the proposal to update the direct PE inputs for the DSMT HCPCS codes based on those assigned to the HCPCS codes for KDE services.

Response: We appreciate the commenters' support for our proposal to establish work RVUs and to update the direct PE inputs for the DSMT services. In conducting our review of the public comments on this issue for this final rule with comment period, we examined newly available PFS claims data for same day billings from one provider for a single Medicare beneficiary. In response to that analysis and in accordance with our PFS methodology which values services as delivered to the typical patient, we note that we have made minor adjustments to some of the direct PE inputs for supplies and equipment times for both HCPCS G-codes for DSMT services, G0108 and G0109, under our final CY 2011 policy. We made these refinements after a review of our PFS utilization data indicated that 2 units of HCPCS code G0108 (a total of 60 minutes) were typically billed together on the same day for the same patient, instead of the one unit of HCPCS code G0108 (30

minutes) which was used as the assumption for the typical session at the time of our CY 2011 proposal. As a result, we have assigned half of the amount of the direct inputs for supplies and equipment time in HCPCS code G0420 (60 minutes individual KDE services) to HCPCS code G0108 (30 minutes individual DSMT services). Regarding the direct PE inputs for HCPCS code G0109, we continue to believe that there is a similarity among the group and individual DSMT and KDE services and the education practices when these services are delivered, as reflected in their PFS utilization patterns. For this reason, we have made minor modifications to the PE inputs for HCPCS code G0109 (30 minutes of group DSMT services) to reflect half of each input for HCPCS code G0421 (60 minutes of group KDE services) that parallel the modifications we made for the individual DSMT HCPCS code described previously. We further note that these refinements to the direct PE inputs for DSMT services are based on the final adjustments that were made to the direct PE inputs for HCPCS codes G0420 and G0421 for KDE services, discussed in section V. B.2.e. of this final rule with comment period, because our approach to establishing the direct PE inputs for the DSMT HCPCS G-codes is based on the inputs for KDE services.

As a result, the modifications we made to the supplies and equipment inputs for the DSMT HCPCS G-codes, G0108 and G0109, equal half of the same supply and equipment times in the one hour HCPCS G-codes for KDE services, G0420 and G0421.

In addition, because the \$200 price of the diabetes educator curriculum does not meet the \$500 floor we established for inclusion in the equipment database, we have bundled the diabetes educator curriculum price with the \$500 data tracking software one because the patient's curriculum information is typically recorded in the tracking software. The equipment descriptor for the data tracking software was modified to read: Diabetes education data tracking software, includes curriculum. Accordingly, we changed the price input from \$500 to \$700 and assigned the bundled equipment a total of 4 minutes. In this way, we are including the cost of the curriculum in the direct PE inputs for DSMT services as we proposed for CY 2011, while remaining consistent with the established \$500 floor on inclusion of equipment in the PE database.

After consideration of the public comments we received, we are finalizing the proposed work RVUs and

direct PE input for DSMT services, with modification to make the PE adjustments described previously. The final CY 2011 direct PE database that lists the direct PE inputs is available on the CMS Web site under the downloads for the CY 2011 PFS final rule with comment period at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>. The final CY 2011 RVUs for HCPCS codes G0108 and G0109 are displayed in Addendum B to this final rule with comment period.

C. End-Stage Renal Disease Related Services for Home Dialysis (CPT codes 90963, 90964, 90965, and 90966)

1. End-Stage Renal Disease Home Dialysis Monthly Capitation Payment Services (CPT codes 90963, 90964, 90965, and 90966)

In the CY 2004 PFS final rule with comment period (68 FR 63216), we established new Level II HCPCS G-codes for end-stage renal disease (ESRD) monthly capitation payment (MCP) services. For center-based patients, payment for the G-codes varied based on the age of the beneficiary and the number of face-to-face visits furnished each month (for example, 1 visit, 2-3 visits and 4 or more visits). Under the MCP methodology, the lowest payment applied when a physician provided one visit per month; a higher payment was provided for two to three visits per month. To receive the highest payment, a physician would have to provide at least four ESRD-related visits per month. However, payment for home dialysis MCP services only varied by the age of beneficiary. Although we did not initially specify a frequency of required visits for home dialysis MCP services, we stated that we "expect physicians to provide clinically appropriate care to manage the home dialysis patient" (68 FR 63219).

Effective January 1, 2009, the CPT Editorial Panel created new CPT codes to replace the G-codes for monthly ESRD-related services, and we accepted the new codes for use under the PFS in CY 2009. The CPT codes for monthly ESRD-related services for home dialysis patients include the following, as displayed in Table 32 of the CY 2011 PFS proposed rule (75 FR 40101) and reprinted as Table 48 below: 90963, 90964, 90965, and 90966. In addition, the clinical vignettes used for the valuation of CPT codes 90963, 90964, 90965, and 90966 include scheduled (and unscheduled) examinations of the ESRD patient.

Given that we pay for a physician (or nonphysician practitioner (NPP)) to

evaluate the ESRD patient over the course of an entire month under the MCP, we believe that it is clinically appropriate for the physician (or NPP) to have at least one in-person, face-to-face encounter with the patient per month. As such, for CY 2011 we proposed to require the MCP physician (or NPP) to furnish at least one in-person patient visit per month for home dialysis MCP services (as described by CPT codes 90963 through 90966). The proposed requirement would be effective for home dialysis MCP services beginning January 1, 2011. As stated in the CY 2011 PFS proposed rule (75 FR 40100), we believe this requirement reflects appropriate, high quality medical care for ESRD patients being dialyzed at home and generally would be consistent with the current standards of medical practice.

Comment: Many commenters stated that a monthly visit embodies the standard of care for home dialysis patients. However, many of the same commenters also stated that it may not always be feasible to furnish a face-to-face visit every month for home dialysis patients due to extenuating circumstances. A number of commenters explained that, in contrast to patients who dialyze in a dialysis center, home dialysis patients would need to travel to the doctor's office (or the physician would need to visit the patient's home) which would be an undue burden on both the physician and the patient. To that end, several commenters urged CMS to provide flexibility in cases where a patient does not show up for their scheduled appointment and for those that cannot travel due to significant geographic distance between the patient and the nephrologist. For example, some specialty societies stated that pediatric home dialysis patients may experience exceptional circumstances due to the scarcity of pediatric nephrologists and remote geographic locations, making the monthly face-to-face visit requirement harder to fulfill. In these circumstances, one commenter requested that CMS consider allowing the MCP physician to furnish at least 1 visit every 3 months and allowing the other monthly visits to be furnished as a telehealth service. Additionally, several commenters explained that the monthly management of a home dialysis patient involves many tasks (in addition to face-to-face visits) including: Reviewing lab tests, treatment data and the dialysis prescription; monitoring the patient's vascular access; and overseeing quality improvement activities (as well as incurring the practice expense

associated with managing the patient's care). The commenters stated that the MCP physician should not be "penalized" if the patient chooses not to attend the monthly visit. Moreover, many of the commenters who agreed that monthly visits are optimal care did not support a monthly visit requirement for the home dialysis MCP service. The commenters stated that the frequency of face-to-face visits should remain at the discretion of the nephrologist and patient. Several of the commenters who did not support a policy change also stated that requiring a monthly visit could create disincentives for providing beneficiaries with home dialysis therapy in circumstances where it may be difficult for the MCP physician to furnish a visit every month. The commenters explained that nephrologists may not want to encourage home dialysis therapy if they will not get paid as a result of a patient "opting out" of a scheduled visit.

Response: We continue to believe that furnishing monthly face-to-face visits is an important component of high quality medical care for ESRD patients being dialyzed at home and generally would be consistent with the current standards of medical practice. However, we also acknowledge that extenuating circumstances may arise that make it difficult for the MCP physician (or NPP) to furnish a visit to a home dialysis patient every month. Therefore, we will allow Medicare contractors the discretion to waive the requirement for a monthly face-to-face visit for the home dialysis MCP service on a case-by-case basis, for example, when the MCP physician's (or NPP's) notes indicate that the MCP physician (or NPP) actively and adequately managed the care of the home dialysis patient throughout the month. Additionally, as we explained in the CY 2004 PFS final rule with comment period (68 FR 63219 through 63220), we also believe that the use of other practitioners working with the MCP physician (or NPP) to furnish the required monthly visit for the home dialysis MCP service could help alleviate scheduling issues and problems related to geographic distance.

With regard to the comment on furnishing the proposed required visit for the home dialysis MCP as a telehealth service, we note that any interested parties may submit requests to add services to the list of Medicare telehealth services. Requests submitted before the end of CY 2010 will be considered for the CY 2012 PFS proposed rule. Requestors should be advised that each request to add a service to the list of Medicare telehealth

services must include any supporting documentation the requestor wishes us to consider, as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to directly mail these requests, we refer readers to section IV.B. of this final rule with comment period and the CMS Web site at: <http://www.cms.hhs.gov/telehealth>.

Comment: Several commenters stated that the conditions for coverage for dialysis facilities require a monthly interaction between a clinician representing the facility and the home dialysis patient. The commenters believe that the conditions for coverage for dialysis facilities permit flexibility in the monthly visit requirement if the patient chooses to opt out of the monthly visit and requested that CMS align the proposed visit requirement for the home dialysis MCP service with the "flexibility" permitted under the conditions for coverage for dialysis facilities.

Response: With regard to conditions for coverage for dialysis facilities, § 494.90(b)(4) of the regulations specifies that the dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly. Section 494.100 requires "a dialysis facility that is certified to provide service to home patients to ensure that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part." In addition, the interpretive guidance for part 494 entitled "Conditions for Coverage for ESRD Facilities" specifies that a monthly visit is required for each home patient by a physician, an advanced practice registered nurse, or a physician assistant. The visit may be conducted in the dialysis facility, at the physician's office, or in the patient's home. The guidelines state that "any patient may choose not to be seen by a physician every month" but also specify that if there is a pattern of a patient consistently missing physician and or practitioner visits, the lack of medical oversight should be addressed with the patient in the plan of care.

The requirement for at least one monthly visit with a clinician associated with the dialysis facility is a condition for coverage for the dialysis facility for purposes of participating in the Medicare program and not a direct factor in determining the payment amount for the dialysis facility. In other words, the clinician visit is not a

component of the facility's composite rate. However, as mentioned in the background section, the clinical vignettes used for the valuation of the home dialysis MCP service under the PFS include scheduled (and unscheduled) examinations of the ESRD patient. Given that physician or NPP visits are a factor in determining the PFS payment amount for the home MCP service that is furnished to the typical Medicare beneficiary, we do not believe that the monthly visit requirement for the home dialysis MCP service is analogous to the visit requirement under the conditions for coverage for dialysis facilities that has no implications for setting payment rates under the PFS. Therefore, we do not agree that the visit requirement for the home dialysis MCP service necessarily should be "aligned" with the conditions for coverage for dialysis facilities.

Comment: One commenter suggested that CMS consider structuring the home dialysis MCP similar to the center-based MCP. Under this approach, the commenter suggested that a higher payment amount could be made for home dialysis MCP services with at least one in person, face-to-face visit per month.

Response: We will consider the commenter's suggestion as we continue to develop and refine Medicare payment policy for physicians and practitioners managing patients on dialysis. In the event we decide to make changes in the payment amount(s) for the home dialysis MCP services, we would do so in a future proposed rule where the public would have the opportunity to provide comments as afforded by the rulemaking process.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal, with modification. We will require the MCP physician (or NPP) to furnish at least one in-person patient visit per month for home dialysis MCP services (as described by CPT codes 90963 through 90966). However, Medicare contractors will have the discretion to waive the monthly visit requirement for the home dialysis MCP service on a case-by-case basis.

2. Daily and Monthly ESRD-Related Services (CPT Codes 90951 Through 90970)

In CY 2008, the AMA RUC submitted recommendations for valuing the new CY 2009 CPT codes displayed in Table 48 that replaced the MCP HCPCS G-codes for monthly ESRD-related services. We accepted these codes for use under the PFS.

TABLE 48—MCP CODES RECOGNIZED UNDER THE PFS

MCP Code	Long descriptor
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face physician visits per month.
90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2–3 face-to-face physician visits per month.
90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face physician visit per month.
90954	End-stage renal disease (ESRD) related services monthly, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face physician visits per month.
90955	End-stage renal disease (ESRD) related services monthly, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2–3 face-to-face physician visits per month.
90956	End-stage renal disease (ESRD) related services monthly, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face physician visit per month.
90957	End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face physician visits per month.
90958	End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2–3 face-to-face physician visits per month.
90959	End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face physician visit per month.
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face physician visits per month.
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2–3 face-to-face physician visits per month.
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face physician visit per month.
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents.
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents.
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents.
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older.

There are four additional CPT codes for ESRD-related services that are reported on a per-day basis. These daily CPT codes are: 90967 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age); 90968 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2–11 years of age); 90969 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12–19 years of age); and 90970 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older).

For the MCP codes displayed in Table 32 of the CY 2011 PFS proposed rule, the AMA RUC initially recommended 36 minutes of clinical labor time for the pre-service period. They also recommended an additional 6 minutes

in the post-period for CPT codes 90960, 90961, 90962, and 90966. For the four codes describing daily services (CPT codes 90967 through 90970), the AMA RUC recommended including 1.2 minutes of clinical labor per day, which is the prorated amount of pre-service clinical labor included in the monthly codes. The AMA RUC also recommended that CPT codes 90952 and 90953 be contractor-priced.

In the CY 2009 PFS final rule with comment period (73 FR 69898), we asked the AMA RUC to reconsider their recommended PE inputs in the interest of making certain that they accurately reflected the typical direct PE resources required for these services. In addition, we asked the AMA RUC to review the physician times for CPT codes 90960 and 90961 that are used in the calculation of the PE RVUs. We accepted the work values for the new CPT codes for ESRD-related services

that were recommended by the AMA RUC.

Since CY 2009, we have continued to calculate the PE RVUs for the entire series of MCP codes displayed in Table 32 of the CY 2011 PFS proposed rule (75 FR 40101) by using the direct PE inputs from the predecessor HCPCS G-codes, except for CPT codes 90952 and 90953 which are contractor-priced. We have also continued to use the physician time associated with the predecessor HCPCS G-codes for CPT codes 90960 and 90961 for purposes of calculating the PE RVUs.

In CY 2009, the AMA RUC submitted new recommendations for CPT codes 90951 and 90954 through 90970. For each of the MCP codes (CPT code 90951 and CPT codes 90954 through 90966), the AMA RUC recommended an increased pre-service clinical staff time of 60 minutes. For each of the daily dialysis service codes (CPT codes 90967 through 90970), the AMA RUC

recommended an increased clinical labor time of two minutes, which is the prorated amount of clinical labor included in the monthly codes. The AMA RUC also recommended an additional 38 minutes of physician time for CPT codes 90960 and 90961. This resulted in a total physician time of 128 minutes and 113 minutes, respectively, for these codes. The AMA RUC continued to recommend that CPT codes 90952 and 90953 be contractor-priced.

For CY 2011, we proposed to accept these AMA RUC recommendations as more accurate reflections of the typical direct PE resources required for these services. Therefore, we proposed to develop the PE RVUs for CPT code 90951 and CPT codes 90954 through 90970 using the direct PE inputs as recommended by the AMA RUC and reflected in the proposed CY 2011 PE database, which is available on the CMS Web site under the supporting data files for the CY 2011 PFS proposed rule at: <http://www.cms.gov/PhysicianFeeSched/>. We also proposed to use the AMA RUC-recommended physician times for CPT codes 90960 and 90961. Consistent with the AMA RUC's recommendations, we proposed to continue to contractor-price CPT codes 90952 and 90953.

We did not receive public comment on our proposal to accept these AMA RUC recommendations as more accurate reflections of the typical direct PE resources required for these services. Therefore, we are finalizing our CY 2011 proposal to develop the PE RVUs for CPT code 90951 and CPT codes 90954 through 90970 using the direct PE inputs as recommended by the AMA RUC and reflected in the CY 2011 direct PE database, which is available on the CMS Web site under the supporting data files for the CY 2011 PFS final rule with comment period at: <http://www.cms.gov/PhysicianFeeSched/>. We will also use the AMA RUC-recommended physician times for CPT codes 90960 and 90961. Consistent with the AMA RUC's recommendations, we will continue to contractor-price CPT codes 90952 and 90953.

D. Portable X-Ray Set-Up (HCPCS Code Q0092)

When a portable x-ray is furnished to a single patient, as many as four component HCPCS codes may be billed and paid for the service, including the portable x-ray transportation (HCPCS code R0070 (Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen)); the portable x-ray set-up (HCPCS code Q0092 (Set-

up of portable x-ray equipment)); and the professional and technical components of the x-ray service itself (CPT 70000 series). Currently, the direct PE database contains x-ray equipment in both the radiology codes in the 70000 series of CPT and HCPCS code Q0092, the code for the set-up of a portable x-ray. In the technical component of the x-ray service is the direct PE input of a radiology room which contains x-ray equipment for the various radiology codes in the 70000 series of CPT. In addition, portable x-ray equipment is included as a direct PE input for HCPCS code Q0092. Thus, x-ray equipment currently is recognized within the direct PE values for two of the HCPCS codes that would be reported for the portable x-ray service, resulting in an overvaluation of the comprehensive portable x-ray service.

Therefore, for CY 2011 we proposed to remove portable x-ray equipment as a direct PE input for HCPCS code Q0092, in order to pay more appropriately for the x-ray equipment used to furnish a portable x-ray service. We believe the resulting payment for the comprehensive portable x-ray service would more appropriately reflect the resources used to furnish portable x-ray services by providing payment for the x-ray equipment solely through payment for the technical component of the x-ray service that is furnished.

Comment: Several commenters opposed the removal of portable x-ray equipment as a direct PE input for HCPCS code Q0092. The commenters believe the elimination of the equipment from HCPCS code Q0092 is inconsistent with longstanding CMS payment policy recognizing the unique and additional costs incurred by portable x-ray suppliers in furnishing services that involve special equipment requiring extra assembly and disassembly time. In addition, the commenters believe that the proposed equipment elimination conflicts with the statutory mandate of section 1848(c) of the Act that CMS calculate the PFS RVUs based on the actual resources used in furnishing a service because equipment is a legitimate direct PE component of the set-up component service (HCPCS code Q0092).

Response: We agree that x-ray equipment is used to furnish a portable x-ray service and the equipment set-up is reported with HCPCS code Q0092. However, because the portable x-ray set-up service would always be reported along with the technical component of the x-ray service (CPT 70000 series) that already includes x-ray equipment as a direct PE input, to include x-ray equipment again in the PE of the set-up

code would clearly be duplicative. Only one item of equipment, that is, a single x-ray machine, is used in furnishing the portable x-ray service. We are, therefore, eliminating the portable x-ray equipment from HCPCS code Q0092 and, instead, recognizing the cost of such equipment in the direct PE for the technical component of the x-ray service.

Comment: According to several commenters, because CMS has not undertaken a review of all combinations of services paid under the PFS that together might comprise a "comprehensive service" to identify potentially duplicative direct PE inputs when the services are furnished together, CMS should refrain from applying the proposed policy to suppliers of portable x-ray services.

Response: While it would require an extensive analysis to review all combinations of PFS services that may be furnished together and identify potentially duplicative PE inputs, the PFS has several longstanding policies that were adopted to provide appropriate payment when certain services are furnished together. For example, existing multiple procedure payment reduction policies reduce payment for the second and subsequent surgical procedures or technical components of imaging services when furnished to the same patient by the same physician on the same day, based partly on the presence of efficiencies in the PE under such circumstances. Furthermore, as discussed in section II.C.4. of this final rule with comment period, we are adopting a new multiple procedure payment reduction policy for CY 2011 for therapy services because of the duplication in the PE when therapy services are furnished together. Finally, we note that for those CPT codes that are designated as add-on codes to primary services, we ensure that the direct PE inputs do not duplicate inputs in the primary services. Given our ongoing efforts to more appropriately value services furnished together, we believe that HCPCS code Q0092 essentially functions as an "add-on" code to the primary service that it generally accompanies, which is the technical component of an x-ray service. Therefore, we believe it is fully consistent with our ongoing efforts to recognize efficiencies through payment policy when multiple services are furnished together to remove the duplicative x-ray equipment from the direct PE inputs for HCPCS code Q0092.

Comment: A few commenters believe that elimination of x-ray equipment in HCPCS code Q0092 would have a negative impact on the financial status

of portable x-ray suppliers who are typically small business owners. According to the commenters, CMS should heed the statutory mandates of the Regulatory Flexibility Act (RFA) which require mitigation of such adverse effects.

Response: We note that the RFA requires only that we analyze regulatory options for small businesses that include a justification for the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. The CY 2011 PFS proposed rule included a regulatory impact analysis (75 FR 40230 through 40245), as does section XI.A. of this final rule with comment period. As a specialty, the aggregate impact on portable x-ray suppliers from the PFS changes proposed for CY 2011 was an increase of 8 percent in the proposed rule (75 FR 40232), and it is an increase of 6 percent for CY 2011 as displayed in Table 101 of this final rule with comment period. Therefore, the combined effect of all final PFS policies for CY 2011 will not adversely impact portable x-ray suppliers.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to remove portable x-ray equipment as a direct PE input for HCPCS code Q0092.

E. Pulmonary Rehabilitation Services (HCPCS Code G0424)

In the CY 2010 PFS proposed rule (74 FR 33614), we proposed to create new HCPCS G-code G0424 (Pulmonary rehabilitation, including aerobic exercise (includes monitoring), per session, per day) to describe the services of a pulmonary rehabilitation (PR) program as specified in section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Using CPT code 93797 (Cardiac rehab without telemetry) as a reference code, we proposed to assign 0.18 work RVUs and 0.01 malpractice RVUs to G0424. To establish PE RVUs, we reviewed the PE inputs of similar services, particularly those of the respiratory therapy HCPCS codes G0237 (Therapeutic procedures to increase strength or endurance or respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring)) and G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring)), as well as the cardiac rehabilitation codes, CPT codes 93797 and 93798 (Physician services for outpatient cardiac

rehabilitation; with continuous ECG monitoring (per session)). In the CY 2010 PFS final rule with comment period (74 FR 61886), we finalized our proposal with modifications to the code descriptor and PE inputs, as recommended by some commenters.

Based on commenters' recommendations from the CY 2010 PFS final rule with comment period and further information furnished by stakeholders, for CY 2011 we proposed to increase the work RVUs for HCPCS code G0424 to 0.28 for CY 2011 to be comparable to the work RVUs for cardiac rehabilitation with monitoring (CPT code 93798) in view of the monitoring required for HCPCS code G0424.

We also proposed to increase the clinical labor time for the respiratory therapist from 15 minutes to 30 minutes and to crosswalk the PE equipment inputs for HCPCS code G0424 to those for respiratory treatment services (HCPCS code G0238), which include a 1-channel ECG and a pulse oximeter. We retained the treadmill currently assigned to HCPCS code G0424 and adjusted the equipment time to 45 minutes. While several public commenters recommended this equipment, these commenters also requested a full 60 minutes of respiratory therapist time be included in the PE for HCPCS code G0424, comparable to the 15 minutes of respiratory therapist time included in the one-on-one codes for 15 minutes of respiratory treatment services (HCPCS codes G0237 and G0238). However, because pulmonary rehabilitation services reported under HCPCS code G0424 can be furnished either individually or in groups, we believe that 30 minutes of respiratory therapist time would be more appropriate for valuing the typical pulmonary rehabilitation service.

Comment: Many commenters applauded CMS for its proposal to increase the work RVUs for HCPCS code G0424 to 0.28. While the commenters supported the increase in work RVUs in the short term, they believe that an accurate, independent assessment of the work value associated with physician's office-based pulmonary rehabilitation is the only reasonable way to determine actual physician work. The commenters stated that continuing to rely on work values related to cardiac rehabilitation is flawed, noting that the clinical characteristics of the cardiac rehabilitation patient are different from the pulmonary rehabilitation patient. Due to the expected frequency and duration of acute events, the commenters explained that the

pulmonary rehabilitation patient would require greater physician involvement.

Response: Until we gain more data and experience on the use of this code to report pulmonary rehabilitation services furnished to Medicare beneficiaries under the new comprehensive benefit, we believe using the work RVUs for cardiac rehabilitation with monitoring (CPT code 93798) as a crosswalk is appropriate for this service. We further note that the crosswalk methodology is commonly used by the AMA RUC in recommending work RVUs to us for new or revised codes.

Comment: A number of commenters generally supported the increase in the clinical labor time for a respiratory therapist from 15 minutes to 30 minutes. While the commenters generally agreed with CMS' reasoning for not increasing the respiratory therapist time to 60 minutes, the commenters noted that in the physician's office setting, pulmonary therapy items and services are routinely provided one-on-one, face-to-face, requiring 60 minutes of individualized therapy services by a respiratory therapist. Some commenters believe that the proposal to increase the respiratory therapist time to only 30 minutes would place physicians at an economic disadvantage in the provision of pulmonary rehabilitation items and services when furnished in an office setting due to the limited amount of office space available to treat more than one patient in the same time period. One commenter suggested that the respiratory therapist time be increased to 45 minutes or that CMS consider the development of a HCPCS code for the provision of pulmonary rehabilitation items and services to patients on a one-on-one, face-to-face per 15 minute basis to ensure that physicians can provide this service in the office setting. Another commenter believed that HCPCS code G0424 is undervalued at 0.46 PE RVUs in comparison to the PE RVUs for other PFS services that are conceptually similar but do not include a treadmill, arm ergometer, monitoring devices, or emergency carts.

Response: Payment for services under the PFS is resource-based, and individual services are valued based upon the resources needed to provide the typical service. As we noted in the CY 2011 PFS proposed rule (75 FR 40103), pulmonary rehabilitation services reported under HCPCS code G0424 can be furnished either individually or in groups and we continue to believe that 30 minutes of respiratory therapist time is appropriate for valuing the typical pulmonary rehabilitation service. We believe that

pulmonary rehabilitation in the physician's office is most commonly furnished to a group of patients, rather than one-on-one for 60 minutes of respiratory therapist time. Regarding the commenter who was concerned that the PE for HCPCS code G0424 was undervalued in comparison to similar services that do not use the equipment necessary for HCPCS code G0424, we note that we have utilized the standard PFS PE methodology to develop the PE RVUs for HCPCS code G0424 based on the direct PE inputs we consider to be appropriate.

Comment: One commenter suggested that the valuing of HCPCS code G0424 is flawed and does not fully account for the inclusion of all professionals who are involved in the pulmonary rehabilitation program, specifically physical therapists. In addition, the commenter referenced the CY 2010 PFS final rule with comment (74 FR 61884) where CMS stated and recognized that physical therapists provide pulmonary rehabilitation services. The commenter believes that by only basing the value on services performed by respiratory therapists, CMS has miscalculated the payment for the comprehensive, multidisciplinary pulmonary rehabilitation program and recommended that CMS create a separate HCPCS code with a higher value that could be used to delineate those patients who require individualized physical therapy within the pulmonary rehabilitation program.

Response: Like all services paid under the PFS, pulmonary rehabilitation is valued based on the staff type who would typically perform this service, a respiratory therapist. Because the items and services furnished by a pulmonary rehabilitation program are individualized, we expect that evaluations and individualized treatments would be conducted by one or more members of the multidisciplinary team of the pulmonary rehabilitation program with the appropriate expertise. Therefore, individualized treatment by a physical therapist would be furnished when required by the patient as part of the pulmonary rehabilitation plan of care. However, we do not believe individualized treatment would be typical and, therefore, we do not believe the creation of a separate HCPCS code with a higher value is necessary to recognize those cases that require individualized physical therapy as part of a pulmonary rehabilitation program.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to increase the work RVUs for HCPCS code

G0424 to 0.28 for CY 2011 to be comparable to the work RVUs for cardiac rehabilitation with monitoring (CPT code 93798). In addition, we are finalizing our CY 2011 proposal to increase the clinical labor time for the respiratory therapist from 15 minutes to 30 minutes and to crosswalk the PE equipment inputs for HCPCS code G0424 to those for respiratory treatment services (HCPCS code G0238), which include a 1-channel ECG and a pulse oximeter.

F. Application of Tissue Cultured Skin Substitutes to Lower Extremities (HCPCS Codes G0440 and G0441)

There are currently two biological products, Apligraf and Dermagraft, which are FDA-approved for the treatment of diabetic foot ulcers. While commonly used by podiatrists for this purpose, these products are also used by other specialists in the treatment of other clinical conditions, such as burns.

Many Medicare contractors have established local coverage determinations specifying the circumstances under which these services are covered. In the case of diabetic foot ulcers, clinical studies of Apligraf application were based on up to 5 treatments over a 12-week period. In contrast, Dermagraft was applied weekly, up to 8 treatments over a 12-week period.

The skin substitute CPT codes were reviewed and new codes were last created by the CPT Editorial Panel for CY 2006. There are currently 2 skin repair CPT codes that describe Apligraf application, one primary code, CPT code 15340 (Tissue cultured allogeneic skin substitute; first 25 sq cm or less) and one add-on code, CPT code 15341 (Tissue cultured allogeneic skin substitute; each additional 25 sq cm, or part thereof (List separately in addition to code for primary procedure)) and 4 codes that describe Dermagraft application, two initial codes based on body area, CPT codes 15360 (Tissue cultured allogeneic dermal substitute, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children) and 15365 (Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children) and two add-on codes, CPT codes 15361 (Tissue cultured allogeneic dermal substitute, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)) and 15366 (Tissue cultured allogeneic

dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)).

In the CY 2011 PFS proposed rule (75 FR 40103), we noted that several stakeholders had expressed concern about the appropriateness and equity of the coding and payment for these services, given their similar uses and the office resources required when the products are applied repeatedly over a number of weeks for treatment of lower extremity ulcers. They were concerned that current coding, with the associated payment policies and relative values, does not provide for appropriate payment for the services based on how they are furnished. In addition, some stakeholders believe that the current coding and payment provides a financial incentive for the selection of one tissue cultured product over another, rather than facilitating clinical decision-making based solely on the most clinically appropriate product for the patient's case. For example, the Dermagraft and Apligraf application codes have 90-day and 10-day global periods, respectively, and their current values include several follow-up office visits. When patients are treated periodically with repeated applications of the products over several weeks, the patients may be seen in follow-up by the physician. However, those encounters would not be evaluation and management visits but, instead, would be procedural encounters that would typically be valued differently under the PFS than the follow-up office visits currently included in the values for the Dermagraft and Apligraf application codes. Furthermore, while different stakeholders indicated that debridement and site preparation are variably performed when these products are applied, the CPT codes for Dermagraft application allow separate reporting of these preparation services when they are performed, while the Apligraf application codes bundle these services. Since CY 2006, the PFS has accepted the AMA RUC work and PE recommendations for the Dermagraft and Apligraf application codes and has paid accordingly.

With respect to Medicare payment policy, some Medicare contractors allow the use of modifier -58 (Staged or related procedure or service by the same physician during the postoperative period) to be reported with the skin substitute application codes and provide full payment for the service

each time it is performed, even if the subsequent application(s) is within the global period of the service. Other contractors do not allow the use of modifier -58 and, therefore, provide a single payment for a series of applications over 90 days or 10 days, as applicable to the particular code reported for the product's initial application.

Because of the current inconsistencies in valuing similar skin substitute application services and the common clinical scenarios for their use for Medicare beneficiaries, in the CY 2011 PFS proposed rule (75 FR 40103), we stated that we believe it would be appropriate to temporarily create Level II HCPCS G-codes to report application of tissue cultured skin substitutes applied to the lower extremities in order to provide appropriate and consistent payment for the services as they are commonly furnished. Therefore, we proposed to create two new HCPCS G-codes for CY 2011, GXXX1 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; first 25 sq cm or less) and GXXX2 (Application of tissue cultured allogeneic skin or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm), that would be recognized for payment under the PFS for the application of Apligraf or Dermagraft to the lower limb. These codes would not allow separate reporting of CPT codes for site preparation or debridement. We emphasized that we would expect that the use of these HCPCS G-codes for payment under Medicare would be temporary, while stakeholders work through the usual channels to establish appropriate coding for these services that reflects the current common clinical scenarios in which the skin substitutes are applied. Furthermore, we stated that we would expect to receive recommendations from the AMA RUC for appropriate work values and direct practice expense inputs for the applicable codes, according to the usual process for new or revised codes.

Under the PFS, as a temporary measure, the HCPCS G-codes would be assigned a 0-day global period so payment would be made each time a covered service was furnished. We proposed to base payment on the physician work relative values and the direct PE inputs for the existing CPT codes for Apligraf application, with adjustments for the global period differences because the HCPCS G-codes and the Apligraf application CPT codes.

These CPT codes resemble the new HCPCS G-codes in terms of wound size description and the inclusion of site preparation and debridement in their current values so we believe they appropriately represent the physician work involved in the proposed HCPCS G-codes. However, we proposed to adjust the work RVUs of the Apligraf application codes to derive the HCPCS G-code proposed CY 2011 work values by extracting the values for any office visits and discharge day management services because the HCPCS G-codes have a 0-day global period. In addition, we proposed to adjust the direct PE inputs of the Apligraf application codes to develop the proposed CY 2011 direct PE inputs of the HCPCS G-codes that have a 0-day global period.

Our crosswalks and adjustments resulted in proposed CY 2011 work RVUs of 2.22 for HCPCS code GXXX1 and 0.50 for HCPCS GXXX2. The proposed direct PE inputs for HCPCS codes GXXX1 and GXXX2 are included in the direct PE database for the CY 2011 proposed rule that is posted on the CMS Web site at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp>.

We noted that many Medicare contractors currently have local coverage policies that specify the circumstances under which Medicare covers the application of skin substitutes. The local coverage policies may include diagnostic or prior treatment requirements, as well as frequency limitations on the number and periodicity of treatments. We stated our expectation that these policies would be updated in the context of the temporary new HCPCS G-codes that we proposed for use in CY 2011 to report the application of tissue cultured allogeneic skin or dermal substitutes. We proposed to establish the HCPCS G-codes for temporary use in CY 2011 in order to improve the consistency and resource-based nature of PFS payments for skin substitute application services that require similar resources. However, we noted our continued interest in ensuring that skin substitutes are properly utilized for Medicare beneficiaries who will benefit from that treatment. We indicated that we would continue to monitor the utilization of these services and plan to identify any concerning trends in utilization that contractors may want to examine further through medical review or other approaches.

Comment: While acknowledging concerns with the existing CPT codes for the application of skin substitutes, several commenters opposed the proposed HCPCS G-codes because the commenters believe that CMS should

wait for new codes to be created by the CPT Editorial Panel and the associated recommendations to be developed by the AMA RUC for physician work and direct PE inputs for any new codes. The commenters argued that CMS' proposal to create new temporary codes would circumvent or otherwise influence the well-established processes already underway to address issues identified by the stakeholders. Several commenters pointed out that CMS' proposal would not treat the application of skin substitutes that are not tissue cultured similarly to the procedures for the application of Apligraf and Dermagraft. Because these commenters argued that inconsistencies in coding and payment for the other products would continue, several commenters recommended that CMS await a more comprehensive solution from the CPT Editorial Panel.

On the other hand, a number of commenters supported the proposal to establish the two new HCPCS G-codes, and a few of these commenters recommended no changes to the proposed HCPCS code descriptors. However, one commenter who generally supported the proposal recommended that CMS expand the proposed HCPCS code descriptors to incorporate the application of a broader range of skin substitutes that were not tissue cultured, specifically to include the application of biologically active skin substitutes.

Another commenter requested that CMS clarify the meaning of "dermal substitute." This commenter also requested that CMS delete the words "for use on lower limb" and allow the new codes to be used for application of tissue cultured skin or dermal substitutes on locations other than the lower limb. Consistent with this perspective, the commenter further recommended that CMS not recognize the existing CPT codes for application of Apligraf and Dermagraft on other areas of the body. The commenter argued that, as proposed, the HCPCS G-codes would lead to confusion and the potential for fraudulent billing because both a HCPCS G-code and a CPT code could describe the application of the same product to the lower extremities. The commenter believes that CMS should only recognize the proposed G-codes under the PFS for the application of tissue cultured skin or dermal substitutes to any body site, to allow for consistency in reporting and payment of these services.

Several commenters requested that CMS provide guidance on the proper use of the current CPT codes and new HCPCS G-codes for reporting the application of skin substitutes. Other

commenters were concerned that the temporary HCPCS G-codes could create confusion, disrupt physician's office billing policies, and otherwise burden coding staff and advised CMS to not finalize the proposal.

Response: We appreciate the perspectives of stakeholders and we share the commenters' desire for appropriate and consistent payment that is resource-based for the application of skin substitutes as these services are commonly furnished for appropriate clinical indications. We appreciate and value the work of the CPT Editorial Panel in evaluating the complexities and nuances in this area and look forward to reviewing any new codes created for CY 2012 or later years and the AMA RUC recommendations for the physician work and direct PE inputs for those new codes. We note that there are no new codes for CY 2011 that describe the application of skin substitutes and, therefore, new codes would not be available before CY 2012 at the earliest.

In proposing to create two temporary HCPCS G-codes for CY 2011, we sought a fair and balanced temporary alternative to provide appropriate and equitable payment for the application of tissue cultured skin or dermal substitutes to the lower extremities. While we understand from stakeholders that the work of the CPT Editorial Panel is ongoing in this area, our proposal was specifically to establish temporary HCPCS G-codes that would allow for more appropriate reporting and payment under certain scenarios in the short term while a more comprehensive solution is being developed and refined by expert advisors. Because our proposal was so limited in scope and temporary, clearly it was not our intention to circumvent or unduly influence the CPT Editorial Panel or the AMA RUC as these groups proceed in their comprehensive work to establish new codes and values for the application of skin substitutes. We would also not expect that the characteristics of the temporary HCPCS G-codes, in terms of terminology in the code descriptors, global periods, work values, or direct PE inputs, should shape or otherwise affect the ongoing work of stakeholders who are developing a complete approach to coding for the application of skin substitutes. We acknowledge that new CPT codes and their AMA RUC-recommended values and direct PE inputs arising from these processes may appropriately differ in one or multiple characteristics from the temporary HCPCS G-codes.

With regard to the commenters who were concerned about the limited scope

of our proposal and suggested that we not proceed or that we broaden the scope of the proposed code descriptors to address inequities and inconsistencies that the commenters believe would persist under our proposal, we believe that the limited proposal continues to be the most appropriate temporary approach for CY 2011. First, it was not our intention to comprehensively address the issue of coding revisions for the application of skin substitutes because we are aware of the ongoing work of the CPT Editorial Panel in this area and would not want to undermine its deliberative process. Moreover, based on the public comments we received, we have reason to believe that a revised coding structure for the application of skin substitutes will be available soon. Second, the HCPCS G-codes that we proposed had a 0-day global period based on the FDA-approved indications and regimens for the application of the tissue cultured products to which the codes would apply, and we are not certain to what extent a 0-day global period would be appropriate for the application of other skin substitutes. Third, while several commenters provided suggestions regarding alternative language that could be used in the HCPCS G-code descriptors, it is unclear which skin substitutes products would be incorporated under the revised terms. Some of the suggested alternatives would use phrases such as "biologically active" that, as far as we know, are not fully defined in the medical community and are not currently used in the CPT code descriptors that describe the application of skin substitutes. Because of our uncertainty in this regard, we would be hesitant to make such significant revisions to the HCPCS G-code descriptors without the opportunity for public notice and comment, which would allow stakeholders the opportunity to provide input about revised code descriptors and the appropriateness of the values for the HCPCS G-codes. In contrast, our proposal relied upon the use of terms in the HCPCS G-code descriptors that are already included in the descriptors for established CPT codes and, therefore, we do not believe we would be setting a precedent that would affect the current work of the CPT Editorial Panel on this issue. Finally, we do not see a need to further clarify terms, such as "dermal substitute," in the HCPCS G-code descriptors because these are currently used in the CPT code descriptors and the same definitions would apply to the G-codes.

Furthermore, we believe it would continue to be appropriate to recognize the existing CPT codes for the application of tissue cultured skin or dermal substitutes to areas of the body other than the lower extremities. We established the 0-day global period, the physician work values, and the direct PE inputs for the proposed HCPCS G-codes based on the specific clinical scenarios where Apligraf or Dermagraft would be applied to treat lower extremity ulcers. We do not necessarily believe that the same global periods and values would be appropriate for the application of these products to other body areas under different clinical scenarios. The usual coding guidance that providers should report the most specific HCPCS code that describes the service furnished would apply in the case of the application of Apligraf or Dermagraft. If one of these products were applied to the lower extremities, we would expect the HCPCS G-codes to be reported, rather than the CPT codes, as the HCPCS G-codes are more specific to application in that body area.

Finally, because it is our common practice to create one or more new HCPCS G-codes for payment under the PFS each year, we believe that physicians' offices are experienced in integrating new codes into the reporting of services furnished and paid under the PFS. Not only are local coverage determinations commonly applicable to the application of skin substitutes, we also understand that there are a subset of physicians who regularly apply tissue cultured skin or dermal substitutes to lower extremities to treat ulcers. In this context, we believe that our national educational efforts, in addition to education by local contractors, will quickly disseminate information to the relevant practitioners about these new HCPCS G-codes and their appropriate use in CY 2011.

After consideration of the public comments we received, we are finalizing our proposal, with editorial modification, to create two new HCPCS G-codes for reporting the application of tissue cultured skin substitutes and dermal substitutes to the lower extremities in CY 2011. For internal consistency, we are changing the descriptors of HCPCS codes GXXX1 and GXXX2 from the proposed language to both refer to "skin substitute or dermal substitute." HCPCS code GXXX2 as proposed read "Application of tissue cultured allogeneic skin or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm." The final codes are HCPCS code G0440 (Application of

tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; first 25 sq cm or less) and HCPCS code G0441 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm) that will be recognized for payment under the PFS in CY 2011.

Comment: A number of commenters supported the assignment of a 0-day global period to the application of tissue cultured skin or dermal substitutes. Many expressed the view that assigning a 0-day global period to the codes would allow the products to be prescribed and administered based on their clinical value, without concern for payment differences between products. The commenters who did not support the 0-day global period were those who believe that the proposal would further payment inequities between products used similarly. For example, one commenter reasoned that, insofar as a patient is likely to require multiple administrations of a skin substitute product during a 90-day period, providers would have a significant incentive to use the products whose application would be reported under the proposed codes rather than a product whose application procedure continues to have a 90-day global period.

Another commenter addressed the bundling of site preparation and debridement into the proposed HCPCS codes GXXX1 and GXXX2. The commenter argued that the proposed values for the new codes HCPCS G-codes would not be sufficient to account for this work. The commenter recommended that the proposed values should be adjusted upward or separate payment should be allowed for site preparation and/or debridement.

In reviewing CMS' proposed methodology for setting the physician work values for the HCPCS G-codes, one commenter contended that CMS should finalize a total of 2.86 work RVUs for GXXX1 instead of the proposed 2.22 work RVUs. The commenter claimed that the work RVUs for GXXX1 should be crosswalked from CPT code 15340 less only the physician work for the two post-procedure visits in CPT code 15340 which are not included in HCPCS code GXXX1.

Another commenter recommended that CMS review the proposed PE inputs for the new HCPCS G-codes. Specifically, the commenter explained that the only difference in clinical labor time between CPT code 15340 and

HCPCS code GXXX1 should be an adjustment to account for the difference in the global period (10 days for CPT code 15340 and 0 days for HCPCS code GXXX1). The commenter also stated that HCPCS code GXXX1 should include all the pre-service clinical staff time in CPT code 15340, yet did not for the proposed rule. The commenter was unclear on whether the post-service clinical labor time was properly adjusted to account for the change in global period from CPT code 15340 to HCPCS code GXXX1.

Response: We agree with the commenters that a 0-day global period is the most appropriate for the application of tissue cultured skin substitutes or dermal substitutes to the lower limb for purposes of the temporary HCPCS G-codes, pending a comprehensive change in coding established by the CPT Editorial Panel. As discussed in the previous response, we sought a fair and balanced temporary solution to provide appropriate and consistent payment for the application of tissue cultured skin substitutes or dermal substitutes to the lower limb. The commenters who did not support the 0-day global period were those who were more broadly against the creation of the new HCPCS G-codes codes because of potential payment imbalances between products that would be included in the new codes and those that would not be. No commenters asserted that the 0-day global period would be inappropriate for the codes to which we proposed to apply that period.

The proposed physician work values for HCPCS G-codes G0440 and G0441 (proposed as HCPCS codes GXXX1 and GXXX2, respectively) were crosswalked, with adjustment for the different global periods, from CPT codes 15340 and 15341. CPT codes 15340 and 15341 currently include site preparation and debridement and, as such, the additional reporting of a separate CPT code for these activities, if performed on the same site as the skin substitute application procedure, is not permitted. We believe that the values for both the current CPT codes and the HCPCS G-codes are clinically appropriate for the services they describe, with payment for site preparation and debridement bundled if furnished.

In response to a commenter's concern, we reviewed the proposed valuation of the physician work for HCPCS codes G0440 and G0441 to ensure consistency with our proposed methodology, and we continue to believe that the appropriate work value for HCPCS code G0440 is 2.22 RVUs as we proposed. HCPCS code G0440 was crosswalked to CPT code

15340, with adjustments to account for the 0-day global period of the HCPCS G-code. CPT code 15340, with a 10-day global period, is currently valued to include two CPT code 99212 (level 2 established patient office or other outpatient visit) post-operative visits (0.48 RVUs each, 0.96 RVUs total) and half of one CPT code 99238 (Hospital discharge day management; 30 minutes or less) visit (1.28 RVUs each, 0.64 RVUs total). CPT code 15340 has a current total physician work value of 3.82 RVUs. To adjust for the 0-day global period for the minor procedure described by HCPCS code G0440, we believe it would be appropriate to deduct the value of both the two post-operative office visits and the discharge day visit. In the case of post-operative office visits, these may be separately reported and paid if medically reasonable and necessary. In addition, we also do not believe that a half discharge day visit should be a building block based on the clinical characteristics of the procedure described by HCPCS code G0440. When we make these adjustments to the work value of 3.82 RVUs for CPT code 15340, 2.22 work RVUs, the value we proposed for HCPCS code G0440, remain.

We also reviewed the proposed PE inputs included in the direct PE database for the CY-2011 PFS proposed rule. Like the physician work values, to determine the PE inputs we crosswalked HCPCS code G0440 from CPT code 15340 and HCPCS code G0441 from CPT code 15341. As one commenter observed, the difference in the values should reflect the shift from a 10-day global period to a 0-day global period. However, for PE inputs, the change in global period typically affects both the pre- and post-service PE inputs. To establish the post-operative clinical labor time for HCPCS code G0440, we subtracted out the time associated with the two CPT code 99212 visits that were removed (32 minutes total) and the half discharge day visit (19 minutes total) that was eliminated, bringing the post-operative clinical labor time down from 54 minutes to three minutes. For the pre-service activities, while 0-day global period procedures generally have 0 minutes of pre-service clinical labor time allocated to them, we believe that 5 minutes in the nonfacility setting and 10 minutes in the facility setting reflect more appropriate pre-service clinical labor times in the instance of HCPCS code G0440. These revised pre- and post-service clinical labor times were reflected in the proposed CY 2011 direct PE database for HCPCS code G0440.

While we valued the physician work and clinical labor time PE inputs

according to the crosswalk methodology as described in the CY 2011 PFS proposed rule (75 FR 40103 through 40104), upon review of the new CY 2011 HCPCS G-codes for this final rule with comment period, we noticed that we had not applied the proposed methodology to the PE inputs for equipment and supplies. Therefore, consistent with our proposal, we have adjusted the supply and equipment PE inputs for HCPCS codes G0440 and G0441 in the final CY 2011 PE database to reflect the shift to a 0-day global period from a 10-day global period for these HCPCS codes. As the equipment and supply PE inputs for the 10-day global period CPT codes reflect those necessary for multiple visits to the provider, the equipment and supply inputs for the new HCPCS G-codes codes should reflect more appropriate values for codes with a 0-day global period.

After consideration of the public comments we received, we are finalizing our proposal to value HCPCS codes G0440 and G0441 as 0-day global procedures into which site preparation and debridement are bundled. As we proposed, under our final policy we have crosswalked the physician work RVUs and direct PE inputs from CPT codes 15340 and 15341 to HCPCS codes G0440 and G0441, respectively, with adjustments. We have adjusted the work RVUs and the direct PE inputs (clinical labor, equipment, and supplies) to reflect the shift from a 10-day global period to a 0-day global period for the new HCPCS G-codes.

Comment: Several commenters were concerned about the use of the -58 modifier for 10-day and 90-day global surgical procedures for the application of skin substitutes when repeated application of a product within the global period is the typical case. The commenters were largely supportive of eliminating the use of the -58 modifier for the two new HCPCS codes which, the commenters remarked, has been the source of some confusion and has been interpreted inconsistently by Medicare contractors. The commenters explained that the change to a 0-day global period would result in no need for the -58 modifier to be reported with the HCPCS G-codes. Several commenters recommended that CMS provide guidance on use of the -58 modifier with the existing CPT codes for the application of skin substitutes, most of which have 90-day global period and all of which would continue to be recognized for payment under the PFS.

Response: Assignment of a 0-day global period for the two HCPCS G-codes eliminates the need for use of the

-58 modifier with these two new codes. We recognize that the -58 modifier may continue to be used in conjunction with the other CPT codes with 10-day or 90-day global periods for the application of skin substitutes. Specific determinations of the appropriate use of the -58 modifier will continue to be the responsibility of individual Medicare contractors.

In summary, after consideration of the public comments we received, we are finalizing our CY 2011 proposal, with modification to adjust the supply and equipment direct PE inputs, as well as editorial modification to the code descriptors for consistency, to create two new HCPCS G-codes for CY 2011, G0440 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; first 25 sq cm or less) and G0441 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm), that will be recognized for payment under the PFS for the application of products described by the codes to the lower limb. These codes do not allow separate reporting of CPT codes for site preparation or debridement. Providers reporting the application of tissue cultured allogeneic skin substitute or dermal substitutes to the lower limb for payment under the PFS in CY 2011 should report HCPCS code G0440, along with HCPCS code G0441 if applicable based on wound size, and not CPT code 15340, 15341, 15360, 16361, 15365, or 15366.

Under the PFS, as a temporary measure, the HCPCS G-codes are assigned a 0-day global period so payment is made each a time a covered service is furnished. As proposed, we are basing payment on the physician work relative values and the direct PE inputs for the existing CPT codes 15340 and 15341 for Apligraf application, with adjustments for the global period differences between the HCPCS G-codes and the Apligraf application CPT codes. However, as we proposed, we have adjusted the work RVUs of the Apligraf application codes to derive the final CY 2011 HCPCS G-code work values by extracting the values for any office visits and discharge day management services because the HCPCS G-codes have a 0-day global period. In addition, with modifications of our proposed PE equipment and supply inputs to be fully consistent with our crosswalk proposal, we have adjusted the direct PE inputs of the Apligraf application codes to

develop the final CY 2011 direct PE inputs for the HCPCS G-codes that have a 0-day global period.

Our crosswalks and adjustments result in CY 2011 final work RVUs of 2.22 for HCPCS code G0440 and 0.50 for HCPCS G0441. The final direct PE inputs for HCPCS codes G0440 and G0442 are included in the direct PE database for the CY 2011 PFS final rule with comment period rule.

G. Canalith Repositioning (CPT code 95992)

For CY 2009, CPT created a new code for canalith repositioning, specifically CPT code 95992 (Canalith repositioning procedure(s) (eg, Epley maneuver, Semont maneuver), per day). This service may be furnished by both physicians and therapists. Although we accepted the AMA RUC-recommended work RVUs and PE inputs, we initially bundled this procedure on an interim basis in the CY 2009 PFS final rule with comment period (73 FR 69896), indicating that we believed it would be paid through the E/M service that it would accompany. Subsequently, in view of concerns from therapists who cannot furnish E/M services, we clarified that therapists could report one of the generally defined therapy CPT codes when canalith repositioning was furnished. In the CY 2010 PFS final rule with comment period (74 FR 61766), we changed the code's status under the PFS to "not recognized for payment under Medicare," consistent with our expectation that another payable code would be reported when the service was furnished.

Based on further information from stakeholders regarding the distinct and separate nature of this procedure from an E/M service and their request that we recognize this CPT code for payment, similar to our separate payment for most other procedures commonly furnished in association with an E/M service, we proposed to recognize CPT code 95992 for payment under the CY 2011 PFS, consistent with our typical treatment of most other codes for minor procedures. In doing so, we proposed to change the code's status to "A" and utilize the CY 2009 RUC recommendations for work RVUs (0.75) and PE inputs for establishing its payment in CY 2011. (That is, status "A" means Active code. These codes are separately payable under the PFS if covered.) Because canalith repositioning (CPT code 95992) can be furnished by physicians or therapists as a therapy service under a therapy plan of care or by physicians as physicians' services outside of a therapy plan of care, we would add CPT code

95992 to the "sometimes therapy" list on the therapy code abstract file.

Comment: Many commenters supported CMS' proposal to acknowledge the distinct and separate nature of CPT code 95992 from an E/M service by recognizing CPT code 95992 for separate payment and agreed with the proposed use of the AMA RUC-recommended values for work RVUs (0.75) and PE inputs for establishing payment in CY 2011.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to recognize CPT code 95992 for payment under the PFS. As a result, the code's status has been changed to "A" in Addendum B to this final rule with comment period and the CY 2009 AMA RUC recommendations for work RVUs (0.75) and PE inputs will be used for establishing its payment in CY 2011. (That is, status "A" means Active code. These codes are separately payable under the PFS if covered.) CPT code 95992 has also been added to the "sometimes therapy" list on the therapy code abstract file.

H. Intranasal/Oral Immunization Codes (CPT codes 90467, 90468, 90473, and 90474)

To ensure that the PE RVUs are consistent between the intranasal/oral and injectable immunization administration CPT codes that describe services that utilize similar PE resources, we proposed to crosswalk the PE values for CPT code 90471 (Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)) to CPT codes 90467 (Immunization administration younger than age 8 years (includes intranasal or oral routes of administration) when the physician counsels the patient/family; first administration (single or combination vaccine/toxoid), per day) and 90473 (Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)).

Similarly, we also proposed to crosswalk the PE values for CPT code 90472 (Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)) to CPT codes 90468 (Immunization administration younger than age 8 years (includes intranasal or oral routes of administration) when the

physician counsels the patient/family; each additional administration (single or combination vaccine/toxoid), per day (List separately in addition to code for primary procedure)) and 90474 (Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)).

Comment: Many commenters expressed support for the proposal. One commenter questioned why the PE values are currently different and several other commenters urged CMS to utilize the AMA RUC recommendations and the resource-based methodology to develop PE RVUs for these services in CY 2011, rather than crosswalk the PE RVUs.

Response: We appreciate the support from the commenters for our proposal. We would note that, even with the same direct PE inputs, somewhat different PE RVUs for the various CPT codes may result from our PE methodology that relies upon the historical specialty mix, as reflected in the most recent PFS utilization data, of providers who furnished the services to allocate the indirect PE. Therefore, because we believe it is especially important to have consistent PE values for payment of these similar services under the PFS, we are unable to utilize the AMA RUC direct PE input recommendations and the resource-based methodology to develop PE RVUs for these services. While in general we value services under the PFS with reference to the direct PE inputs recommended by the AMA RUC and our standard resource-based approach to establishing PE RVUs, we note that we also commonly use crosswalks to other similar codes to establish the values for services in certain circumstances. In this instance, we believe a crosswalk is particularly appropriate in order to maintain appropriate relativity between similar services and avoid the potential for non-clinically-based bias in favor of one vaccine administration technique over another.

Comment: A few commenters questioned why the CY 2011 proposed rule referenced "physician" counseling when identifying CPT codes 90467 and 90468 and requested clarification that nurse practitioners (NPs) and physician assistants (PAs) also be included within the scope of this proposal.

Response: We would like to clarify that the reference to "physician" counseling noted by the commenters is part of the official CPT code descriptors for CPT codes 90467 and 90468. Consistent with our usual interpretation of CPT codes that include the term

physician in the code descriptor, for Medicare payment purposes this specificity does not exclude NPs or PAs from providing counseling to the patient/family that is within the NP's or PA's scope of practice.

Comment: Several commenters recommended modifying the proposal by crosswalking the PE RVUs for CPT code 90466 (Immunization administration younger than age 8 years of age (includes percutaneous, intradermal, subcutaneous, or intramuscular injections) when the physician counsels the patient/family; each additional injection (single or combination vaccine/toxoid) per day (List separately in addition to code for primary procedure)) to CPT code 90468 to achieve parity and reflect the additional clinical time and other practice expenses expended to provide immunizations to young children.

Response: For CY 2011, the CPT Editorial Panel revised the reporting of immunization administration services for the pediatric population. As a result, CPT codes 90466 and 90468 have been deleted and replaced with CPT code 90461 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health professional; each additional vaccine/toxoid component (List separately in addition to code for primary procedure)). In addition, CPT codes 90465 (Immunization administration younger than 8 years of age (includes percutaneous, intradermal, subcutaneous, or intramuscular injections) when the physician counsels the patient/family; first injection (single or combination vaccine/toxoid), per day) and 90467 were deleted and replaced with CPT code 90460 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first vaccine/toxoid component).

We agree with the commenters who believe that consistency in the PE RVUs across CPT codes with different code descriptors reflecting immunization services to different populations or using different routes of administration is desirable. As a matter of longstanding policy (69 FR 66307), we have crosswalked the nonfacility PE value from CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) [predecessor CPT codes 90782 and 90772] to the PE values for CPT code 90471 and to the HCPCS G-codes for administration of specific vaccines. We

will continue this crosswalk for CY 2011 and, as we proposed, also crosswalk the nonfacility PE value of CPT code 90471 to CPT code 90473. The PE value for CPT code 90472 is based on the direct PE inputs for that code, according to the usual PFS methodology. We will crosswalk the nonfacility PE value of CPT code 90472 to CPT code 90474 for CY 2011 as we proposed. Finally, we are modifying our CY 2011 proposal and crosswalking the nonfacility PE RVUs for CPT codes 90472 and 90474 to new CPT code 90461 (replacement code for CPT codes 90466 and 90468) for CY 2011. In addition, we will crosswalk the nonfacility PE RVUs for CPT codes 90471 and 90473 to new CPT code 90460 (replacement code for CPT codes 90465 and 90467).

After consideration of the public comments we received and the CY 2011 changes in codes for pediatric immunization services by the CPT Editorial Panel, we are finalizing our CY 2011 proposals, with the following modifications. In summary, for CY 2011 we will—

- Crosswalk the nonfacility PE RVUs for CPT codes 90472 and 90474 to new CPT code 90461; and
- Crosswalk the nonfacility PE RVUs for CPT codes 90471 to 90473 to new CPT code 90460.

I. Refinement Panel Process

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on interim physician work RVUs for CPT codes with an interim final status in each year and developing final work values for the subsequent year. We decided that the panel would be comprised of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each individual would individually rate the work of the procedure. We believed that establishing the panel with a multispecialty group would balance the interests of those who commented on the work RVUs against the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. Historically, the refinement panel has based its recommendation to change a work value or to retain the interim value has hinged solely on the outcome of a statistical test on the ratings (an F-test).

Depending on the number and range of codes that public commenters, typically specialty societies, request be

subject to refinement, we establish refinement panels with representatives from 4 groups of physicians: Clinicians representing the specialty most identified with the procedures in question; physicians with practices in related specialties; primary care physicians; and contractor medical directors (CMDs). Typically the refinement panels meet in the summer prior to the promulgation of the final rule finalizing the RVUs for the codes. Typical panels have included 8 to 10 physicians across the 4 groups. Over time, the statistical test used to evaluate the RVU ratings of individual panel members have become less reliable as the physicians in each group have tended to select a previously discussed value, rather than independently evaluating the work. In addition, the resulting RVUs have occasionally exhibited rank order anomalies (that is, a more complex procedure is assigned lower RVUs than a less complex procedure).

Recently, section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) authorized the Secretary to review potentially misvalued codes and make appropriate adjustments to the relative values. In addition, MedPAC has encouraged CMS to critically review the values assigned to the services under the PFS. MedPAC has stated its belief that CMS has historically relied too heavily on specialty societies to identify services that are misvalued by accepting a high proportion of the recommendations of the AMA RUC.

We believe the refinement panel process continues to provide stakeholders with a meaningful opportunity to review and discuss the interim work RVUs with a clinically diverse group of experts which then provides informed recommendations to CMS. Therefore, in the CY 2011 proposed rule (75 FR 40105), we indicated that we would like to continue the refinement process, including the established composition that includes representatives from the 4 groups of physicians, but with administrative modification and clarification. Specifically, for refinement panels beginning in CY 2011 (that is, for those codes with CY 2011 interim values that would be subject to refinement during CY 2011), we proposed to eliminate the use of the F-test and instead base revised RVUs on the median work value of the panel members' ratings. We believe this approach will simplify the refinement process administratively, while resulting in a final panel recommendation that reflects the summary opinion of the panel members

based on a commonly used measure of central tendency that is not significantly affected by outlier values. In addition, we clarified that we have the final authority to set the RVUs and, therefore, may make adjustments to the work RVUs resulting from refinement if policy concerns warrant their modification.

Comment: Most commenters expressed support for the proposal to eliminate the F-test, including the increased transparency of the refinement panel process that the commenters believe would result from this change. Many commenters, including the AMA RUC, agreed with the use of the median work value of the panel members' ratings and believe the median would provide a clearer view of the central tendency of the estimates provided by the survey respondents. On the other hand, several commenters believe the current process is effective and eliminates the effects of agreement between the panel members' ratings.

The AMA RUC recommended that CMS be mindful when assigning individuals to the refinement panel to ensure that all members, including CMDs, are not from the same specialties that were involved in the public comment originating the issue under review. Another commenter cautioned CMS that the refinement panels need to be balanced and should ensure that there is at least one representative on the panel who has direct experience with the procedure or service under review.

Response: We appreciate the support of the commenters regarding our proposal to use the median work value of the panel members' ratings and will move forward to finalize our proposal for refinement panels beginning in CY 2011 (refinement of CY 2011 new/ revised codes with interim values).

When identifying individuals for the refinement panel, including CMDs, we attempt to select individuals from each of the different specialties with an interest in the codes being refined, not just the specialty or specialties responsible for the public comment originating the request for refinement. We also take steps to ensure that the panel members have direct experience and knowledge of the procedure or service under review. We will certainly continue our efforts in this regard. However, we note that in recent years the number of physicians who are available to participate in the refinement panel has been limited at times, and some specialty societies have had difficulty obtaining representation for the panel.

Comment: Several commenters urged CMS to use a methodology that would allow the AMA RUC-recommended value to prevail when appropriately supported by the pertinent specialty societies and when the value is strongly supported by the rank order and resources of the procedure, since the PFS final rule with comment period is the first opportunity for the public to see the RVUs for the coming calendar year. These commenters also believe a full and fair review process is warranted prior to the publication of these values in the final rule with comment period.

Response: We note that PFS payments for services are resource-based. When reviewing the AMA RUC recommendations, our decisions to value services are based on the resources needed to perform the typical service and, therefore, these decisions are based upon a thorough review of the AMA RUC recommendations in the context of the specific new or revised codes. In those cases where we reject the AMA RUC recommendations, we publish our rationale in the PFS final rule with comment period where we first make the values public. These values are published as interim final values that are subject to public comment. The public comment period serves as the opportunity for public review and we see no other alternative to this timing, given the timeframes in which the new or revised CPT codes and the AMA RUC recommendations regarding their values are available to us and in which the new or revised CPT codes must be incorporated into the PFS for payment.

Comment: Several commenters expressed concerns about the proposal to allow CMS to have the final authority to set the work RVUs if policy concerns warrant modifications to the values derived from the refinement process. These commenters opposed this proposal and recommended that the decisions of the refinement panels remain unchanged by CMS. The commenters believe a major strength of the current process is that it gives stakeholders a strong incentive to participate, knowing that the outcomes of the process will not be overturned by CMS.

Response: Although we appreciate the concerns raised by the commenters, by law, we retain the final responsibility and authority to set the RVUs and, therefore, may make adjustments to the work RVUs resulting from refinement if policy concerns (such as a rank order anomaly) warrant their modifications.

Comment: One commenter urged CMS to make the refinement process transparent and open to the public.

Response: We believe our proposal would make the refinement process more transparent, as noted by some commenters. We further believe that representation from specialty societies as part of the AMA RUC process for valuing the codes allows the input of physicians who have direct experience with the procedure or service under review.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to eliminate the use of the F-test for the refinement panels and, instead, we will base the revised RVUs on the median work value of the panel members' ratings. In addition, we note that CMS retains the final authority to set the RVUs and, therefore, make adjustments to the work RVUs resulting from refinement if policy concerns warrant their modification.

J. Remote Cardiac Monitoring Services (CPT codes 93012, 93229, 93268, and 93271)

In the CY 2011 PFS proposed rule (75 FR 40105), we reiterated our concerns about the issue of developing PE RVUs for services that are utilized 24 hours a day, 7 days a week (24/7), such as those that require certain centralized monitoring system equipment and which have been discussed in earlier PFS rulemaking cycles, most recently in the CY 2010 PFS final rule with comment period (74 FR 61755). We stated that the PE equipment methodology was developed for equipment that is in use during standard physician's office business hours and not equipment that is used in furnishing such continuous services, and that we would conduct further analysis of this issue. We indicated that services that were contractor-priced in CY 2009 remained contractor-priced in CY 2010 and that any proposed changes would be communicated through future rulemaking.

In the CY 2011 PFS proposed rule (75 FR 40105), we explained that since publication of the CY 2010 PFS final rule with comment period, we focused our additional analysis on 4 of the CPT codes that commenters have brought to our attention because they involve concurrent, remote, 24/7 attended monitoring of multiple patients from a central location: CPT code 93012 (Telephonic transmission of post-symptom electrocardiogram rhythm strip(s)); 24-hour attended monitoring, per 30 day period of time; tracing only); CPT code 93229 (Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data

analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports); CPT code 93268 (Wearable patient activated electrocardiographic rhythm derived event recording with presymptom memory loop, 24-hour attended monitoring, per 30 day period of time; includes transmission, physician review and interpretation); and CPT 93271 code (Wearable patient activated electrocardiographic rhythm derived event recording with presymptom memory loop, 24-hour attended monitoring, per 30 day period of time; monitoring, receipt of transmissions, and analysis).

We pointed out that of these four codes, CPT code 93229 is currently contractor-priced in CY 2010, meaning that the local Medicare contractors determine payment rates for the service within the PFS geographic areas in their jurisdiction. The three services that are currently nationally-priced on the PFS are in the first year of a 4-year transition to lower payment rates based on the use of the PPS data adopted in the CY 2010 PFS final rule with comment period. We refer readers to section II.A.2. of this final rule with comment period for a description of the general PFS PE methodology that is the basis for the following discussion of approaches to establishing PE RVUs for these four CPT codes.

In the CY 2011 PFS proposed rule, we explained that we examined several alternative methods for developing PE RVUs upon which PFS payment rates for these four CPT codes could be based. Each of these services involves transmission of information from multiple patients who wear individual monitoring devices that transmit patient-specific information to centralized equipment that is simultaneously in use for multiple patients. We stated that we believed it would be most consistent with the principles underlying the PFS PE methodology to classify the centralized monitoring equipment as an indirect cost since it is servicing multiple patients at the same time. We explained that after classifying this equipment as an indirect cost, we used our standard methodology to calculate an indirect practice cost index value for each code based on the PE/HR survey data of the historical mix of specialties providing these services. We went on to state that

establishing payment rates for these codes based on this approach would result in decreases in the payment rates for these services, including the typical contractor's price for CPT code 93229. For the three services that are nationally priced, these decreases would be relative to the lower payment rates based on the use of the PPIS data after the 4-year transition.

In the CY 2011 PFS proposed rule, we acknowledged that we had also received PE/HR data from the Remote Cardiac Services Provider Group (RCSPG), a group of Independent Diagnostic Testing Facility (IDTF) suppliers of these types of services. We explained that for sensitivity analysis purposes, we substituted these data for the PE/HR data of the specialties performing these services, while continuing to treat the centralized monitoring equipment as an indirect cost. We stated that we found that establishing payment rates for these codes based on the approach of using the submitted RCSPG PE/HR data would again result in decreases in the payment rates for these services, including the typical contractor's price for CPT code 93229. As in the prior alternative, the decreases for the nationally priced codes would be relative to the payment rates reflecting the 4-year transition to the PPIS data.

We indicated that although we believed that it would be most consistent with the principles underlying the PE methodology to classify the centralized monitoring equipment as an indirect cost, we also performed a sensitivity analysis of the payment rates if the centralized monitoring equipment were classified as a direct cost. In this simulation, we assumed that the centralized monitoring equipment was in year-round use, 7 days per week for 24 hours per day. We found that establishing payment rates for these codes based on the approach of classifying the centralized monitoring equipment as a direct cost would again result in decreases in the payment rates for the nationally priced services relative to their payment rates after the 4-year transition to the use of the PPIS data, as well as to the typical current contractor's price for CPT code 93229.

Finally, we explained that we considered proposing contractor-pricing for all four of these services for CY 2011 but were cognizant of past public comments on this issue that had requested that all of these services be priced nationally on the PFS, including the one service (CPT code 93229) that is currently contractor-priced.

In the CY 2011 PFS proposed rule, we also considered that the services currently priced nationally on the PFS

were scheduled to receive lower payment rates under the 4-year transition to the PPIS data and that the contractor's price for CPT 93229 was recently reduced in the area where the majority of the billings for this service currently occur.

We concluded that after taking all these factors into consideration, we were not proposing CY 2011 methodological or direct cost input changes for CPT codes 93012, 93268, or 93271—the services that are nationally priced under the PFS. We proposed to continue contractor-pricing for CPT 93229 for CY 2011. We solicited public comments on this issue, including responses to our analysis of alternative approaches to establishing PE RVUs for 24/7 services, and further discussion of the issues we identified in our alternative pricing methodologies. In addition, while we had focused the 24/7 services analysis up until that point in time on developing the PE RVUs for remote cardiac monitoring services, we observed that there may be 24/7 services in other areas of medicine, either currently paid under the PFS or in development for the future. Therefore, we also solicited public comments on these current or emerging 24/7 services, including descriptions of the similarities or differences between these other services and remote cardiac monitoring services, particularly with respect to the issues we identified in our analysis of alternative approaches to establishing PE RVUs for remote cardiac monitoring services under the PFS.

Comment: Several commenters expressed concerns regarding CMS' discussion of PFS payment for remote cardiac monitoring, which included no proposal of changes for CY 2011. The commenters pointed out the benefits of 24/7 remote monitoring services for cardiac and other specialty services and argued that these types of services can differ in complexity and frequency from one another and from traditional medical services. In general, the commenters expressed interest in CMS accurately capturing the cost components for all of these services, primarily arguing for the consideration of these costs as direct costs.

One commenter explained that the current methodology for assigning PE RVUs does not work for remote cardiac providers whose businesses are structured differently from physicians' practices and, as a result, the RVUs assigned to the services do not reflect their proper relative cost. Although CMS focused its analysis on services characterized by concurrent, remote, 24/7 attended monitoring of multiple patients from a single location, the

commenter addressed cardiac event monitoring, pacemaker monitoring, Holter monitoring, International Normalized Ratio (INR) monitoring, and a number of new monitoring technologies such as cardiac telemetry under the umbrella term of remote cardiac monitoring. The commenter asserted that the IDTF providers of remote cardiac monitoring services operate on a 24/7 basis because the services that they furnish require round-the-clock service and are, therefore, structured very differently from physicians' offices and other IDTFs. The commenter argued that CMS should utilize PE/HR data submitted by RCSPG, a group of IDTF suppliers of these types of services, to the entire ranging of cardiac monitoring services furnished by these providers. Alternatively, the commenter indicated that CMS could use the all physician indirect percentage, use an indirect practice cost index (IPCI) of one, and add equipment costs to the PE formula for allocating indirect costs in setting the PE RVUs for cardiac monitoring services. Finally, the commenter requested that if CMS did not adopt one of the previous two suggestions, then CMS should temporarily suspend the phase-in of the use of PPIS data for cardiac monitoring services. Several other commenters also requested that CMS suspend the PPIS transition for remote cardiac monitoring services.

Several commenters disagreed with CMS regarding the appropriateness of treating the centralized monitoring equipment as an indirect cost, arguing that the equipment is used specifically for patients that are receiving a specific service and, therefore, represents a direct cost like other medical equipment. The commenters contended that the centralized equipment is inherently different from other indirect practice expenses that are used to run a practice and are not tied directly to any one particular service. One commenter speculated that considering the cardiac monitoring equipment as an indirect expense would dilute the payment for this cardiac telemetry by distributing it to many people who are not providing it. Another commenter expressed concern that an indirect cost approach does not appropriately account for the significant differences in remote monitoring services and thus cannot accurately capture the cost components of each.

With respect to the remote cardiac monitoring service described by CPT code 93229 which is contractor-priced, one commenter made several specific requests, namely that CMS: (1) Nationally price CPT code 93229 rather

than contractor-price the service; (2) consider the centralized monitoring equipment associated with CPT code 93229 as a direct cost; (3) adjust the equipment utilization assumption for the centralized monitoring equipment from 100 percent to 50 percent; (4) use new direct cost inputs (for example, the cost of the monitoring device worn by patient) supplied by the commenter; (5) incorporate a new PE/HR, based on the cardiac monitoring industry-wide RCSPG PE/HR data applied to all cardiac monitoring services, based on data from two telemetry providers for CPT code 93229 that yields a PE/HR of \$243.22 that would be applied to CPT code 93229, or based on data for telemetry and cardiac event monitoring (CEM) which results in a PE/HR of \$214.79 that would be applied to telemetry and CEM services; and (6) apply an additional indirect allocation in the CMS PE methodology based on the equipment direct costs as previously recommended by one telemetry provider. The commenter provided equipment inputs and the associated prices and further recommended that CMS should continue to apply the clinical labor and supply input items associated with this services as recommended by the AMA RUC.

Response: We appreciate the continuing interest of the commenters in the pricing of cardiac monitoring services under the PFS. After further review of this issue, while we continue to recognize there are some unique aspects to the services, we do not agree with the commenters that the PE for cardiac monitoring services cannot be appropriately valued using the PFS PE methodology. After our review, we believe that we can appropriately identify and price the direct cost inputs for these services. Furthermore, we note that the PPIS data for allocating indirect costs is from a multispecialty, nationally representative PE survey of both physicians and NPPS and, as the most comprehensive source of PE information available to date, appropriate for use for cardiac monitoring services. Therefore, we disagree that we should suspend the PE transition to the PPIS data or otherwise change our established methodology for setting the PE RVUs furnished by a subset of providers in a certain specialty area.

We continue to believe that it is more appropriate to classify the costs associated with the centralized monitoring equipment, including the hardware and software, workstation, webserver, and call recording system, as indirect costs since it is difficult to allocate those costs to services furnished to individual patients in a manner that

adequately reflects the number of patients being tested. This would be true for CPT code 93229 which has not previously been nationally priced. We believe that the ability to appropriately allocate costs to individual services is a key concept that should guide our adoption of the direct PE inputs for services paid under the PFS. Having drawn this conclusion, we plan to review the direct PE inputs for other nationally priced services that include centralized monitoring equipment under the PFS and, if we find that we have not consistently treated that equipment as an indirect cost, we may propose changes to the direct PE inputs for existing codes in a future PFS rulemaking cycle.

We agree with several commenters that it would be appropriate at this time to nationally price CPT code 93229, especially in light of our conclusion regarding how the centralized monitoring system should be treated under the PFS PE methodology and the fact that the commenters have provided current prices and associated documentation for the direct PE inputs used in the typical case. Therefore, we are accepting the AMA RUC recommendations originally made for CY 2009 (73 FR 69896) for clinical labor and supplies for CPT code 93229 and are utilizing these direct PE inputs for CY 2011. With respect to the equipment inputs provided to us by one commenter who currently furnishes the majority of services described by CPT code 93229, under our final CY 2011 policy the only piece of equipment that would be appropriately treated as a direct PE input is the cardiac telemetry monitoring device worn by the patient. The other equipment items, including the monitoring system software and hardware, workstation, webserver, and call recording system are indirect practice costs. Therefore, we are accepting the commenter's submission of \$21,575 as the price for this device in the typical case, and applying a 50 percent utilization rate and useful life of 3 years as recommended by the commenter.

We do not believe it would be appropriate to deviate from our standard PFS PE methodology to adopt a PE/HR that is specific to CPT code 93229 or any other set of cardiac monitoring codes based on data from two telemetry providers, from a subset of services provided by certain specialty cardiac monitoring providers, or from a certain group of specialty providers that overall furnish only a portion of cardiac monitoring services, nor to change our established indirect PE allocation methodology. We believe the current PE

methodology appropriately captures the relative costs of these services in setting their PE RVUs, based on the conclusion we have drawn following our assessment of the centralized monitoring system that is especially characteristic of services such as CPT code 93229. We note that these direct PE inputs are included in the final CY 2011 direct PE database that is posted on the CMS Web site under downloads for this CY 2011 PFS final rule with comment period at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>. We further note that the CY 2011 payment for CPT code 93229 (without considering the negative PFS update that will apply for CY 2011 under current law) is close to the current typical contractor's price for the service in CY 2010.

After consideration of the public comments we received, we are establishing a national price for CPT code 93229 based on nationally set RVUs, instead of maintaining the code as contractor-priced as we proposed. We are adopting the AMA RUC's recommendations for the clinical labor and supply inputs, and utilizing price, utilization, and useful life information provided by the commenters as equipment inputs for the cardiac telemetry monitoring device worn by the patient. The final CY 2011 RVUs for CPT code 93229 are displayed in Addendum B to this final rule with comment period. While we are making no changes to the direct PE inputs for other remote cardiac monitoring CPT codes for CY 2011, we will consider in the future whether changes could be appropriate if we conclude that these services utilize a centralized monitoring system that would most appropriately be treated an indirect cost.

Comment: While most of the commenters addressed remote cardiac monitoring services specifically discussed in the CY 2011 PFS proposed rule, several commenters addressed other types of emerging 24/7 services. One commenter described a pilot program that utilizes telehealth to monitor certain health status indicators for cardiac patients. This monitoring occurs during the day and night and includes an assessment by a nurse. The commenter stated that the initial results of the pilot show a lower rate of hospital readmissions for participants. The commenter asserted that there is currently no payment for this service, and urged CMS to consider funding for these types of programs.

Outside of cardiac monitoring, another commenter noted that there are many types of remote monitoring

services that provide important benefits, especially for chronically ill patients. The commenter explained that these may include health status monitoring services, activity and sensor monitoring services, and medication dispensing and monitoring services. The commenter asserted that the resource requirements for these types of services can differ in complexity and frequency and may involve varied resources, including equipment and other fees; training and coaching; data collection, monitoring and documentation; and personal emergency response. As such, the commenter recommended that CMS' PE methodology for remote monitoring services be as transparent and flexible as possible to allow for these differences, and to accurately capture the cost components for each. Therefore, the commenter, concluded that a direct cost approach would be the most appropriate approach in most cases.

Response: We thank the commenters for providing information on other current and emerging 24/7 services. We will consider appropriate payment for other 24/7 services under the PFS as specific codes for such services are created by the CPT Editorial Panel. Regarding direct PE inputs for other remote monitoring services, we acknowledge diversity in the direct and indirect costs to providers for furnishing various monitoring services—and all services—and believe that our current PE methodology, as discussed earlier in this section, is able to yield appropriate values across this wide range. As stated earlier in the context of remote cardiac monitoring, we believe that the ability to appropriately allocate costs to the services furnished to individual patients is a key concept that should guide our adoption of the direct PE inputs for services paid under the PFS, including remote monitoring and other 24/7 services.

We look forward to continuing a dialogue with stakeholders involved in developing and furnishing 24/7 services as medical practice evolves in order to ensure that the PFS pays appropriately for those 24/7 services that are covered by Medicare and paid as physicians' services.

IV. Medicare Telehealth Services for the Physician Fee Schedule

A. Billing and Payment for Telehealth Services

1. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional

model of medical care. Examples of these services included interpretation of an x-ray or electrocardiogram or electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment which would have been made to the consultant for the service provided. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106-554) (BIPA) added a new section 1834(m) to the Act which significantly expanded Medicare telehealth services. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when delivered via a telecommunications system. We first implemented this provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified in regulations at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined, as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the practitioner at the distant site. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system

is generally required as a condition of payment; however, section 1834(m)(1) of the statute does allow the use of asynchronous "store-and-forward" technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at § 410.78(a)(1), store and forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be provided to an eligible telehealth individual notwithstanding the fact that the individual practitioner providing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site. As specified in BIPA, originating sites are limited under section 1834(m)(3)(C) of the statute to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, a critical access hospital (CAH), a rural health clinic (RHC), a federally qualified health center (FQHC) and a hospital. More recently, section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) (MIPPA) expanded the list of telehealth originating sites to include hospital-based renal dialysis centers, skilled nursing facilities (SNFs), and community mental health centers (CMHCs). In order to serve as a telehealth originating site, these sites must be located in an area designated as a rural HPSA, in a county that is not in a metropolitan statistical area (MSA), or must be an entity that participate in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000. Finally, section 1834(m) of the statute does not require the eligible telehealth individual to be presented by a practitioner at the originating site.

2. Current Telehealth Billing and Payment Policies

As noted above, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in an originating site. An originating site is defined as one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system. In general, originating sites must be located in a rural HPSA or in a county outside of an MSA. The

originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner
- Hospitals
- CAHs
- RHCs
- FQHCs
- Hospital-Based or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites)

• SNFs

• CMHCs

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations
- Follow-up inpatient consultations
- Office or other outpatient visits
- Individual psychotherapy
- Pharmacologic management
- Psychiatric diagnostic interview examination
- End Stage Renal Disease (ESRD) related services
- Individual medical nutrition therapy (MNT)
- Neurobehavioral status exam
- Individual health and behavior assessment and intervention (HBAI).

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under State law to furnish the service being furnished via a telecommunications system:

- Physician
- Physician assistant (PA)
- Nurse practitioner (NP)
- Clinical nurse specialist (CNS)
- Nurse midwife
- Clinical psychologist
- Clinical social worker
- Registered dietitian or nutrition professional.

Practitioners furnishing Medicare telehealth services are located at a distant site, and they submit claims for telehealth services to the Medicare contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service, appended with the -GT (Via interactive audio and video telecommunications system) or -GQ (Via asynchronous telecommunications system) modifier. By reporting the -GT or -GQ modifier with a covered telehealth procedure code, the distant

site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (Telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site authenticates that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As described above, certain professional services that are commonly furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as

in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the -GT or -GQ modifier appended).

B. Requests for Adding Services to the List of Medicare Telehealth Services

As noted above, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. We assign any request to make additions to the list of Medicare telehealth services to one of the following categories:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the in-person delivery of the same service. Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person delivery of the requested service.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: individual HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA in order to examine the vascular access site); individual MNT; neurobehavioral status exam; and initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and skilled nursing facilities (SNFs).

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2010 are considered for the CY 2012 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at <http://www.cms.gov/telehealth/>.

C. Submitted Requests for Addition to the List of Telehealth Services for CY 2011

We received requests in CY 2009 to add the following services as Medicare telehealth services effective for CY 2011: (1) Individual kidney disease education (KDE) services; (2) individual diabetes self-management training (DSMT) services; (3) group KDE, DSMT, MNT, and HBAI services; (4) initial, subsequent, and discharge day management hospital care services; (5) initial, subsequent, discharge day management, and other nursing facility care services; (6) neuropsychological testing services; (7) speech-language pathology services; and (8) home wound care services. The following presents a discussion of these requests, including our proposed additions to the CY 2011 telehealth list.

1. Individual KDE Services

The American Society of Nephrology, Dialysis Patient Citizens, AMGEN, and Kidney Care Partners submitted requests to add individual KDE services, reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour), to the list of approved telehealth services for CY 2011 on a category 1 basis.

Individual KDE services, covered under the new Medicare KDE benefit effective for services furnished beginning in CY 2010, are defined as face-to-face educational services provided to a patient with stage IV chronic kidney disease (CKD). We believe the interaction between a

practitioner and a beneficiary receiving individual KDE services is similar to the education, assessment, and counseling elements of individual MNT services, reported by HCPCS code G0270 (Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face to face with the patient, each 15 minutes); CPT code 97802 (Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes); and CPT code 97803 (Medical nutrition therapy; reassessment and intervention, individual, face-to-face with the patient, each 15 minutes); all services that are currently on the telehealth list.

Therefore, we proposed to add HCPCS code G0420 to the list of telehealth services for CY 2011 on a category 1 basis and to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include individual KDE as a Medicare telehealth service.

Comment: Several commenters expressed support for CMS' proposal to add KDE services to the list of Medicare telehealth services for CY 2011. One commenter stated that the proposal would provide patients at risk for developing chronic kidney disease and ESRD with access to educational services that may help in controlling the progression of disease. Another commenter suggested that delivery of KDE services through telehealth would provide beneficiaries with the flexibility to interact with practitioners in a manner tailored to their needs, thus facilitating a more patient-centered approach. Another commenter noted that greater flexibility in the provision of KDE services is particularly important in rural areas where individuals do not have as much access to dialysis centers.

Response: We agree with the commenters that adding KDE services to the list of Medicare telehealth services may be valuable to Medicare beneficiaries, especially insofar as it helps provide greater access to the services for beneficiaries in rural or other isolated areas.

Comment: One commenter who supported the proposal also encouraged the CMS to maintain its existing policy regarding the qualified providers for KDE services in order to appropriately ensure the quality and content conveyed to patients in educational sessions and remain concordant with the intent of MIPPA.

Response: We note that the addition of KDE to the list of Medicare telehealth services does not alter the qualifications for providers of KDE services as specified in § 410.48 of the regulations.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to add HCPCS code G0420 to the list of telehealth services for CY 2011 on a category 1 basis and to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include individual KDE as a Medicare telehealth service.

2. Individual DSMT Services

The Tahoe Forest Health System and the Marshfield Clinic submitted requests to add individual DSMT services, reported by HCPCS code G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes), to the list of telehealth services for CY 2011 on a category 1 basis. In the CY 2009 PFS final rule with comment period (73 FR 69743), we stated that we believe individual DSMT services are not analogous to individual MNT services because of the element of skill-based training that is encompassed within individual DSMT services that is not an aspect of individual MNT services (or any other services currently approved for telehealth). Due to the statutory requirement that DSMT services include teaching beneficiaries the skills necessary for the self-administration of injectable drugs, we have stated our belief that DSMT, whether provided to an individual or a group, must be evaluated as a category 2 service as specified in the CY 2009 PFS proposed rule (73 FR 38516). Prior to CY 2011 rulemaking, we had considered several previous requests to add DSMT to the list of Medicare telehealth services. We had not added individual DSMT to the list of telehealth services because we believe that skill-based training, such as teaching patients how to inject insulin, would be difficult to accomplish effectively without the physical presence of the teaching practitioner (70 FR 45787 and 70157, and 73 FR 38516 and 69743).

In considering the new request to add individual DSMT services to the list of telehealth services in CY 2011, we took into account requestors' argument that individual DSMT services are highly similar to individual MNT services and that injection training constitutes just a small proportion of DSMT services. Except for the component of individual DSMT services that involves instruction in self-administration of injectable drugs for eligible beneficiaries, we agreed with the requestors that individual DSMT

services are similar to individual MNT services, which are currently on the list of Medicare telehealth services. We note that Medicare coverage of DSMT services was initially authorized in the BBA. After more than a decade of Medicare coverage, the most recent information shows that DSMT continues to be significantly underutilized in the context of the eligible population of Medicare beneficiaries. While we are uncertain to what extent geographic barriers to care contribute to this underutilization, given the morbidity associated with poorly managed diabetes and the growing evidence-base regarding effective DSMT services, we believe it is very important to facilitate Medicare beneficiary access to these underutilized services. While we were previously concerned about treating the components of DSMT services differently in the context of considering DSMT services for the telehealth list, in the CY 2011 PFS proposed rule (75 FR 40108), we stated our belief that our concern regarding the skill-based injection training component of DSMT services could be addressed by imposing a requirement that a minimum portion of the training be furnished in-person. We noted that for beneficiaries who meet the coverage criteria, Medicare covers 10 hours of DSMT services in the year following the initial training, as described in the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 15, Section 300.3). Taking into consideration the initial year coverage of DSMT services, for CY 2011 we proposed that a minimum of 1 hour of instruction in injection training must be furnished in-person during the year following the initial DSMT service. Imposing this condition would allow us to expand access to DSMT services by adding individual DSMT services to the list of telehealth services, while ensuring effective injection training for beneficiaries.

Therefore, we proposed to add HCPCS code G0108 to the list of telehealth services beginning in CY 2011. We also proposed that, as a condition of payment for individual DSMT services furnished as telehealth services to an eligible telehealth individual, a minimum of 1 hour of in-person instruction in the self-administration of injectable drugs must be furnished to the individual during the year following the initial DSMT service. The injection training may be furnished through either individual or group DSMT services. By reporting the -GT or -GQ modifier with HCPCS code G0108 as a telehealth service, the distant site practitioner would certify that the

beneficiary has received or will receive 1 hour of in-person DSMT services for purposes of injection training during the year following the initial DSMT service. Consistent with this proposal, we proposed to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include individual DSMT services as a Medicare telehealth service, with the exception of 1 hour of in-person instruction in self-administration of injectable drugs which must be furnished to the eligible telehealth individual as individual or group DSMT services during the year following the initial DSMT service.

Comment: A number of commenters expressed support for CMS' proposal to add DSMT services to the list of Medicare telehealth services. One commenter requested that CMS clarify that this proposal would permit NPs and PAs in all patient care settings to provide and bill for DSMT services furnished through telehealth technologies.

Response: As we stated in the CY 2011 PFS proposed rule (75 FR 40109), our proposal is consistent with the statutory requirements of section 1834(m)(1) of the Act and as provided in § 410.141(e) that individual DSMT services may be furnished by a physician, individual, or entity that furnishes other services for which direct Medicare payment may be made and that submits necessary documentation to, and is accredited by, an accreditation organization approved by us as described in the Benefit Policy Manual (Pub. 100-04, chapter 15, section 300.2). However, consistent with the statutory requirements of section 1834(m)(1) of the Act and as provided in § 410.78(b)(1) and (b)(2) of our regulations, Medicare telehealth services, including individual DSMT furnished as a telehealth service, can only be furnished by a licensed physician, PA, NP, CNS, certified nurse-midwife, clinical psychologist, clinical social worker, or registered dietitian or nutrition professional. Additionally, the site of the beneficiary must conform with the statutory requirements of telehealth originating sites from section 1834(m)(3)(C) of the Act and described in section IV.A. 2. of this final rule with comment period.

Comment: One commenter requested that pharmacists be added to the list of eligible Medicare telehealth distant site practitioners. The commenter stated that since pharmacists are already providing valuable DSMT services to patients in-person, these practitioners should not be excluded from providing those same valuable services via telehealth.

Response: Under section 1834(m) of the Act, payment is made for a Medicare

telehealth service furnished by a physician or practitioner in a distant site. For purposes of Medicare telehealth services, the physician or practitioner must either be a physician as defined in section 1861(r) of the Act or another practitioner as defined in section 1842(b)(18)(C) of the Act. Because pharmacists do not fall within these statutory definitions, we do not have the authority to make payment to pharmacists as eligible distant site practitioners for Medicare telehealth services.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to add HCPCS code G0108 to the list of telehealth services beginning in CY 2011. As a condition of payment for individual DSMT services furnished as telehealth services to an eligible telehealth individual, a minimum of 1 hour of in-person instruction in the self-administration of injectable drugs must be furnished to the individual during the year following the initial DSMT service. The injection training may be furnished through either individual or group DSMT services. By reporting the -GT or -GQ modifier with HCPCS code G0108 as a telehealth service, the distant site practitioner certifies that the beneficiary has received or will receive 1 hour of in-person DSMT services for purposes of injection training during the year following the initial DSMT service. Consistent with this final policy, we are revising our regulations at § 410.78(b) and § 414.65(a)(1) to include individual DSMT services as a Medicare telehealth service, with the exception of 1 hour of in-person instruction in self-administration of injectable drugs which must be furnished to the eligible telehealth individual as individual or group DSMT services during the year following the initial DSMT service.

We note that, as specified in § 410.141(e), individual DSMT services may be furnished by a physician, individual, or entity that furnishes other services for which direct Medicare payment may be made and that submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS. However, consistent with the statutory requirements of section 1834(m)(1) of the Act and as provided in § 410.78(b)(1) and (b)(2) of our regulations, Medicare telehealth services, including individual DSMT furnished as a telehealth service, can only be furnished by a licensed physician, PA, NP, CNS, certified nurse-midwife, clinical psychologist, clinical social worker, or registered dietitian or nutrition professional.

3. Group KDE, MNT, DSMT, and HBAI Services

The American Society of Nephrology, Dialysis Patient Citizens, AMGEN, Tahoe Forest Health Systems, Kidney Care Partners, the American Telemedicine Association, and the Marshfield Clinic submitted requests to add one or more of the following group services to the telehealth list for CY 2011:

- Group KDE services, reported by HCPCS code G0421 (Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour);
- Group MNT services, reported by CPT code 97804 (Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes);
- Group DSMT services, reported by HCPCS code G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes); and/or
- Group HBAI services, reported by CPT code 96153 (Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)) and 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)).

When furnished as individual services, HBAI and MNT services are currently on the list of Medicare telehealth services. Furthermore, we proposed to add individual KDE and DSMT services to the list of Medicare telehealth services beginning in CY 2011 as described above.

In the CY 2007 and CY 2010 PFS rulemaking cycles (70 FR 45787 and 70157, and 74 FR 33543 and 61764), we stated that we did not believe that group services could be appropriately delivered through telehealth. In the CY 2011 PFS proposed rule (75 FR 40109), we observed that currently there are no group services approved as Medicare telehealth services and that there is a different interactive dynamic between the practitioner and his or her patients in group services as compared to individual services. We previously had considered requests to add various group services to the list of Medicare telehealth services on a category 2 basis because we had believed that, especially given the interactive dynamic between practitioners and their patients, group services were not similar to other services on the list of Medicare telehealth services. Therefore, we had maintained that it was necessary to evaluate the addition of group services by comparing diagnostic findings or therapeutic interventions when services

are furnished via telehealth versus when services are furnished in-person.

In the CY 2011 proposed rule (75 FR 40109), we stated that we continue to believe that the group dynamic may be a critical and defining element for certain services, and that this characteristic precludes many group services from being considered on a category 1 basis for addition to the list of Medicare telehealth services. For example, we believe that due to the therapeutic nature of the group dynamic that is integral to group psychotherapy, group psychotherapy is fundamentally different from other Medicare telehealth services and, therefore, could not be considered on a category 1 basis for addition to the telehealth services list. For the same reason, in the absence of evidence to the contrary, we do not believe group psychotherapy services could be appropriately delivered through telehealth.

However, upon further consideration, with regard to the particular group education and training services for which we received requests for addition to the Medicare telehealth services list, for CY 2011 we concluded that we believe the group dynamic is not central to the core education and training components of these particular services, specifically DSMT, MNT, KDE, and HBAI services. We believe that these group services are sufficiently similar to the individual, related services that are already on the telehealth services list or were proposed for addition beginning in CY 2011. Specifically, we believe that for these group services, which consist principally of an information exchange for the purpose of education and training, the roles of, and interactions between, the patients and the practitioner are sufficiently similar to the related individual education and training services that the services can be furnished appropriately as a telehealth service.

Therefore, we proposed to add HCPCS code G0421 for group KDE services, CPT code 97804 for group MNT services, HCPCS code G0109 for group DSMT services, and CPT codes 96153 and 96154 for group HBAI services to the Medicare telehealth services list on a category 1 basis for CY 2011. Furthermore, because the concerns we raised above regarding adequate injection training with the addition of individual DSMT are also present for group DSMT, we proposed to require the same minimum of 1 hour of in-person instruction for injection training within the year following the initial DSMT service for any beneficiary that receives DSMT services via telehealth. By reporting the -GT or -GQ modifier

with HCPCS code G0109, the distant site practitioner would certify that the beneficiary has received or will receive 1 hour of in-person instruction in self-administration of injectable drugs which must be furnished to the eligible telehealth individual as individual or group DSMT services during the year following the initial DSMT service. Consistent with this proposal to add these group education and training services, we also proposed to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include group KDE, MNT, DSMT, and HBAI services as Medicare telehealth services, with the exception of 1 hour of in-person instruction in self-administration of injectable drugs which must be furnished to the eligible telehealth individual as individual or group DSMT services in the year following the initial DSMT service.

Comment: Many commenters agreed with CMS' proposal to add group KDE, MNT, DSMT, and HBAI to the list of Medicare telehealth services for CY 2011. Some commenters commended CMS' willingness to expand the list of Medicare telehealth services and explained that the additions would facilitate beneficiary access to care.

Many commenters also urged CMS to make further additions to the list of Medicare telehealth services beyond those proposed for CY 2011.

Response: We believe adding these group services to the list of Medicare telehealth services will facilitate beneficiary access to care, and we appreciate the commenters' shared interest in that goal.

The process for requesting additional services to be added to the list of Medicare telehealth services is described in section IV.B. of this final rule with comment period. Requests for additions for CY 2012 must be received by the end of CY 2010. Further information is available about the process on the CMS web site at: <http://www.cms.gov/telehealth/>.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to add HCPCS code G0421 for group KDE services, CPT code 97804 for group MNT services, HCPCS code G0109 for group DSMT services, and CPT codes 96153 and 96154 for group HBAI services to the Medicare telehealth services list on a category 1 basis. Furthermore, because we have the same concerns for group DSMT services that we raised above regarding adequate injection training for individual DSMT services, we are requiring the same minimum of 1 hour of in-person instruction for injection training within

the year following the initial DSMT service for any beneficiary that receives DSMT services via telehealth. By reporting the -GT or -GQ modifier with HCPCS code G0109, the distant site practitioner would certify that the beneficiary has received or will receive 1 hour of in-person DSMT services for purposes of injection training during the year following the initial DSMT service. Consistent with the addition of these group education and training services, we are also revising our regulations at § 410.78(b) and § 414.65(a)(1) to include group KDE, MNT, DSMT, and HBAI services as Medicare telehealth services, with the exception of 1 hour of in-person instruction for injection training within the year following the initial DSMT service.

As described above for individual DSMT services, we note that group DSMT services may be furnished by a physician, individual, or entity that furnishes other services for which direct Medicare payment may be made and that submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS, as specified in § 410.141(e) for DSMT services. However, consistent with the statutory requirements of section 1834(m)(1) of the Act and as provided in § 410.78(b)(1) and (b)(2) of our regulations, Medicare telehealth services, including group DSMT furnished as a telehealth service, can only be furnished by a licensed physician, PA, NP, CNS, certified nurse-midwife, clinical psychologist, clinical social worker, or registered dietitian or nutrition professional.

4. Initial, Subsequent, and Discharge Day Management Hospital Care Services

The University of Louisville School of Medicine, the American Telemedicine Association, and Mille Lacs Health System submitted various requests to add initial hospital care services (reported by CPT codes 99221 (Level 1 initial hospital care), 99222 (Level 2 initial hospital care), and 99223 (Level 3 initial hospital care)); subsequent hospital care services (reported by CPT codes 99231 (Level 1 subsequent hospital care), 99232 (Level 2 subsequent hospital care), and 99233 (Level 3 subsequent hospital care)); and/or hospital discharge day management services (reported by CPT codes 99238 (Hospital discharge day management; 30 minutes or less) and 99239 (Hospital discharge day management; more than 30 minutes) to the Medicare telehealth services list beginning in CY 2011, generally on a category 1 basis. Some of the requestors also recommended that we limit the delivery of these services

through telehealth to the provision of services to patients with a psychiatric diagnosis or to those treated in a psychiatric hospital or licensed psychiatric bed.

We appreciate the recommendations of the requestors to substantially expand the list of Medicare telehealth services. The requestors submitted a number of studies regarding the outcomes of telehealth services in caring for patients with psychiatric diagnoses. However, we note that the CPT codes for hospital care services are used to report care for hospitalized patients with a variety of diagnoses, including psychiatric diagnoses. In the CY 2011 PFS proposed rule (75 FR 40110), we stated our belief that it would not be appropriate to add services to the telehealth list only for certain diagnoses because the service described by a HCPCS code is essentially the same service, regardless of the patient's diagnosis. When evaluating the addition of services for telehealth on a category 1 basis, our focus is on the roles of, and interactions among, the beneficiary, the physician or practitioner, and the telepresenter (if applicable), which generally are similar across diagnoses for services that may be reported with the same HCPCS codes. Even in the unique case of certain ESRD services, we limited additions to the list of Medicare telehealth services based on the appropriateness of certain specific codes, taking into consideration the full service descriptions (69 FR 47511). Therefore, we continue to believe that it is most appropriate to consider additions to the list of telehealth services based on the overall suitability of the services described by the relevant HCPCS codes to delivery through telehealth.

In the CY 2005, CY 2008, and CY 2009 PFS rulemakings (69 FR 47510 and 66276, 72 FR 38144 and 66250, and 73 FR 38517 and 69745, respectively), we did not add initial, subsequent, or discharge day management hospital care services to the list of approved telehealth services because of our concern regarding the use of telehealth for the ongoing evaluation and management (E/M) for the generally high acuity of hospital inpatients. While we continue to have some concern in this area, we also share the requestors' interest in improving access for hospitalized patients to care furnished by treating practitioners. Therefore, we reevaluated these services in the context of the CY 2011 requests, including considering the possibility that these services could be added on a category 1 basis based on their resemblance to services currently on the telehealth list,

such as initial and follow-up inpatient telehealth consultations. The following presents a discussion of our review for the CY 2011 proposed rule of the subcategories of hospital care services included in these requests.

Currently, one of the three codes for an initial hospital care service (specifically CPT codes 99221, 99222, or 99223) is reported for the first hospital inpatient E/M visit to the patient by the admitting or a consulting practitioner when that visit is furnished in person. In addition, we note that currently there are several HCPCS G-codes on the Medicare telehealth services list that may be reported for initial and follow-up inpatient consultations through telehealth, specifically HCPCS codes G0406 (Follow-up inpatient telehealth consultation, limited, physicians typically spend 15 minutes communicating with the patient via telehealth); G0407 (Follow-up inpatient telehealth consultation, intermediate, physicians typically spend 25 minutes communicating with the patient via telehealth); G0408 (Follow-up inpatient telehealth consultation, complex, physicians typically spend 35 minutes or more communicating with the patient via telehealth); G0425 (Initial inpatient telehealth consultation, typically 30 minutes communicating with the patient via telehealth); G0426 (Initial inpatient telehealth consultation, typically 50 minutes communicating with the patient via telehealth); and G0427 (Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth).

While initial inpatient consultation services are currently on the list of approved telehealth services, there are no services on the current list of telehealth services that resemble initial hospital care for an acutely ill patient by the admitting practitioner who has ongoing responsibility for the patient's treatment during the hospital course. Therefore, we were unable to consider initial hospital care services on a category 1 basis for the telehealth list for CY 2011.

We reviewed the documentation submitted in support of adding the initial hospital care codes to the Medicare telehealth services list as category 2 requests. Most of the studies provided by the requestors were specific to the treatment of patients with particular diagnoses. Additionally, the studies were not specific to initial hospital care visits by admitting practitioners. Finally, most of the studies concluded that more research was required in order to establish medical equivalence between telehealth

and in-person services. Therefore, we received no information that provides robust support for the addition of initial hospital care services to the approved telehealth list on a category 2 basis. The initial hospital care codes describe the first visit to the hospitalized patient by the admitting practitioner who may or may not have seen the patient in the decision-making phase regarding hospitalization. We believe it is critical that the initial hospital visit by the admitting practitioner be conducted in-person to ensure that the practitioner with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination. Therefore, we did not propose to add initial hospital care services to the Medicare telehealth services list for CY 2011.

We again considered adding subsequent hospital care services reported by CPT codes 99231 through 99233 to the telehealth list for CY 2011 on a category 1 basis. In the CY 2005 and CY 2008 PFS proposed rules (69 FR 47511 and 72 FR 38155), we stated that the potential acuity of patients in the hospital setting precludes consideration of subsequent hospital visits as similar to existing telehealth services. However, as stated earlier, we also note that HCPCS codes for initial and follow-up inpatient consultation services are on the list of telehealth services. These E/M services are furnished to high acuity hospitalized patients, although not by the admitting practitioner himself or herself. However, in light of the increasingly prevalent care model that entails multidisciplinary team care for patients with complex medical illnesses that involve multiple body systems, consulting practitioners may often play a key, intensive, and ongoing role in caring for hospitalized patients. Therefore, we believe that subsequent hospital care visits by a patient's admitting practitioner may sufficiently resemble follow-up inpatient consultation services to consider these subsequent hospital care services on a category 1 basis for the telehealth list. While we still believe the potential acuity of hospital inpatients is greater than those patients likely to receive currently approved Medicare telehealth services, we also believe that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth in order to ensure that hospitalized patients have frequent encounters with their admitting practitioner. However, we also continue to believe that the majority of these visits should be in-

person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis.

Therefore, for CY 2011 we proposed that subsequent hospital care services, specifically CPT codes 99231, 99232, and 99233, be added to the list of telehealth services on a category 1 basis for CY 2011, but with some limitations on the frequency with which these services may be furnished through telehealth. Because of our concerns regarding the potential acuity of hospital inpatients, we proposed to limit the provision of subsequent hospital care services through telehealth to once every 3 days. We were confident that admitting practitioners would continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Consulting practitioners should continue to use the inpatient telehealth consultation HCPCS G-codes, specifically G0406, G0407, G0408, G0425, G0426, or G0427 when reporting consultations furnished to inpatients via telehealth.

Consistent with this proposal, we proposed to revise § 410.78(b) and § 414.65(a)(1) to include subsequent hospital care services as Medicare telehealth services, with the limitation of one telehealth subsequent hospital care service every 3 days.

We also considered adding hospital discharge day management services to the list of telehealth services. These services, reported by CPT codes 99238 and 99239, include the final examination of the patient, discussion of the hospital stay, instructions for continuing care to all relevant caregivers, and preparation of discharge records, prescriptions, and referral forms. These services are furnished when a practitioner deems it medically reasonable and necessary to assess a patient's readiness for discharge and to prepare a patient for discharge from an acute care environment to a less intensive setting. There are no services on the current list of telehealth services that resemble such preparation of a patient for discharge. We believe it is especially important that, if a practitioner furnishes a discharge day management service, the service be furnished in-person in order to allow the practitioner to comprehensively assess the patient's status in preparation for discharge so that the patient will have a higher likelihood of making a successful transition to the less intensive setting. Therefore, we did not consider hospital discharge day management services for addition to the Medicare telehealth services list on a category 1 basis.

We reviewed the documentation submitted by requestors in support of adding these codes to the Medicare telehealth services list on a category 2 basis. Most of the submitted studies were specific to the treatment of patients with specific diagnoses and were not specific to discharge services. Additionally, most of the studies concluded that more research was required in order to establish medical equivalence between telehealth and in-person services. The submitted documentation did not provide the necessary evidence to alter our previous conclusion that hospital discharge day management services should be provided in-person in light of the acuity of hospitalized patients, their typically complex post-hospitalization care needs, and the importance of patient education by the admitting practitioner who had ongoing responsibility for the patient's treatment during the hospital stay. Therefore, we did not propose to add hospital discharge day management services to the list of telehealth services for CY 2011.

Comment: Many commenters expressed support for all of CMS' proposed additions to the list of Medicare telehealth services, including subsequent hospital care services. One commenter urged CMS to focus on adding services where research demonstrates that technology can facilitate medically equivalent services and improve beneficiary access to providers, and to carefully monitor implementation of any new telehealth services to ensure that patients' experience of the care is positive and that patient outcomes are not compromised. The commenter encouraged CMS' continued attention to the evidence and the role of patient needs as CMS evaluates telehealth requests. The commenter cited CMS' decision not to propose the addition of hospital discharge day management services as a Medicare telehealth service as an example of the agency applying appropriate rigor to best reflect patient needs and preferences.

Response: We appreciate the support for our proposed additions, as well as our consideration and decisions regarding requested additions to telehealth services that we did not propose to add to the list of telehealth services for CY 2011.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to add subsequent hospital care services, specifically CPT codes 99231, 99232, and 99233, to the list of telehealth services on a category 1 basis for CY 2011, but with the limitation of one

subsequent hospital care service furnished through telehealth every 3 days. We are revising § 410.78(b) and § 414.65(a)(1) accordingly to include subsequent hospital care services as Medicare telehealth services, with the limitation of one telehealth subsequent hospital care service every 3 days. We are also finalizing our decision not to add initial or discharge day management hospital care services to the list of Medicare telehealth services.

5. Initial, Subsequent, Discharge Day Management, and Other Nursing Facility Care Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add nursing facility care codes, covering the spectrum of initial (reported by CPT codes 99304 (Level 1 initial nursing facility care), 99305 (Level 2 initial nursing facility care) and 99306 (Level 3 initial nursing facility care)); subsequent (reported by CPT codes 99307 (Level 1 subsequent nursing facility care), 99308 (Level 2 subsequent nursing facility care), 99309 (Level 3 subsequent nursing facility care), and 99310 (Level 4 subsequent nursing facility care)); discharge day management (reported by CPT codes 99315 (Nursing facility discharge day management; 30 minutes or less) and 99316 (Nursing facility discharge day management; more than 30 minutes)); and other (reported by CPT code 99318 (Evaluation and management of a patient involving an annual nursing facility assessment)) services, to the Medicare telehealth services list beginning in CY 2011. The commenters requesting the addition of these services expressed concerns regarding limited access to care if we did not allow these services to be furnished through telehealth, and requested that CMS acknowledge the recent Congressional inclusion of nursing facilities as telehealth originating sites by adding these codes to the list of Medicare telehealth services.

In the CY 2010 PFS proposed and final rules (74 FR 33544 and 74 FR 61762), we discussed concerns about potential disparities in patient acuity between nursing facility services and the current list of Medicare telehealth services. We also declined to add HCPCS codes to the Medicare telehealth services list that are used exclusively to describe Federally-mandated nursing facility visits. As discussed in the CY 2010 PFS proposed rule (74 FR 33543), the long-term care regulations at § 483.40(c) require that residents of SNFs receive initial and periodic

personal contact between a practitioner and a SNF resident is maintained, both at the point of admission to the facility and periodically during the course of the resident's stay. We continue to believe that these Federally-mandated visits should be conducted in-person, and not as Medicare telehealth services. Therefore, in the CY 2010 PFS final rule with comment period, we revised § 410.78 to preclude physicians and other practitioners from furnishing the physician visits required under § 483.40(c) through telehealth.

We reviewed the use of telehealth for each of the subcategories of nursing facility services included in the requests for CY 2011. We identified the E/M services that fulfill Federal requirements for personal visits under § 483.40(c), and we did not propose for CY 2011 to add any HCPCS codes to the Medicare telehealth services list that are used exclusively to describe these Federally-mandated visits. These codes include the CPT codes for initial nursing facility care (CPT codes 99304 through 99306) that are used to report the initial E/M visit that fulfills Federally-mandated requirements under § 483.40(c) and other nursing facility service (CPT code 99318) that is only payable by Medicare if the visit is substituted for a Federally-mandated visit under § 483.40(c).

The nursing facility discharge day management services reported under CPT code 99315 and 99316 are E/M visits that prepare a nursing facility resident for discharge from the facility. There are no Medicare requirements that such a service be furnished. If a practitioner chooses to furnish this service, we continue to believe that an in-person visit is most appropriate in order to ensure the resident is prepared for discharge from the nursing facility. These services are furnished when a practitioner deems it medically reasonable and necessary to assess a patient's readiness for and to prepare a patient being discharged from the monitored nursing facility environment to another typically less intensive setting. There are no services on the current list of telehealth services that resemble such preparation of a patient for discharge. As in the case of hospital discharge day management services, we believe it is especially important that, if a practitioner furnishes a nursing facility discharge day management service, the service be furnished in-person. The practitioner must be able to comprehensively assess the patient's status in preparation for discharge so that the patient will have a higher likelihood of making a successful transition from the nursing facility to

another setting. Therefore, we did not consider nursing facility discharge day management services for addition to the Medicare telehealth services list on a category 1 basis for CY 2011. When we considered the addition of these services under category 2, we had no evidence that nursing facility discharge services furnished through telehealth are equivalent to in-person discharge services. Therefore, we did not propose to add nursing facility discharge day management services to the CY 2011 telehealth list.

Subsequent nursing facility services, reported by CPT codes 99307 through 99310, may be used to report either a Federally-mandated periodic visit under § 483.40(c) or another E/M visit, prior to or after the initial nursing facility care visit, as long as the subsequent nursing facility care visit is medically reasonable and necessary for the resident's care. While we continue to believe that many SNF residents have complex medical care needs, we believe that it is appropriate to consider the addition of these codes to the telehealth list on a category 1 basis. As we state above in the context of our discussion of subsequent hospital care services, the HCPCS codes for initial and follow-up inpatient consultation services for nursing facility patients are on the list of Medicare telehealth services, and subsequent nursing facility services are similar to those services. These E/M services are furnished to high acuity, complex SNF patients, although not by the admitting practitioner himself or herself. Therefore, we believe that subsequent nursing facility visits by a patient's admitting practitioner sufficiently resemble follow-up inpatient consultation services to consider them on a category 1 basis for the telehealth list. We concluded for CY 2011 that it would be appropriate to permit some subsequent nursing facility care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, although we continue to believe that the Federally-mandated visits should be in-person to facilitate the comprehensive, coordinated, and personal care that these complex patients require on an ongoing basis.

Therefore, we proposed that subsequent nursing facility care services, specifically CPT codes 99307, 99308, 99309 and 99310, be added to the list of Medicare telehealth services on a category 1 basis beginning in CY 2011, with some limitations on furnishing these services through telehealth. Because of our concerns regarding the potential acuity and

complexity of SNF inpatients, we proposed to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. We were especially interested in public comments, including any evidence regarding patterns of high quality care and clinical outcomes, regarding this proposal to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. We remain committed to ensuring that SNF inpatients receive appropriate in-person visits and that Medicare pays only for medically reasonable and necessary care. Currently and continuing in CY 2011, an unlimited number of initial and follow-up consultation services may be furnished through telehealth to these patients, so we believe that only a limited number of subsequent nursing facility care services by the admitting practitioner would be appropriate for SNF inpatients. Finally, we specified that subsequent nursing facility care services reported for a Federally-mandated periodic visit under § 483.40(c) may not be furnished through telehealth. In light of this CY 2011 proposal, we were confident that admitting practitioners would continue to make appropriate in-person visits to all patients who need such care during their SNF stay.

Consistent with our proposal, we proposed to revise § 410.78(b) and § 414.65(a)(1) to include subsequent nursing facility care services as Medicare telehealth services, with the limitation of one telehealth subsequent nursing facility care service every 30 days. Federally-mandated periodic visits may not be furnished through telehealth, as specified currently in § 410.78(e)(2).

Comment: One commenter recommended that CMS limit the use of telehealth for subsequent nursing facility care services to CPT codes 99307 and 99308, the lower two levels of care. The commenter stated that the subsequent nursing facility care services described by CPT codes 99309 and 99310, the higher two levels of care, require a detailed to comprehensive history and examination, along with moderate to complex decisionmaking that warrant an in-person visit with the physician. The same commenter disagreed with the limitation of one telehealth subsequent nursing facility care service every 30 days and suggested that unless and until evidence of overutilization is obtained, the limit could hinder access to appropriate care under the telehealth benefit. The commenter agreed with the CMS policy that all Federally-mandated visits as

defined by the long-term care regulations § 483.40(c) should be conducted in-person and not as Medicare telehealth services.

Response: We appreciate the response to our specific request for public comment regarding the addition of subsequent nursing facility care services to the list of Medicare telehealth services with the limitation of one telehealth subsequent nursing facility care service every 30 days. As we stated in the proposed rule (75 FR 40112), we remain committed to ensuring that SNF inpatients receive appropriate in-person visits and that Medicare pays only for medically reasonable and necessary care. We received no new evidence from the commenter regarding patterns of high quality care and clinical outcomes in terms of our proposal to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. Because we want to ensure that nursing facility patients with complex medical conditions have appropriately frequent medically reasonable and necessary encounters with their admitting practitioner, we continue to believe that it would be appropriate to permit the full range of subsequent nursing facility care services to be furnished through telehealth. At the same time, because of our concerns regarding the potential acuity and complexity of SNF inpatients, we want to ensure that these patients continue to receive in-person visits as appropriate to manage their care. We are adding these services as Medicare telehealth services with the limitation as we proposed, and we remain confident that admitting practitioners will continue to make appropriate in-person visits to all patients who need such care during their SNF stay.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to add subsequent nursing facility care services, specifically CPT codes 99307, 99308, 99309 and 99310, to the list of Medicare telehealth services on a category 1 basis beginning in CY 2011, with limits to the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. We are revising § 410.78(b) and § 414.65(a)(1) to include subsequent nursing facility care services as Medicare telehealth services, with the limitation of one telehealth subsequent nursing facility care service every 30 days. Federally-mandated periodic visits may not be furnished through telehealth, as specified currently in § 410.78(e)(2).

6. Neuropsychological Testing Services

The American Telemedicine Association submitted a request to add neuropsychological testing services, described by CPT codes 96119 (Neuropsychological testing (for example, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and 96119 (Neuropsychological testing (for example, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face), to the list of telehealth services for CY 2011 based on their similarity to other telehealth services.

In the CY 2008 PFS final rule with comment period (72 FR 66251), we stated that we have received conflicting comments and data regarding the appropriateness of furnishing neuropsychological testing via telehealth. While we appreciate the recent request for addition of these same services to the Medicare telehealth services list, we did not believe that these services are similar to services currently on the Medicare telehealth services list and, therefore, we concluded that they would not be appropriate for consideration or addition under category 1 for CY 2011. In the CY 2011 request for the addition of these services, we received no information to indicate that the diagnostic findings of neuropsychological testing through telehealth are similar to those based upon in-person testing, and therefore that testing through telehealth does not affect the patient's diagnosis. Consequently, we did not propose to add neuropsychological testing services to the list of approved Medicare telehealth services for CY 2011.

We received no public comments regarding our discussion of the request to add neuropsychological testing to the list of Medicare telehealth services. Therefore, we are finalizing our decision not to add neuropsychological testing to the list of Medicare telehealth services for CY 2011.

7. Speech-Language Pathology Services

The Marshfield Clinic submitted a request to add various speech-language pathology services to the list of approved telehealth services for CY

2011. Speech-language pathologists are not permitted under section 1842(b)(18)(C) of the Act to furnish and receive payment for Medicare telehealth services. Therefore, we did not propose to add any speech-language pathology services to the list of Medicare telehealth services for CY 2011. For further discussion of these services in the context of telehealth, we refer readers to the CY 2005 and CY 2007 PFS proposed and final rules with comment period (69 FR 47512 and 66276, and 71 FR 48995 and 69657).

Comment: One commenter stated that research has proven that audiology procedures offered via telehealth services have great potential. The commenter also stated that CMS should use its broad discretion in implementing programs to expand the list of available telehealth services to include audiology.

Response: It is not within our administrative authority to pay speech language pathologists and audiologists for services furnished via telehealth. The statute authorizes the Secretary to pay for telehealth services only when furnished by a physician or a practitioner as those terms are defined in section 1834(m)(4)(D) and (E) of the Act.

After consideration of the public comment we received, we are finalizing our decision not to add various speech-language pathology services to the list of approved telehealth services for CY 2011.

8. Home Wound Care Services

Wound Care Associates, LLC, submitted a request to add wound care in the home setting to the list of Medicare telehealth services. A patient's home is not permitted under current statute to serve as an originating site for Medicare telehealth services. Therefore, we did not propose to add home wound care services to the list of Medicare telehealth services for CY 2011.

We received no public comments regarding our discussion of the request to add wound care in the home setting to the list of Medicare telehealth services. Therefore, we are finalizing our decision not to add wound care in the home setting to the list of Medicare telehealth services for CY 2011.

9. Other Issues

We received other public comments on matters related to Medicare telehealth services that were not the subject of proposals in the CY 2011 PFS proposed rule. We thank the commenters for sharing their views and suggestions. Because we did not make any proposals regarding these matters, we do not generally summarize or

respond to such comments in this final rule with comment period. However, we are summarizing and responding to the following comments in order to reiterate certain information.

Comment: One commenter requested an explanation of the acceptable time and format to request or recommend changes to the criteria set in 2003 by which CMS considers specific services for Medicare coverage when furnished through telehealth.

Response: As we discussed in the CY 2010 PFS final rule with comment period (74 FR 61766), our established criteria and process for reviewing requests to add to the list of approved Medicare telehealth services were subject to full notice and comment procedures in the CY 2003 PFS proposed and final rules. Since we did not make any proposals relating to the criteria or process for CY 2011, any potential revisions to the process for adding or deleting services from the list of approved Medicare telehealth services are outside the scope of this CY 2011 final rule with comment period.

Throughout the year, we regularly meet with parties who want to share their views on topics of interest to them. These discussions may provide us with information regarding changes in medical practice and afford opportunities for the public to bring to our attention issues they believe we should consider for future rulemaking. Thus, we encourage stakeholders to contact us at any time if there are topics related to physician payment policy that they would like to discuss.

Comment: One commenter requested an explanation regarding how the payment rates for telehealth consultations are set in a manner that is consistent with section 1834(m)(2)(A) of the Act that requires Medicare to pay a practitioner who furnishes a telehealth service an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

Response: As we stated in the CY 2009 PFS final rule with comment period (73 FR 69745), we established the RVUs for follow-up inpatient telehealth consultations at the same level as the RVUs established for subsequent hospital care (as described by CPT codes 99231 through 99233). For CY 2010, we established the RVUs for initial inpatient telehealth consultations at the same level as the RVUs for initial hospital care (as described by CPT codes 99221 through 99223) (75 FR 61775). We believe this is appropriate because a physician or practitioner furnishing a telehealth service is paid an amount

equal to the amount that would have been paid if the service had been furnished without the use of a telecommunication system. Since physicians and practitioners furnishing follow-up inpatient consultations in an in-person encounter must continue to utilize subsequent hospital care codes (as described by CPT codes 99231 through 99233) and those furnishing initial inpatient consultations in an in-person encounter must generally utilize initial hospital care codes (as described by CPT codes 99221 through 99223), we believe it is appropriate that the RVUs for the subsequent and initial telehealth HCPCS G-codes are set at the same level as the subsequent and initial hospital care codes, respectively.

D. Summary of CY 2011 Telehealth Policies

In summary, we are finalizing our proposals to add the following requested services to the list of Medicare telehealth services for CY 2011:

- Individual and group KDE services (HCPCS codes G0420 and G0421, respectively);
- Individual and group DSMT services, with a minimum of 1 hour of in-person instruction to be furnished in the year following the initial DSMT service to ensure effective injection training (HCPCS codes G0108 and G0109, respectively);
- Group MNT and HBAI services (CPT codes 97804, and 96153 and 96154, respectively);
- Subsequent hospital care services, with the limitation for the patient's admitting practitioner of one telehealth visit every 3 days (CPT codes 99231, 99232, and 99233); and
- Subsequent nursing facility care services, with the limitation for the patient's admitting practitioner of one telehealth visit every 30 days (CPT codes 99307, 99308, 99309, and 99310).

Furthermore, we are revising § 410.78(b) and § 414.65(a)(1) accordingly. Specifically, we are adding individual and group KDE services, individual and group DSMT services, group MNT services, group HBAI services, and subsequent hospital care and nursing facility care services to the list of telehealth services for which payment will be made at the applicable PFS payment amount for the service of the practitioner. In addition, we have reordered the listing of services in these two sections and removed "initial and follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals and SNFs" in § 410.78(b) because these are described by the more general term "professional

consultations" that is in the same section. Finally, we are continuing to specify that the physician visits required under § 483.40(c) may not be furnished as telehealth services.

E. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through December 31, 2002, at \$20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2011 is 0.4 percent. Therefore, for CY 2011, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or \$24.10. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 49.

TABLE 49—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE AND MEI INCREASE BY THE APPLICABLE TIME PERIOD

Facility fee	MEI increase (%)	Period
\$20.00	N/A	10/01/2001–12/31/2002
\$20.60	3.0	01/01/2003–12/31/2003
\$21.20	2.9	01/01/2004–12/31/2004
\$21.86	3.1	01/01/2005–12/31/2005
\$22.47	2.8	01/01/2006–12/31/2006
\$22.94	2.1	01/01/2007–12/31/2007
\$23.35	1.8	01/01/2008–12/31/2008
\$23.72	1.6	01/01/2009–12/31/2009
\$24.00	1.2	01/01/2010–12/31/2010
\$24.10	0.4	01/01/2011–12/31/2011

V. Addressing Interim Final Relative Value Units From CY 2010 and Establishing Interim Relative Value Units for CY 2011

A. Background

In accordance with section 1848(c) of the Act, CMS determines work, PE, and malpractice RVUs for each service paid under the PFS. On an annual basis, the AMA RUC provides CMS with recommendations regarding physician

work values for new, revised, and potentially misvalued codes. Over the last several years, CMS, in conjunction with the AMA RUC, has identified and reviewed numerous potentially misvalued CPT codes. In 2006, the AMA RUC established the Five-Year Review Identification Workgroup to identify potentially misvalued services using the following screens: "New Technology;" "Site-of-Service Anomalies;" "High Volume Growth;" "CMS Fastest Growing;" "High Intra-Service Work per Unit Time (IWPUT);" "Services Surveyed by One Specialty—Now Performed by a Different Specialty;" "Harvard-Valued, Utilization over 1 Million;" "Harvard Valued, Utilization over 100,000;" and "Codes Reported Together/Bundled CPT Services." In addition to providing recommendations to CMS for work RVUs, the AMA RUC's Practice Expense Subcommittee reviews and then the AMA RUC recommends direct PE inputs (clinical labor, medical supplies, and medical equipment) for individual services. To guide the establishment of malpractice RVUs for new and revised codes before the next 5-Year Review of Malpractice, the AMA RUC also provides crosswalk recommendations, that is, "source" codes with a similar specialty mix of practitioners furnishing the source code and the new/revised code. CMS reviews the AMA RUC recommendations on a code-by-code basis. For AMA RUC recommendations regarding physician work RVUs, we determine whether we agree with the recommended work RVUs for a service (that is, we agree the valuation is accurate), or, if we disagree, we determine an alternative value that better reflects our estimate of the physician work for the service. Because of the timing of the CPT Editorial Panel decisions, AMA RUC recommendations, and our rulemaking cycle, we publish these work RVUs in the PFS final rule with comment period as interim final values, subject to public comment. Similarly, we assess the AMA RUC's recommendations for direct PE inputs and malpractice crosswalks, and establish PE and malpractice interim final values, which are also subject to comment. We note that, with respect to interim final PE RVUs, the main aspect of our valuation that is open for public comment for a new, revised, or potentially misvalued code is the direct PE inputs and not the other elements of the PE valuation methodology, such as the indirect cost allocation methodology, that also contribute to establishing the PE RVUs for a code. The public comment period on the PFS

final rule with comment period remains open for 60 days after the rule is issued.

If we receive public comments on the interim final work RVUs for a specific code indicating that refinement of the interim final work value is warranted based on sufficient information from the commenters concerning the clinical aspects of the physician work associated with the service (57 FR 55917), we refer the service to a refinement panel, as discussed in further detail in sections III.I. and V.B.1. of this final rule with comment period.

In the interval between closure of the comment period and the subsequent year's PFS final rule with comment period, we consider all of the public comments on the interim final work, PE, and malpractice RVUs for the new, revised, and potentially misvalued codes and the results of the refinement panel, if applicable. Finally, we address the interim final RVUs (including the interim final direct PE inputs) by providing a summary of the public comments and our responses to those comments, including a discussion of any changes to the interim final work or malpractice RVUs or direct PE inputs, in the following year's PFS final rule with comment period. We then typically finalize the direct PE inputs and the work, PE, and malpractice RVUs for the service in that year's PFS final rule with comment period, unless we determine it would be more appropriate to continue their interim final status for another year and solicit further public comment.

B. Addressing Interim Final RVUs From CY 2010

In this section, we address the interim final values published in Appendix C of the CY 2010 PFS final rule with comment period (74 FR 62144 through 62146), as subsequently corrected in the December 10, 2009 (74 FR 65449) and May 11, 2010 correction notices (75 FR 26350). We discuss the results of the CY 2010 refinement panel, respond to public comments received on specific interim final values (including direct PE inputs) from CY 2010, address the status of the interim final values of a number of potentially misvalued codes from CY 2009 and CY 2010, and address the other new, revised, or potentially misvalued codes with interim final values for CY 2010 that are not specifically discussed elsewhere in this final rule with comment period.

We note that the final CY 2011 direct PE database that lists the direct PE inputs is available on the CMS Web site under the downloads for the CY 2011 PFS final rule with comment period at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/>

list.asp#TopOfPage. The final CY 2011 work, PE, and malpractice RVUs are displayed in Addendum B to this final rule with comment period.

1. CY 2010 Interim Final Work RVUs Referred to the Refinement Panel

We received public comments on 4 CPT codes with CY 2010 interim final work values. We referred these services to the CY 2010 refinement panel for further review. For ease of discussion, we will be referring to these services as "refinement codes." Consistent with past practice (62 FR 59084), we convened a multispecialty panel of physicians to assist us in the review of the comments. The panel was moderated by our physician advisors, and consisted of the following voting members:

- One or two clinicians representing the commenting organization.
 - Two primary care clinicians nominated by the American Academy of Family Physicians and the American College of Physicians.
 - Three contractor medical directors (CMDs).
 - Clinicians with practices in related specialties who were expected to have knowledge of the services under review.
- We assembled a set of 300 reference services and asked the panel members to compare the clinical aspects of physician work for the refinement code to one or more of the reference services. In compiling the set of reference services, we attempted to include: (1) Services that are commonly performed for which the work RVUs are not controversial; (2) services that span the spectrum of work intensity; and (3) at least three services performed by each of the major specialties that furnish the refinement codes so that the perspective of relevant specialties would be

represented. The panel process was designed to capture each participant's independent judgment and his or her clinical experience which informed and drove the discussion of the refinement code during the refinement panel proceedings. Following the discussion, each voting participant rated the physician work of the refinement code. Ratings were obtained individually and confidentially, with no attempt to achieve consensus among the panel members.

We then analyzed the ratings for each refinement code based on a presumption that the interim final work RVUs were correct unless the ratings clearly indicated a different result. Ratings of work were analyzed for consistency among the four different groups (commenting organization, primary care physicians, CMDs, and related clinicians) represented on the panel. In addition, we used statistical tests to determine whether there was sufficient agreement among the groups of the panel and whether the agreed-upon RVUs differed significantly from the interim final RVUs published in Addendum C of the CY 2010 final rule with comment period. We did not modify the interim final RVUs unless there was clear agreement for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group and looked for agreement among the remaining groups as the basis for new RVUs for the refinement code. This methodology is consistent with the historical refinement process as established in the November 25, 1992 PFS final rule with comment period (57 FR 55938).

Our decision to convene multispecialty panels of physicians and

to apply the statistical tests described above has historically been based on our need to balance the interests of those who commented on the interim final work values with the redistributive effects that would occur in other specialties if the work values were changed. We refer readers to section III.I. of this final rule with comment period for a full discussion of the changes to the refinement process that we are adopting for refinement panels beginning in CY 2011.

Table 50 lists those refinement codes reviewed under the CY 2010 refinement panel process described in this section. The table includes the following information:

- CPT Code. This is the CPT code for a service.
- Short Descriptor. This is an abbreviated version of the narrative description of the code.
- CY 2010 Interim Final Work RVUs. The interim final work RVUs that appeared in the CY 2010 PFS final rule with comment period (74 FR 61949 through 61953), as subsequently corrected in the December 10, 2009 (74 FR 65449) and May 11, 2010 correction notices (75 FR 26350), are shown for each reviewed code.
- Requested Work RVUs. This column identifies the work RVUs requested by the commenters.
- CY 2011 Final Work RVUs. This column contains the final work RVUs after consideration by the refinement panel.

We note that we are accepting the results of the CY 2010 refinement panel for all of these codes as the final work RVUs for CY 2011. These final values are also displayed in Addendum B to this final rule with comment period.

TABLE 50—CPT CODES REVIEWED UNDER THE CY 2010 REFINEMENT PANEL PROCESS

CPT Code	Mod	Short descriptor	CY 2010 interim final work RVUs	Requested work RVUs	CY 2011 final work RVUs
74261	26	Ct colonography, w/o dye	2.28	2.40	2.40
78451	26	Ht muscle image spect, sing	1.38	1.40	1.38
78452	26	Ht muscle image spect, mult	1.62	1.75	1.62
95905	26	Motor/sens nrv conduct test	0.05	0.15	0.05

2. CY 2010 Interim Final RVUs for Which Public Comments Were Received

a. Insertion of Breast Prosthesis (CPT Code 19340)

CPT code 19340 (Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction) was identified by CMS for AMA RUC review as requested by the specialty society. The AMA RUC

recommended 13.78 work RVUs for CY 2010, which CMS accepted. However, as noted by a public comment on the CY 2010 PFS final rule with comment period, the interim final CY 2010 work RVUs published in the CY 2010 PFS final rule with comment period (74 FR 61779, 62023 and 62144) for this service did not reflect the increases in the evaluation and management services for the post-operative visits associated with

this service that resulted from the CY 2010 changes to the consultation code policy. The work RVUs for CPT code 19340 with these increases included are 13.99 RVUs. This correction was included in the May 11, 2010 correction notice to the CY 2010 final rule with comment period (75 FR 26356). We are finalizing the interim work RVUs for CPT code 19340 of 13.99 for CY 2011.

b. Computed Tomographic Colonography (CPT Code 74261)

For CPT code 74261, (Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material), the AMA RUC recommended 2.40 work RVUs. During the AMA RUC meeting, this code was compared to two CPT codes: 75635 (Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing (work RVUs = 2.40)) and 78815 (Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh (work RVUs = 2.44)). Based on the comparisons of similar physician work, physician time, and intensity/complexity measures, the AMA RUC determined that work RVUs of 2.40 were appropriate for CPT code 74261. We disagreed with the AMA RUC-recommended work RVUs and believe CPT code 74263 (Computed tomographic (CT) colonography, screening, including image postprocessing) represents a more comparable service because it has virtually the same description of work, pre-, intra-, and post-service time for which the AMA RUC recommended work RVUs of 2.28. Therefore, we assigned interim final work RVUs of 2.28 to CPT code 74261 for CY 2010.

Comment: Several commenters disagreed with the interim final work RVUs assigned by CMS and believe that equalizing the work RVUs for diagnostic and screening computed tomographic colonography ignores the reality that patients referred for diagnostic study, by definition, have greater complexity. These commenters believed that for this reason and the increased time involved with a diagnostic study, higher work RVUs are necessary to maintain the proper relativity with the corresponding screening CPT code 74263. The commenters recommended that CMS accept the AMA RUC-recommended work RVUs of 2.40 for CPT code 74261 and refer this code to the CY 2010 refinement panel for review.

Response: Based on the concerns expressed by the commenters, we referred this code to the CY 2010 refinement panel for review. As a result of the statistical analysis of the CY 2010 refinement panel ratings, we are assigning 2.40 work RVUs to CPT code 74261 as the final value for CY 2011.

c. Myocardial Perfusion Imaging (CPT Codes 78451, 78452, 78453, and 78454)

For CPT code 78451 (Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)), the AMA RUC recommended 1.40 work RVUs, while the AMA RUC recommended 1.75 work RVUs for CPT code 78452 (Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection).

Upon review of the AMA RUC recommendations for these codes, it was unclear what methodology the AMA RUC used to calculate the recommended work RVUs for CPT code 78451. Therefore, we disagreed with the AMA RUC-recommended work RVUs of 1.40 for CPT code 78451 and believe the work RVUs for the survey 25th percentile were more appropriate. Therefore, we assigned interim final work RVUs of 1.38 to CPT code 78451 for CY 2010.

For CPT code 78452, we disagreed with the reference code used, CPT code 70496 (Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing (work RVUs = 1.75)). We believe CPT code 78452 is comparable to CPT code 73219 (Magnetic resonance (eg, proton) imaging, upper extremity, other than joint; with contrast material(s) (work RVUs = 1.62)), which has the same pre-, intra-, and post-service time. Therefore, we assigned interim final work RVUs of 1.62 to CPT code 78452 for CY 2010.

We accepted the CY 2010 recommendations of the AMA RUC for the direct PE inputs for CPT codes 78451, 78452, 78453, and 78454 (75 FR 61955).

Comment: Several commenters disagreed with the interim final work RVUs assigned by CMS for these two services. The commenters pointed out that the specialty and AMA RUC recommendations for both of these services already reflected a tremendous reduction from the work RVUs for the services as reported by multiple component codes in previous years and expressed disappointment that

additional reductions were made by CMS. The commenters explained that in an effort to maintain relativity between CPT codes 78451 and 78452, the recommended RVUs for 78451 were derived by calculating the relationship between the median survey RVUs for CPT codes 78451 and 78452 and maintaining this relationship between the recommended RVUs for CPT codes 78451 and 78452. That is, the survey work RVU relationship between CPT code 78451: 78452 is [1.50: 1.87], leading to the same relationship between the AMA RUC-recommended RVUs for 78451: 78452 of [1.40: 1.75]. The AMA RUC agreed that the computed work RVUs, 1.40 for CPT code 78451, maintain the relativity of the original survey data and provide an appropriate measure of the work for CPT code 78451.

The commenters believe that CMS does not have the special expertise necessary to choose a different reference code than the code selected by the multispecialty AMA RUC panel and disagreed with the reference code used by CMS for establishing work RVUs for CPT code 78452. The AMA RUC pointed out that the reference code has no associated computer post-processing analysis, requires the interpretation of fewer images, and has no additional cine-motion images to analyze and interpret, all of which are included in the myocardial perfusion imaging procedures.

The commenters requested that CMS accept the AMA RUC recommendations of 1.40 work RVUs for CPT code 78451 and 1.75 work RVUs for CPT code 78452 and refer these codes to the CY 2010 refinement panel for review.

Response: Based on the concerns expressed by the commenters, these codes were referred to the CY 2010 refinement panel for review. As a result of the statistical analysis of CY 2010 refinement panel ratings, the work RVUs for these codes were unchanged. Therefore, we are adopting the interim final values for these codes as final, with 1.38 work RVUs for CPT code 78451 and 1.62 work RVUs for CPT code 78452 for CY 2011.

Comment: Several commenters asserted that CMS had incorrectly crosswalked equipment time inputs for several myocardial perfusion imaging codes (CPT codes 78451, 78452, 78453, and 78454), rather than accepting the AMA RUC recommendations for these codes as CMS had stated in the CY 2010 PFS final rule with comment period (74 FR 61955). One commenter further suggested that the useful life of 5 years for the Cobalt-57 flood source was incorrect.

Response: We appreciate the commenters' assistance, and we corrected the equipment times in the May 11, 2010 correction notice to the CY 2010 PFS final rule with comment period (75 FR 26356 and 26570). We are finalizing these direct PE inputs for CY 2011. We also proposed to change the useful life of the Cobalt-57 flood source from 5 to 2 years for CY 2011 (75 FR 40056). We address our final policies regarding this proposal in section II.A.3.b.(4) of this final rule with comment period.

Comment: Several commenters expressed concern that CMS applied fully transitioned PE RVUs to the new and revised CY 2010 CPT codes, specifically CPT codes 78451, 78452, 78453, and 78554. The commenters argued that the result of the lack of a transition to use of the PPIS data was an immediate 26 percent reduction for myocardial perfusion imaging services, simply because the CPT code descriptors had been revised to capture multiple procedure components. The commenters requested that the new CPT codes follow the same blend of new and previous PE RVUs that was applied to the existing CPT codes in CY 2010 and later years.

Response: Our longstanding policy is that if the CPT Editorial Panel creates a new code for a given year, the new code would be paid at its fully implemented PFS amount and not at a transition rate for that year. Consistent with this policy, the new CY 2010 myocardial perfusion imaging codes, and all other new CY 2010 CPT codes, are not being paid based on transitional PE RVUs in CY 2010. We will continue to pay these services based on the fully implemented PE RVUs in CY 2011, the same approach we are applying to other CPT codes that were new for CY 2010 or CY 2011.

d. Nerve Conduction Test (CPT Code 95905)

For CPT code 95905 (Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report), the AMA RUC recommended 0.05 work RVUs, which we accepted in the CY 2010 PFS final rule with comment (74 FR 61953).

Comment: One commenter requested that CMS refer CPT code 95905 to the CY 2010 refinement panel for review. The commenter believes the AMA RUC erred in its recommendation to CMS in regard to the physician work involved. The commenter noted that when this code was discussed at the AMA RUC meeting, the commenter and other

specialty societies that presented this code to the AMA RUC recommended assignment of 0.15 work RVUs. The commenter also believes that the undervaluation of the physician work for this service may undermine the ability of physicians to provide the service.

Response: Based on the concerns expressed by the commenter, this code was referred to the CY 2010 refinement panel for review. As a result of the statistical analysis of the CY 2010 refinement panel ratings, the work RVUs for this code were unchanged. Therefore, we are finalizing the interim final values for CPT code 95905 as 0.05 work RVUs for CY 2011.

e. Kidney Disease Education Services (HCPCS Codes G0420 and G0421)

During rulemaking for CY 2010, we adopted policies to provide for the implementation of section 152(b) of the MIPPA which created a new benefit category for kidney disease education (KDE) services for Medicare beneficiaries diagnosed with Stage IV chronic kidney disease (CKD). The MIPPA also amended section 1848(j)(3) of the Act which allows for payment of KDE services under the PFS. For CY 2010, we proposed and finalized the RVUs for the two HCPCS G-codes established for the payment of KDE services (74 FR 61901), G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour) and G0421 (Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour). For purposes of valuing the HCPCS codes for KDE services, we based the work RVUs and the PE inputs, with minor modifications, on CPT codes for medical nutrition therapy (MNT) services, specifically CPT code 97802 (Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes) and CPT code 97804 (Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes), because we believed these services to be similar. We crosswalked the work RVUs for HCPCS code G0420 from CPT code 97802 and for HCPCS code G0421 from CPT code 97804. We multiplied the work RVUs for HCPCS code G0420 by four and the work RVUs for HCPCS code G0421 by two to account for the fact that we crosswalked a 15 minute code to a 60 minute code (CPT code 97802 to HCPCS code G0420) and a 30 minute code to a 60 minute code (CPT code 97804 to HCPCS code G0421). In order to determine the direct PE inputs for the KDE services, we indicated that

we did not perform straight multiplication of the actual MNT inputs because we did not believe that the required equipment and supplies for the KDE services would increase in direct proportion to the increased time for the codes. For both HCPCS codes G0420 and G0421, we noted that we did not increase the equipment time-in-use for the body analysis machine, printer, or scale, and that we did increase the inputs for the table, computer, paper, and other printed materials.

Comment: Several commenters expressed support for the CY 2010 work RVUs for the KDE HCPCS codes G0420 and G0421. However, one commenter requested that CMS include the supplies for the KDE services as directly proportional multiple units of the MNT services in order to appropriately pay for the costs of care, noting that HCPCS code G0420 (60 minutes) should have 4 times as many supplies as those in CPT code 97802 (15 minutes) and HCPCS code G0421 (60 minutes) should have 2 times as many as those in CPT code 97804 (30 minutes).

Response: We appreciate the commenters' support for the interim final work

Response: We appreciate the commenters' support for the interim final work RVUs we established for HCPCS codes G0420 and G0421 for KDE services and we are finalizing those work RVUs for CY 2011. After reviewing the direct PE inputs for supplies in both the KDE HCPCS G-codes (G0420 and G0421) and the MNT CPT codes (CPT codes 97802 and 97804), we agree with the commenter that we had not increased the number of sheets of paper for either HCPCS code G0420 or G0421 as we indicated we would (74 FR 61901). Therefore, we have increased the number of paper sheets from 2 in CPT code 97802 (15 minutes) to 8 in HCPCS code G0420 (60 minutes) and from 2 in CPT code 97804 (30 minutes) to 4 in HCPCS code G0421 (60 minutes). We have also made conforming changes to the printer times for both KDE HCPCS G-codes in the equipment file because we base the printer time on the number of sheets of paper. We are adopting these modified direct PE inputs for HCPCS codes G0420 and G0421 as final for CY 2011.

f. Excision of Soft Tissue, and Bone Tumors (CPT codes 21011 through 21016, 21552, 21554 through 21558, 21930 through 21933, 21395, 21936, 22900 through 22905, 23071, 23073, 23075 through 23078, 23200, 23210, 23220, 24071, 24073, 24075 through 24077, 24079, 24150 through 24153, 25071, 25073, 25075 through 25078, 25170, 26111, 26113, 26115 through 26118, 26250, 26255, 26260, 26262, 27043, 27045, 27047 through 27049, 27059, 27075 through 27078, 27327 through 27329, 27337, 27339, 27364, 27365, 27615, 27616, 27618, 27619, 27632, 27634, 27619, 27645 through 27647, 28039, 28041, 28043, 28045 through 28047, 28171, 28173, and 28175)

For CY 2010, the CPT Editorial Panel split 31 excision codes into 62 codes differentiated by the size of the excised lesion, 18 codes were revised, and 12 additional codes were created. Although we had significant concerns with the pre-service times and the AMA RUC-recommended work RVUs for these codes for CY 2010, in the context of public comments on the CY 2010 proposed rule regarding the site-of-service anomaly codes, we agreed to accept the AMA RUC-recommended work values for these codes on an interim final basis for CY 2010 (74 FR 61954). We also requested that the AMA RUC reexamine the minutes allocated for positioning of the patient for these codes. We noted that we would work with the AMA RUC to address our concerns about the valuation of these codes and would consider whether it would be appropriate to propose further changes in future rulemaking. We indicated that we did not agree with the AMA RUC's recommendations for the inclusion of inpatient hospital care services in these codes, particularly in the cases of codes that would be reported for the smaller-sized tumors. As a result, we stated that we would monitor the frequency data for these codes and may propose further changes to the work RVUs in the future based on these data. We emphasized that the AMA RUC itself recommended that these services be re-reviewed to determine the accuracy of the utilization assumptions once 2 years of utilization data were available.

In addition, we noted that the CPT 2010 instructions regarding the use of the excision and resection of soft tissue and bone tumor codes advised that a complex repair may be separately reported. However, longstanding Medicare policy generally includes payment for all simple, intermediate, and complex repairs of procedural

incisions and, therefore, Medicare would not separately pay for complex repairs associated with procedures reported by these codes.

Comment: Several commenters were pleased that CMS agreed to accept the AMA RUC-recommended values for these new and revised codes. One commenter endorsed CMS' decision to closely monitor the utilization rates for these codes and believes this would be important to ensure accurate payment. The commenters did not see a need for CMS or the AMA RUC to review the pre-service times assigned to the codes and stated that all of these times were derived from the AMA RUC's pre-service time package methodology, a methodology that CMS has historically supported. The commenters asserted that the times assigned are reflective of the actual patient positioning times. Therefore, the commenters urged CMS to withdraw the request that the AMA RUC revisit the pre-service times for these codes. The commenters asserted that further review would add extra time and work to the already significant workload of the AMA RUC and would not result in any changes.

Response: We appreciate the commenters' support for our acceptance of the AMA RUC-recommended values for these new and revised codes and we are finalizing the interim final work RVUs for these codes for CY 2011. As we stated in the CY 2010 PFS final rule with comment period, we will continue to monitor the frequency data for these codes and work with the AMA RUC to address our concerns and, if appropriate, propose further changes in future rulemaking. In addition, we are reiterating our request originally made in the CY 2010 PFS final rule with comment period (74 FR 61954) that the AMA RUC review the pre-service times for these codes and provide their recommendations to us.

g. Cryoablation of Prostate (CPT code 55873)

In June 2008, CMS requested that the AMA RUC review the nonfacility direct PE inputs for CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement). During this review, the AMA RUC recognized that this service was initially reviewed as a new code by the AMA RUC in February 2001. The AMA RUC believed that the intra-service physician time since the initial review had declined (from 200 minutes) as the service is now more commonly performed. The AMA RUC agreed with the specialty society that the service should be surveyed for physician work

and also recommended revisions in the direct PE inputs. As a result of the AMA RUC review and input from the specialty society, the AMA RUC recommended 13.45 work RVUs and revisions to the direct PE inputs for this service for CY 2010. We reviewed these recommendations and accepted the AMA RUC-recommended work RVUs for this code and the direct PE inputs in the CY 2010 PFS final rule with comment (74 FR 61954 and 61955).

Comment: One commenter expressed concern about the reduction in the work RVUs for CPT code 55873 and the lack of public notice given prior to the reduction. The commenter believes that the intra-service time was underestimated and could vary based on the skill set of the physician. The commenter requested that CMS reinstate the work RVUs as included in the CY 2010 PFS proposed rule for CY 2010 (74 FR 33740).

Response: While we originally requested that the AMA RUC review the nonfacility direct PE inputs for CPT code 55873, we believe that it is appropriate for the AMA RUC to respond to its findings during a limited review by taking other actions that it believes to be appropriate for the particular circumstances, such as requesting that procedures be resurveyed. We followed our usual methodology for revised codes whereby we respond to the AMA RUC work recommendations and adopt interim final values in the final rule with comment period for the upcoming year. In this way, we facilitate appropriate payment for the services on an interim final basis while providing public notice and the opportunity for public comment prior to finalizing the values in the following year.

We note that the RVUs for services paid under the PFS are resource-based, and individual services are valued based upon the typical resources used to provide the service. Because clinical utilization of this service has increased over the last several years and information from the current AMA RUC survey suggests there has been a decrease in intra-service time from 200 to 100 minutes, we continue to believe the reduction in intra-service time and the revised work RVUs as recommended to us by the AMA RUC are clinically appropriate for this service. We commonly expect greater work efficiency as clinical experience with a new service increases over time, and this service fits that profile. Therefore, we are finalizing the interim final work RVUs of 13.60 for CPT code 55873 for CY 2011.

Comment: One commenter stated that the 162 minutes of clinical labor time for CPT code 55873 in the final CY 2010 PFS direct PE database should be 168 minutes. The commenter also indicated that supply code SD074 be included as an input for CPT code 55873 based on the AMA RUC's CY 2010 recommendations.

Response: We appreciate the commenter bringing this information to our attention and agree with the commenter's assessment. The 6 minutes of clinical labor time missing from the direct PE inputs for CPT code 55873 have now been included, as has the filiform, and these changes are reflected in the final CY 2011 PFS direct PE database. We are finalizing these direct PE inputs for CPT code 55873 for CY 2011.

h. Urodynamics Studies (CPT Codes 51728 and 51729)

In February 2008, the AMA RUC identified CPT codes 51726 (Complex cystometrogram (ie, calibrated electronic equipment)); 51772 (Urethral pressure profile studies (UPP) (urethral closure pressure profile), any technique); 51795 (Voiding pressure studies (VP); bladder voiding pressure, any technique); and 51797 (Voiding pressure studies, intra-abdominal (ie, rectal, gastric, intraperitoneal) (List separately in addition to code for primary procedure)) through the "Codes Reported Together" potentially misvalued codes screen as combinations of codes that were reported together more than 95 percent of the time. The AMA RUC referred all four codes to the CPT Editorial Panel for creation of CPT codes for new comprehensive services and for reorganization of the coding structure to reflect the typical procedures performed. As a result, CPT codes 51772 and 51795 were deleted, CPT code 51797 was revised, and CPT codes 51727 (Complex cystometrogram (ie, calibrated electronic equipment); with urethral pressure profile studies (ie, urethral closure pressure profile), any technique); 51728 (Complex cystometrogram (ie, calibrated electronic equipment); with voiding pressure studies (i.e., bladder voiding pressure), any technique); and 51729 (Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (ie, bladder voiding pressure) and urethral pressure profile studies (i.e., urethral closure pressure profile), any technique) were created for CY 2010. Accordingly, the AMA RUC reviewed the clinical labor inputs for the typical patient and made minor edits regarding the intra-service time for these services. In addition, the

AMA RUC made adjustments to the medical supplies and equipment. As noted in the CY 2010 PFS final rule with comment period (74 FR 61955), we accepted these recommendations for the direct PE inputs on an interim final basis.

Comment: Several commenters asserted that CPT codes 51728 and 51729 should have additional clinical labor inputs, including a greater number of minutes during the intra-service period and minutes during the pre-service period. These commenters also requested revisions to the PE supply inputs for the codes.

Response: We discuss our CY 2011 proposal and the final CY 2011 policy with respect to the direct PE inputs for CPT codes 51728 and 51729 in section II.A.3.c.(5) of this final rule with comment period. As we state there, we reviewed the direct PE inputs for these two CPT codes and three related CPT codes following revised AMA RUC recommendations for CY 2011. We agreed with the AMA RUC recommendations regarding changes for CY 2011. Specifically, we believe the pre-service nonfacility clinical labor time for the 0-day global period CPT codes 51725 (simple cystometrogram (CMG) (eg, spinal manometer)) and 51726 should be removed and the intra-service clinical labor time for CPT code 51726 should also be reduced, consistent with the usual treatment of other 0-day global codes. We believe the AMA RUC provided recommendations to us regarding the direct PE inputs for these cystometrogram services that accurately reflect the costs of the resources (that is, the clinical labor, equipment, and supplies) typically required to furnish these services to Medicare beneficiaries.

Comment: Several additional commenters alerted CMS to incorrect supply inputs for CPT codes 51728 and 51729. The commenters noted that the AMA RUC direct PE recommendations for CPT code 51728 included an additional beaker. In the case of CPT code 51729, the commenters stated that CMS did not include the recommended beaker and tubing in the direct PE database for the CY 2010 final rule with comment period.

Response: We appreciate the commenters' assistance, and we made these corrections in the May 11, 2010 correction notice to the CY 2010 PFS final rule with comment period (75 FR 26356 and 26478). We are finalizing these direct PE inputs, as corrected, for CPT codes 51728 and 51239 for CY 2011.

i. Coronary Computed Tomographic Angiography (CPT Codes 75571, 75572, 75573, and 75574)

In October 2008, the CPT Editorial Panel deleted eight Category III CPT codes (0144T through 0151T) and created four new codes for CY 2010, specifically CPT codes 75571 (Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium); 75572 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)); 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)); and 75574 (Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)) to describe the evolution of the performance of cardiac and coronary computed tomography for specific clinical scenarios. We accepted the AMA RUC recommendations for direct PE inputs for these codes on an interim final basis for CY 2010 (74 FR 61955).

Comment: Several commenters stated that the final CY 2010 PFS direct PE database included incomplete direct PE inputs for CPT codes 75572 and 75573. The commenters also submitted updated pricing information for the 64-slice CT scanner.

Response: We appreciate the commenters' assistance, and we corrected these errors in the May 11, 2010 correction notice to the CY 2010 PFS final rule with comment period (75 FR 26356 and 26543). We are finalizing the direct PE inputs for CPT codes 75571, 75572, 75573, and 75574, as corrected, for CY 2011. Additionally, we proposed an updated price for the 64-slice CT scanner and its accompanying software in the CY 2011 PFS proposed rule (75 FR 40062). We address that proposal and our final CY 2011 policy in section II.A.3.c.(2) of this final rule with comment period.

j. Adjacent Tissue Transfer or Rearrangement (CPT Codes 14301 and 14302)

CPT code 14300 (Adjacent tissue transfer or rearrangement, more than 30 sq cm, unusual or complicated, any area) was identified by the Five-Year Review Identification Workgroup through its "Site-of-Service Anomalies" screen for potentially misvalued codes and subsequently identified through the "CMS Fastest Growing" screen. The service was referred to the CPT Editorial Panel to clarify the coding for tissue transfers involving different size areas. As a result, CPT code 14300 was deleted and two new codes, CPT codes 14301 (Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm) and 14302 (Adjacent tissue transfer or rearrangement, any area; each additional 30.0 sq cm, or part thereof (List separately in addition to code for primary procedure)) were created. We accepted the AMA RUC recommendations for direct PE inputs on an interim final basis for CY 2010 (74 FR 61955).

Comment: One commenter stated that there were discrepancies between the AMA RUC recommendations and the direct PE inputs for CPT codes 14301 and 14302.

Response: We appreciate the commenters' assistance, and we corrected these errors in the May 11, 2010 correction notice to the CY 2010 PFS final rule with comment period (75 FR 26356 and 26368). Upon additional review of the direct PE inputs for consistency with the CY 2010 AMA RUC recommendations for this CY 2011 final rule with comment period, we also found that the instrument pack for CPT code 14301 should be EQ138 (instrument pack, medium (\$1500 and up)) instead of EQ137 (instrument pack, basic (\$500-\$1499)). Furthermore, CPT code 14301 should have one SA054 (pack, post-op incision care (suture)) as a supply input in both the nonfacility and facility settings. The final CY 2011 PFS direct PE database reflects these additional corrections. We are finalizing the direct PE inputs for CPT codes 14301 and 14302 for CY 2011.

k. Insertion of a Temporary Prostatic Urethral Stent (CPT code 53855)

CPT code 53855 (Insertion of a temporary prostatic urethral stent, including urethral measurement) was created for CY 2010 to describe the service previously reported under the Category III CPT code 0084T. We accepted the AMA RUC recommendations for direct PE inputs

on an interim final basis for CY 2010 (74 FR 61955).

Comment: One commenter stated that CPT code 53855 was incorrectly missing supply codes SD074 and SH050 as inputs in the final CY 2010 PFS direct PE database. The commenter also noted that SJ038 was incorrectly substituted for SJ032.

Response: We appreciate the commenter bringing these items to our attention and agree with the commenter's assessment. The supply items for CPT code 53588 (filiform and one unit of lidocaine) have been included in the direct PE inputs and we have replaced petroleum jelly with lubricating jelly. These changes are reflected in the final CY 2011 PFS direct PE database. We are finalizing the revised direct PE inputs for CPT code 53855 for CY 2011.

l. High Dose Rate Brachytherapy (CPT codes 77785, 77786, and 77787)

CPT codes 77785 (Remote afterloading high dose rate radionuclide brachytherapy; 1 channel); 77786 (Remote afterloading high dose rate radionuclide brachytherapy; 2–12 channels); and 77787 (Remote afterloading high dose rate radionuclide brachytherapy; over 12 channels) were identified by the Five-Year Review Identification Workgroup through the "CMS Fastest Growing" and "High Volume Growth" potentially misvalued codes screens and later revised by the CPT Editorial Panel for CY 2009. As a result, the AMA RUC made recommendations for physician work and direct PE inputs for these revised services for CY 2009, which we accepted in the CY 2009 PFS final rule with comment period (73 FR 69892). Upon acceptance of the AMA RUC recommendations, we received several comments concerning the direct PE direct inputs (for example, supply costs and the useful life of the renewable sources) related to several high dose radiation therapy and placement CPT codes. In the CY 2010 PFS proposed rule (74 FR 33532), we requested that the AMA RUC revisit the direct PE inputs for these services. In response to our request, the AMA RUC reviewed the direct PE inputs for these services and made adjustments to the clinical labor staff type, changed the time for some activities, and edited the medical supplies and equipment for the typical patient scenario. In addition, the AMA RUC also recommended further discussion between the specialty and CMS regarding appropriate resolution of the PE input price for the Iridium-192 brachytherapy source typically used in CPT codes 77785, 77786, and 77787. We

accepted these direct PE recommendations for CY 2010 on an interim final basis (74 FR 61782).

Comment: One commenter informed CMS of two concerns regarding CPT codes 77785, 77786, and 77787. The commenter stated that the AMA RUC summary direct PE output table included incorrectly doubled PE inputs for each of the codes. The commenter also pointed out that the medical physicist clinical labor time for CPT code 77786 should be 54 minutes instead of 29 minutes.

Response: We appreciate the commenters' assistance, and we corrected these errors in the May 11, 2010 correction notice to the CY 2010 PFS final rule with comment period (75 FR 26356 and 26564). We are finalizing the direct PE inputs for CPT codes 77785, 77786, and 77787, as corrected, for CY 2011.

m. Injection of Facet Joint (CPT Codes 64490, 64491, 64492, 64493, 64494, and 64495)

Facet joint injection services were identified by the Five-Year Review Identification Workgroup "High Volume Growth" potentially misvalued codes screen and referred to the CPT Editorial Panel to create an appropriate coding structure to report primary and additional injections. As a result, the four existing codes describing these services were deleted and CPT codes 66490 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level); 64491 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure)); 64492 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)); 64493 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level); 64494 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or

sacral; second level (List separately in addition to code for primary procedure)); and 64495 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)) were created for CY 2010. Accordingly, the AMA RUC reviewed the direct PE inputs as recommended by the specialty and made some minor edits to the clinical labor and medical supplies to reflect the typical patient service, which we accepted in the CY 2010 PFS final rule with comment on an interim final basis (74 FR 61955).

Comment: Several commenters stated that the equipment and supplies listed in the final CY 2010 PFS direct PE database for CPT codes 64490, 64491, 64492, 64493, 64494, and 64495 were incorrect and not consistent with the AMA RUC's recommendations.

Response: We verified that the equipment and supplies listed as direct inputs for these codes in the final CY 2011 direct PE database match the CY 2010 recommendations provided to us by the AMA RUC. We encourage stakeholders who believe a change is required in the direct PE inputs associated with a particular service in the typical case that is furnished in the facility or nonfacility setting to address these concerns with the AMA RUC. We are finalizing these direct PE inputs for CPT codes 64490, 64491, 64492, 64493, 64494, and 64495 for CY 2011.

n. Knee Arthroscopy (CPT Code 29870)

In the CY 2008 PFS final rule (72 FR 66238), we deferred the establishment of nonfacility direct PE inputs for CPT code 29870 (Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)) and stated that the physicians performing arthroscopic services in the nonfacility setting should be given the opportunity to have a multispecialty review by the AMA RUC. We accepted the AMA RUC recommendations for nonfacility direct PE inputs in the CY 2010 PFS final rule with comment period on an interim final basis (74 FR 61955).

Comment: One commenter indicated that the wrong arthroscopic system was approved by the AMA RUC for CPT code 29870.

Response: We verified that the equipment input for this code in the final CY 2011 PFS direct PE database matches the recommendation provided to us by the AMA RUC. We encourage stakeholders who believe a change is required in the direct PE inputs

associated with a particular service in the typical case that is furnished in the facility or nonfacility setting to address these concerns with the AMA RUC. We are finalizing the direct PE inputs for CPT code 298770 for CY 2011.

3. Status of Interim Final Work RVUs for Potentially Misvalued Site-of-Service Anomaly Codes From CY 2009 and CY 2010

In previous years, we have requested that the AMA RUC review codes that, according to Medicare claims data, have experienced a change in the typical site-of-service since the original valuation of the code. The AMA RUC reviewed and recommended to CMS revised work RVUs for 29 codes for CY 2009 and 11 codes for CY 2010 that were identified as having site-of-service anomalies. In the CYs 2009 and 2010 PFS final rules with comment period (73 FR 69883 and 74 FR 61776 through 61778, respectively), we indicated that although we would accept the AMA RUC valuations for these site-of-service anomaly codes on an interim final basis through CY 2010, we had ongoing concerns about the methodologies used by the AMA RUC to review these services. We requested that the AMA RUC reexamine the site-of-service anomaly codes and use the building block methodology to revalue the services (74 FR 61777).

For CY 2011, as discussed in more detail in section II.C.3.d. of this final rule with comment period, we are requesting that the AMA RUC reconsider its previously recommended values, which have been applied on an interim final basis in CYs 2009 and 2010, and revise the work RVUs to better reflect the intensity of the services and the revised physician times and post-procedure visits included in the valuation of these codes. Until we receive the revised values from the AMA RUC for CY 2012 and can make a determination regarding them, we are continuing to accept the existing AMA RUC-recommended work RVUs listed in Tables 14 and 15 in section II.C.3.d. of this final rule with comment period on an interim final basis for CY 2011.

4. Other New, Revised, or Potentially Misvalued Codes With CY 2010 Interim Final RVUs Not Specifically Discussed in the CY 2011 Final Rule With Comment Period

For all other CY 2010 new, revised, or potentially misvalued codes with CY 2010 interim final RVUs that are not specifically discussed in this final rule with comment period, we are finalizing, without modification, the interim final work and malpractice RVUs and direct

PE inputs that we initially adopted for CY 2010.

C. Establishment of Interim Final RVUs for CY 2011

In this section, we discuss the establishment of work, PE, and malpractice interim final RVUs for CY 2011 and issues related to the processes for establishing these values. These CY 2011 work, PE, and malpractice interim final RVUs, and the associated direct PE inputs, are open to comment on this CY 2011 final rule with comment period. In general, the work, PE, and malpractice RVUs and the associated direct PE inputs for the CY 2011 new and revised codes will be finalized in the CY 2012 PFS final rule with comment period, where we will also respond to the public comments received on the values and direct PE inputs that are adopted on an interim final basis in this CY 2011 final rule with comment period. The final CY 2011 PFS direct PE database and the crosswalks for the malpractice RVUs for new and revised codes are posted on the CMS Web site under the downloads for the CY 2011 PFS final rule with comment period at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

For CY 2011, we received AMA RUC recommendations for 325 new, revised, and potentially misvalued CPT codes and 93 recommended deletions. Of the 325 codes, 84 were identified as potentially misvalued, 125 as new, and 116 as revised. After subtracting out CPT codes for which no work RVU recommendation were given—including codes listed on the Clinical Lab Fee Schedule (CLFS), vaccine codes, and technical component only codes—there were 291 codes for which the AMA RUC provided work RVU recommendations for CY 2011: 82 CPT codes classified by the AMA RUC as potentially misvalued, 108 as new, and 101 as revised. Of note, as displayed in Table 53, we consider 204 of the AMA RUC work recommendations for CY 2011 new and established CPT codes to be for codes identified through, created as a result of, or valued in association with service(s) identified through a potentially misvalued code screen. Additionally, we received direct PE input recommendations from the AMA RUC for 325 CPT codes for CY 2011.

For CY 2011, we note that the CPT Editorial Panel deleted CPT codes 0160T (Therapeutic repetitive transcranial magnetic stimulation treatment planning) and 0161T (Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session) and created two new CPT codes, 90867

(Therapeutic repetitive transcranial magnetic stimulation treatment; planning) and 90868 (Therapeutic repetitive transcranial magnetic stimulation treatment; delivery and management, per session). Due to the timing of the creation of these codes, the AMA RUC was unable to provide work and PE recommendations for CY 2011. As a result, these codes will be contractor-priced for CY 2011.

1. Establishment of Interim Final Work RVUs for CY 2011

a. Background

As we previously explained in section V.A. of this final rule with comment period, on an annual basis, the AMA RUC provides CMS with recommendations regarding physician work values for new, revised, and potentially misvalued codes. We review the AMA RUC-recommended work RVUs on a code-by-code basis. We determine whether we agree with the AMA RUC's recommended work RVUs for a service (that is, we agree the valuation is accurate), or, if we disagree, we determine an alternative value that better reflects our estimate of the physician work for the service.

As stated earlier, the AMA RUC provided work RVU recommendations for 291 CPT codes. Of the 291, we are accepting 207 (71 percent) of the AMA RUC-recommended values and providing alternative values for the remaining 84 (29 percent). Over the last several years our rate of acceptance of the AMA RUC recommendations has been higher, at 90 percent or greater. However, in response to concerns expressed by MedPAC, the Congress, and other stakeholders regarding the accurate valuation of services under the PFS, we have intensified our scrutiny of the work valuations of new, revised, and potentially misvalued codes. We note that most recently, the law was amended (section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA)) to add a new requirement which specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. The validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. Furthermore, the Secretary is directed to validate a sampling of the work RVUs of codes identified through any of the seven categories of potentially misvalued codes specified by section

1848(c)(2)(K)(ii) of the Act (as added by section 3134 of the ACA). While we are currently in the planning stage of developing a formal validation process, we believe we should be incorporating, where appropriate, the validation principles specified in the law. That is, in reviewing the CY 2011 AMA RUC recommendations for valuing the work of new, revised, and potentially misvalued services, we have expended significant effort in evaluating whether the recommended values reflect the work elements, such as time, mental effort, and professional judgment, technical skill and physical effort, and stress due to risk, involved with furnishing the service. We subjected each of the CY 2011 codes to a rigorous clinical review, examining the pre-, post-, and intra-service components of the work. If we concluded that the AMA RUC's recommended value for a code was not accurate, we looked for comparisons with other established reference codes with clinical similarity or analogous pre-, post-, and intra-service times, and, where applicable, employed the building block approach to inform our interim final decision to establish an alternative value that we believe is more appropriate.

The AMA RUC has emphasized the need to value services "relative" to other services, explaining in its public comment on the CY 2011 PFS proposed rule that it will "continue to employ magnitude estimation in developing relative value recommendations as it is the cornerstone of the RBRVS (resource-based relative value scale)." We agree that services paid under the PFS should be reviewed and valued in manner consistent with Medicare payment policy to maintain appropriate relativity between services and promote accurate pricing. In our review of the 291 CY 2011 AMA RUC recommendations for work values, we noted that the AMA RUC used a variety of approaches and methodologies to arrive at the recommended work values. For some codes, the AMA RUC used magnitude estimation in conjunction with survey data from physician surveys conducted by the specialty societies to support the values. For other codes, the AMA RUC used magnitude estimation to override the results of the survey data, recommending to CMS a value that was not based on survey data but rather, justified in terms of its appropriate relativity within the system to other similar services. The AMA RUC may also elect to use a crosswalk approach in valuing a code by applying a work value from a currently valued code to the code under review based on the

clinical similarity of the procedures or explicit considerations of pre-, intra-, and post-service times. In some instances, the AMA RUC asserted that it used the building block methodology to value the code, a methodology CMS has historically supported (74 FR 61776).

We understand that the AMA RUC believes that it must approach valuation on a code-by-code basis, and depending on the context of the particular code, some methodologies may be better suited than others for valuation purposes. However, we remain concerned over the variations and some applications of the AMA RUC's methodologies which, if we continue to accept them, could contribute to inaccuracy in the relativity of physician work valued under the PFS for different services. Our concerns at this time include the following methodological issues which we observed during our review of the CY 2011 AMA RUC work recommendations:

- AMA RUC-recommended values without benefit of a survey: For a number of codes, the AMA RUC justified the work RVUs by crosswalking the codes to existing codes deemed comparable by the AMA RUC. Since the specialty society did not conduct a survey for these codes, there are no survey data to back up the recommended work RVUs.

- Surveys conducted on existing codes produced predictable results: In providing recommendations for existing potentially misvalued codes, the AMA RUC often recommended maintaining the current work RVUs and supported this valuation by citing the survey results. Upon clinical review of a number of these cases, we are concerned over the validity of the survey results since the survey values often are very close to the current code values. Increasingly, rather than recommending the median survey value that has historically been most commonly used, the AMA RUC is choosing to recommend the 25th percentile value, potentially responding to the same concern we have identified.

- AMA RUC deviated significantly or disregarded survey results completely: For the majority of codes, the AMA RUC cited the survey results in support of the work RVU recommendations and in many instances adopted either the survey median or 25th percentile value as the AMA RUC-recommended value. However, in some instances, the AMA RUC recommended work RVUs which deviated significantly from the survey results. Rather than using the survey data, the AMA RUC appears to have relied on another methodology to value the code, such as "magnitude

estimation" or crosswalk to a comparable code.

In reviewing the 291 work RVU recommendations from the AMA RUC for CY 2011, we concluded that the strongest support for the valuation of a code occurred when the AMA RUC cited multiple germane methodologies that all yielded a similar value that was also supported by the survey. We tended to accept the AMA RUC-recommended values in these instances. However, we found the weakest and least convincing valuations occurred in cases where the AMA RUC either deviated significantly or disregarded the survey results in favor of tweaking various components of the code in order to justify a value which the AMA RUC believed was correct due to perceived "magnitude estimation" for that code. We are concerned that such actions by the AMA RUC may create problems for any systematic validation processes that could be implemented in the future as required by section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA).

Accordingly, for those CY 2011 codes for which we did not accept the AMA RUC recommendations and are instead establishing alternative interim final values, we discuss our decisions based on groupings of codes in the following sections. Table GG4 at the end of this section displays the AMA RUC recommendations and interim final work RVUs for CY 2011 new, revised, and potentially misvalued codes. b. CY 2011 Interim Final Work RVUs for New and Revised Codes (1) CY 2011 New and Revised Codes that Do Not Represent Major New Comprehensive Services

We provide an explanation in the following sections of our rationale for not accepting particular AMA RUC-recommended or Health Care Professional Advisory Committee (HCPAC)-recommended work RVUs for CY 2011 new and revised CPT codes that do not represent major new comprehensive services that are listed in Table 51 and discussed in the subsequent section. The issues are arranged by type of service in CPT code order and address only work RVUs. These codes are listed in Table 53, which includes a complete list of all new, revised, and potentially misvalued CPT codes with CY 2011 AMA RUC work RVU recommendations and CMS' interim final decisions for CY 2011.

(A) Excision and Debridement (CPT Codes 11010, 11011, 11012, 11042, 11043, 10144, 11045, 11046, 11047, and 97598)

CPT codes 11043 (Debridement; skin, subcutaneous tissue, and muscle) and 11044 (Debridement; skin, subcutaneous tissue, muscle, and bone) were identified by the AMA RUC's Five-Year Review Identification Workgroup through the "Site-of-Service Anomalies" potentially misvalued codes screen in September 2007. The AMA RUC recommended that the entire family of services described by CPT codes 11040 through 11044 and 97597 and 97598 be referred to the CPT Editorial Panel because the current descriptors allowed reporting of the codes for a bimodal distribution of patients and also to better define the terms excision and debridement. These codes were included with many other codes under review by the CPT Excision and Debridement Workgroup. CPT codes 11010, 11011, 11012, and 11042 through 11047 were reviewed by the AMA RUC and CPT codes 97597 and 97598 were reviewed by the HCPAC.

The code descriptors for CPT codes 11010 (Debridement including removal of foreign material at the site of an open fracture and/or an open dislocation (e.g., excisional debridement); skin and subcutaneous tissues); 11011 (Debridement including removal of foreign material at the site of an open fracture and/or an open dislocation (e.g., excisional debridement); skin, subcutaneous tissue, muscle fascia, and muscle); and 11012 (Debridement including removal of foreign material at the site of an open fracture and/or an open dislocation (e.g., excisional debridement); skin, subcutaneous tissue, muscle fascia, muscle, and bone) were revised to clarify to payors and providers that these codes describe debridement of a single traumatic wound caused by an open fracture which creates a single exposure, despite the number of fractures or dislocations in the same anatomic site. The AMA RUC and the specialty society agreed that the revisions made to these descriptors were editorial and the current work RVUs for these services correctly related to the typical patient and should be maintained, recommendations which we have accepted on an interim final basis for CY 2011.

The CPT Editorial Panel revised the descriptor for CPT code 11042 (Debridement subcutaneous tissue (includes epidermis and dermis, if performed); first 20 square centimeters or less). As a result, the AMA RUC

reviewed the specialty-recommended work RVUs for this service, 1.12 work RVUs (the previous AMA RUC HCPAC recommendation as valued during the CY 2005 Five-Year Review of Work), and noted that they were higher than the current PFS value for this service (0.80 work RVUs). The AMA RUC determined that there was compelling evidence to consider new work RVUs for this service. The AMA RUC also reviewed the survey data for CPT code 11042 and made slight changes to the pre-, intra-, and post-service times. This service was compared to the key reference CPT code 16020 (Dressings and/or debridement of partial-thickness burns, initial or subsequent; small (less than 5% total body surface area)) (work RVUs = 0.80) and MPC CPT code 56605 (Biopsy of vulva or perineum (separate procedure); 1 lesion) (work RVUs = 1.10). Based on these comparisons, the AMA RUC agreed that the previous AMA RUC HCPAC recommendation of 1.12 work RVUs was an appropriate value as it would maintain relativity between the key reference code and the surveyed code. The AMA RUC recommended work RVUs of 1.12 for CPT code 11042.

We disagree with the AMA RUC-recommended value for this service and are maintaining the current work RVUs of 0.80. We believe the AMA RUC-recommended value (1.12 work RVUs) was based on the old surveyed value. The reference code, CPT code 16020, has more overall time but is valued at 0.80 work RVUs. In addition, the reference code has a size limitation that varies by individual body size, but the surveyed CPT code 11042 has an add-on code (CPT code 11045) for each additional 20 square centimeters. Therefore, we are not accepting the AMA RUC recommendation and are assigning an alternative value of 0.80 work RVUs to CPT code 11042 on an interim final basis for CY 2011.

For CPT code 11045 (Debridement subcutaneous tissue (includes epidermis and dermis, if performed); each additional 20 square centimeters, or part thereof (List separately in addition to code for primary procedure)), which is the add-on code to CPT code 11042, the AMA RUC recommended 0.69 work RVUs. This value was obtained by applying a 14 percent reduction to the median work value of 0.80 to maintain the relativity between CPT codes 11042 and 11045 of the survey data collected. Due to the reduction in work RVUs to CPT code 11042 by CMS, we reduced the AMA RUC-recommended work RVUs of 0.69 for CPT code 11045 and assigned 0.33 work RVUs to this service. This value was obtained by removing

the pre- and post-service time from the interim final RVUs of 0.80 for the primary procedure (CPT code 11042). Therefore, we are assigning an alternative value of 0.33 work RVUs to CPT code 11045 on an interim final basis for CY 2011.

CPT codes 11043 (Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 square centimeters or less) and 11044 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 square centimeters or less) were surveyed as 90-day global codes. However, due to disagreement with the survey vignettes and the new global period (90 days), in addition to broad variations in surveyed facility length of stay, the AMA RUC requested that CMS change the global period to 0 days. CMS agreed and the codes were resurveyed as 0-day global codes.

For CPT code 11043, the AMA RUC recommended 3.00 work RVUs. The AMA RUC reviewed the survey data and compared the surveyed code to the key reference CPT code 15002 (Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, le.g.s; first 100 sq cm or 1% of body area of infants and children) (work RVUs = 3.65). The AMA RUC noted that the reference code had significantly more total service time as compared to the surveyed code and that the surveyed code was less intense to perform in comparison to the reference code. Based on this comparison, the AMA RUC recommended work RVUs of 3.00, the survey 25th percentile for this service.

The AMA RUC-recommended work inputs for this service include less clinical time and fewer follow-up E/M visits than are currently attributed to the performance of this service; however, the AMA RUC-recommended work RVU value decreased by only 0.14 RVUs. We disagree with the AMA RUC-recommended RVUs for this service and believe 2.00 work RVUs, the survey low value, reflects a more appropriate decrease in work RVU value given the recommended decrease in clinical time and follow-up E/M visits. Therefore, we are assigning an alternative value of 2.00 work RVUs to CPT code 11043 on an interim final basis for CY 2011.

For CPT code 11046 (Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); each additional 20 square centimeters, or part thereof (List separately in addition to code for

primary procedure)), which is the add-on code to CPT code 11043, the RUC recommended 1.29 work RVUs, the survey 25th percentile. To maintain consistency and relativity between this add-on code and its primary code (CPT code 11043), for which we are recommending the survey low value as discussed above, and given the time and intensity the AMA RUC recommended to perform this service, we disagree with the AMA RUC-recommended work RVUs for this service and believe 0.70 work RVUs, the survey low value, are more appropriate. Therefore, we are assigning an alternative value of 0.70 work RVUs to CPT code 11046 on an interim final basis for CY 2011.

For CPT code 11044, the AMA RUC recommended 4.56 work RVUs. The AMA RUC reviewed the survey data and compared the surveyed code to the reference CPT code 15004 (Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children) (work RVUs = 4.58). The AMA RUC noted that the reference code had the same intra-service time and that the surveyed code and the reference code required similar mental effort and judgment to perform. Based on this comparison, the AMA RUC recommended work RVUs of 4.56, the survey 25th percentile, and believes this value accurately reflects the relative physician work to perform this service and maintains proper rank order with CPT codes 11042 and 11043. The AMA RUC-recommended work inputs for this service include less clinical time and fewer follow-up E/M visits than are currently attributed to the performance of this service; however, the AMA RUC-recommended work RVUs increased. We disagree with the AMA RUC-recommended work RVUs for this service and believe 3.60 work RVUs, the survey low value, reflect a more appropriate decrease in work RVU value given the recommended decrease in clinical time and follow-up E/M visits. Therefore, we are assigning an alternative value of 3.60 work RVUs to CPT code 11044 on an interim final basis for CY 2011.

For CPT code 11047 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 square centimeters, or part thereof) the AMA RUC recommended 2.00 work RVUs, the survey median value. To maintain consistency and relativity

between this add-on code and its primary code (CPT code 11044), for which we are recommending the survey low value as discussed above, and given the time and intensity the AMA RUC recommended to perform this service, we disagree with the AMA RUC-recommended value and believe 1.20 RVUs, the survey low value, are more appropriate for this service. Therefore, we are assigning 1.20 work RVUs to CPT code 11047 on an interim final basis for CY 2011.

For CY 2011, the services previously reported by CPT codes 11040 (Debridement; skin, partial thickness) and 11041 (Debridement; skin, full thickness) will now be reported with revised CPT codes 97597 (Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 square centimeters or less) and 97598 (Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 square centimeters, or part thereof (List separately in addition to code for primary procedure)). The HCPAC recommended 0.54 work RVUs for CPT code 97597, which is a value between the CY 2010 values for CPT code 11040 (0.50 work RVUs) and CPT code 97597 (0.58 work RVUs), which we have accepted on an interim final basis in this final rule with comment period for CY 2011. However, the work RVUs for this CPT code were further subject to a work budget neutrality adjustment, as discussed in section V.C.1.b.(iii) of this final rule with comment period.

For CPT code 97598, the HCPAC recommended 0.40 work RVUs, the survey 25th percentile. We disagree with the HCPAC-recommended value for this service and, given the similarity of code descriptors between the 11000 series and the 97000 series CPT codes, we believe a more appropriate value would be 0.25 RVUs, the survey low value, as it is more consistent with the work RVU value associated with new add-on CPT code 11045, discussed above. We also believe the post-service

time for CPT code 97598 should be reduced to 0 minutes to coincide with the CPT codes in the 11000 series, which have 0 or 1 minute of post-service time. Therefore, we are assigning an alternative value of 0.25 work RVUs to CPT code 97598 and reducing the post-service time to 0 minutes on an interim final basis for CY 2011. However, the work RVUs for this CPT code were subject to a work budget neutrality adjustment, as discussed in section V.C.1.b.(iii) of this final rule with comment period.

(B) Arthrodesis Including Discectomy (CPT Code 22551)

As a result of CPT code 22554 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy and decompression of spinal cord and/or nerve roots; cervical, below C2) being reviewed by the AMA RUC because of its identification by the Five-Year Review Identification Workgroup "Codes Reported Together" potentially misvalued codes screen in February 2008, CPT code 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy and decompression of spinal cord and/or nerve roots; cervical, below C2) was created by the CPT Editorial Panel in October 2009, to describe fusion and discectomy of the anterior cervical spine. The AMA RUC recommended 24.50 work RVUs. The specialty society requested 25.00 work RVUs. Upon review of the AMA RUC-recommended value and the reference codes used, it was unclear why the AMA RUC decided not to accept the specialty society's recommended value of 25.00 work RVUs. We disagree with the AMA RUC-recommended value of 24.50 and believe work RVUs of 25.00 are appropriate for this service. We are also requesting that the specialty society re-review with the AMA RUC the pre-service times for codes in this family since concerns were noted in the AMA RUC recommendation about the pre-service time for this service. Therefore, we are assigning an alternative value of 25.00 work RVUs to CPT code 22551 on an interim final basis for CY 2011.

(C) Strapping Lower Extremity (CPT Codes 29540 and 29550)

CPT code 29540 (Strapping; ankle and/or foot) was identified by the Five-Year Review Identification Workgroup "Harvard-Valued" potentially misvalued codes screen with utilization over 100,000 screen in October 2009. The AMA RUC recommended this whole family of services be surveyed.

For CPT code 29540, the HCPAC recommended 0.39 work RVUs. The HCPAC compared the total time required for CPT code 29540 to 29580 (Strapping; Unna boot), 18 and 27 minutes, respectively, and noted that CPT code 29540 requires less time, mental effort/judgment, technical skill and psychological stress than CPT code 29580. The HCPAC determined that CPT code 29540 was approximately 30 percent less intense and complex than CPT code 29580, resulting in work RVUs of 0.39 for CPT code 29540. We disagree with the HCPAC-recommended value for this service and believe work RVUs of 0.32 are appropriate. We believe CPT code 11720 (Debridement of nail(s) by any method(s); 1 to 5) (work RVUs = 0.32) is a more appropriate crosswalk. Therefore, we are assigning an alternative value of 0.32 work RVUs to CPT code 29540 on an interim final basis for CY 2011.

For CPT code 29550 (Strapping; toes), the HCPAC recommended 0.25 work RVUs. The HCPAC compared this service to CPT code 97762 (Checkout for orthotic/prosthetic use, established patient, each 15 minutes) (work RVUs = 0.25), which requires the same intensity and complexity to perform as CPT code 29550. The HCPAC recommended crosswalking the work RVUs for 29550 to reference CPT code 97762. The HCPAC reviewed the survey time and determined that 7 minutes pre-service, 5 minutes intra-service, and 1 minute immediate post-service time were appropriate to perform this service. We disagree with the HCPAC-recommended value for this service and believe work RVUs of 0.15, the survey low value, are appropriate, with 5 minutes of pre- and intra-service time and 1 minute of post-service time, as we believe the HCPAC-recommended pre-service time of 7 minutes is excessive. Therefore, we are assigning an alternative value of 0.15 work RVUs to CPT code 29550 on an interim final basis for CY 2011.

(D) Paraesophageal Hernia Procedures (CPT Codes 43333 and 43335)

In February 2010, the CPT Editorial Panel deleted six existing codes and created ten new codes to remove obsolete and duplicative codes and add new codes to report current surgical techniques for paraesophageal hernia repair. For CPT code 43333 (Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis), the AMA RUC recommended 30.00 work RVUs. The AMA RUC recommended 33.00 work RVUs for CPT code 43335 (Repair, paraesophageal hiatal hernia (including

fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis). While the AMA RUC-recommended values are the survey median values, we disagree with them. We adjusted the AMA RUC-recommended values for the codes without implantation of mesh or other prosthesis upward by 2.50 work RVUs to account for the differential between those codes and the parallel codes with implantation of mesh or other prosthesis. We note that 2.50 work RVUs was the lowest differential that was recommended by the AMA RUC between the with/without implantation of mesh or other prosthesis codes in this family. That is, for CPT code 43333, the revised work RVUs were established by adding 2.50 work RVUs to the AMA RUC-recommended work RVUs of 26.60 for CPT code 43332 (Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis), which resulted in work RVUs of 29.10. Likewise, for CPT code 43335, the revised work RVUs were established by adding 2.50 work RVUs to the AMA RUC-recommended work RVUs of 30.00 for CPT code 43334 (Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis), resulting in work RVUs of 32.50. Therefore, we are assigning alternative work RVUs of 29.10 to CPT code 43333 and 32.50 to CPT code 43335 on an interim final basis for CY 2011. However, the work RVUs for this CPT code were subject to a work budget neutrality adjustment, as discussed in section V.C.1.b.(iii) of this final rule with comment period.

(E) Vaginal Radiation Afterloading Apparatus for Clinical Brachytherapy (CPT Codes 57155 and 57156)

CPT Code 57155 (Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy) was originally identified through the Five-Year Review Identification Workgroup "Site-of-Service Anomalies" potentially misvalued codes screen in September 2007 and was later revised by the CPT Editorial Panel to indicate insertion of a single tandem rather than tandems.

For CY 2011, the AMA RUC recommended 5.40 work RVUs for CPT code 57155 (Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy). This value was established based on the survey 25th percentile and a review of comparable services, specifically CPT codes 55920 (Placement of needles or catheters into pelvic organs and/or genitalia (except

prostate) for subsequent interstitial radioelement application)(work RVUs = 8.31); 50382 (Removal (via snare/capture) and replacement of internally dwelling urethral stent via percutaneous approach, including radiological supervision and interpretation) (work RVUs = 5.50); and 52001

(Cystourethroscopy with irrigation and evacuation of multiple obstructing clots) (work RVUs = 5.44). We disagree with the AMA RUC-recommended value for this service because the method used to derive the value lacked a defined logic. We believe work RVUs of 3.37 are appropriate for this service, which is the same as the value assigned to CPT code 58823 (Drainage of pelvic abscess, transvaginal or transrectal approach, percutaneous (eg, ovarian, pericolic)), which we also believe is a more comparable code. Therefore, we are assigning an alternative value of 3.37 work RVUs to CPT code 57155 on an interim final basis for CY 2011.

For CPT code 57156 (Insertion of a vaginal radiation afterloading apparatus for clinical brachytherapy), the AMA RUC recommended 2.69 work RVUs, the survey 25th percentile. Given our decision to revise downward the work RVUs for CPT code 57185, a related code, upon review of the AMA RUC recommendations for CPT code 57156, we believe that the AMA RUC-recommended value of 2.69 is too high. In light of this, we are crosswalking the value of CPT code 57156 from CPT code 62319 (Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; lumbar, sacral (caudal)) (work RVUs = 1.87), which has the same intra-service time (30 minutes) and overall lower total time than the comparison services referenced by the AMA RUC. Therefore, we are assigning an alternative value of 1.87 work RVUs to CPT code 57156 on an interim final basis for CY 2011.

(F) Vagus Nerve Stimulator (CPT Codes 61885, 64568, 64569, and 64570)

CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) was identified by the Five-Year Review Identification Workgroup by its "Site-of-Service Anomalies" screen for potentially misvalued codes in September 2007. After reviewing the vagal nerve

stimulator family of services, the specialty societies agreed that the family lacked clarity and the CPT Editorial Panel created three new codes to accurately describe revision of a vagal nerve stimulator lead, the placement of the pulse generator and replacement or revision of the vagus nerve electrode.

For CY 2011, the AMA RUC recommended 6.44 work RVUs for CPT code 61885. Upon review of the AMA RUC recommendations, the method used to establish the AMA RUC-recommended value for this service lacked a defined logic. Although the AMA RUC compared this service to the key reference service, CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) (Work RVUs = 6.05) and other relative services and noted the similarities in times, an appropriately rigorous methodology was not used. The AMA RUC-recommended work RVUs did not adequately account for the elimination of two inpatient visits and the reduction in outpatient visits for this service. We disagree with the AMA RUC-recommended value and believe 6.05 work RVUs, the survey 25th percentile, are appropriate for this service. Therefore, we are assigning an alternative value of 6.05 work RVUs to CPT code 61885 on an interim final basis for CY 2011.

For CPT code 64568 (Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator), the AMA RUC recommended 11.19 work RVUs. Similar to the rationale provided by the AMA RUC for the valuation of CPT code 61885, the method used to value this service lacked a defined logic. As with CPT code 61885 discussed above, to which this code is related, we disagree with the AMA RUC-recommended value for this service and believe the survey 25th percentile, 9.00 work RVUs, is appropriate. Therefore, we are assigning an alternative value of 9.00 work RVUs to CPT code 64568 on an interim final basis for CY 2011.

For CPT code 64569 (Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator), the AMA RUC recommended 15.00 work RVUs, the survey median value, and 13.00 work RVUs, the survey median value, for CPT code 64570 (Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator). Based on the reduction in work RVUs for CPT codes 61885 and 64568 that we are adopting on an interim final basis for CY 2011 and to maintain relativity for the codes

in this family, we believe work RVUs of 11.00, the survey 25th percentile, are appropriate for CPT code 64569 and work RVUs of 9.10, the survey 25th percentile, are appropriate for CPT code 64570. Therefore, we are assigning an alternative value of 11.00 work RVUs to CPT code 64569 and 9.10 work RVUs to CPT code 64570 on an interim final basis for CY 2011.

(G) Ultrasound of Extremity (CPT Codes 76881 and 76882)

In October 2008, CPT code 76880 (Ultrasound, extremity, nonvascular, real time with image documentation) was identified by the Five-Year Review Identification Workgroup through its "CMS Fastest Growing" screen for potentially misvalued codes. In February 2009, the CPT Editorial Panel deleted CPT code 76880 and created two new codes, CPT codes 76881 (Ultrasound, extremity, nonvascular, real-time with image documentation; complete) and 76882 (Ultrasound, extremity, nonvascular, real-time with image documentation; limited anatomic specific) to distinguish between the comprehensive diagnostic ultrasound and the focused anatomic-specific ultrasound.

For CPT code 76881, the AMA RUC recommended work RVUs of 0.72 and a total time of 25 minutes. For CPT code 76882, the AMA RUC recommended 0.50 work RVUs and a total time of 21 minutes. The predecessor CPT code 76880 (Ultrasound, extremity, nonvascular, real time with image documentation) described a nonvascular ultrasound of the entire extremity and was assigned work RVUs of 0.59 and a total time of 18 minutes. The new CPT codes describe a complete service, CPT code 76881, and a limited service, CPT code 76882 (defined as examination of a specific anatomic structure, such as a tendon or muscle).

We disagree with the AMA RUC recommendations for these services. For CPT code 76881, we do not believe an increase in work RVUs is justified given that this service will be reported for the evaluation of the extremity, as was CPT code 76800 which is being deleted for CY 2011. Therefore, we believe work RVUs of 0.59 are appropriate for this service, consistent with the value of the predecessor code. For CPT code 76882, we believe a value of 0.41 is more appropriate, representing a statistical computation based on maintaining the relationship between the AMA RUC-recommended values for CPT codes 76881 and 76882. Therefore, we are assigning alternative work RVUs of 0.59 to CPT code 76881 and 0.41 to CPT code

76882 on an interim final basis for CY 2011.

(H) Evaluation of Fine Needle Aspirate (CPT Code 88172)

Due to confusion amongst payers and providers, in February 2010 the CPT Editorial Panel revised the descriptor for CPT code 88172 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy of specimen(s)) and created a new code, CPT code 88177 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site), to report the first evaluation episode and each additional episode of cytopathology evaluation of fine needle aspirate. For CPT code 88172, the AMA RUC recommended work RVUs of 0.69 based on comparing this code to several other services, without the use of an appropriate methodology. We disagree with the AMA RUC-recommended value and believe the current work RVUs of 0.60 are appropriate and should be maintained for this service. Although the code has been revised, no explanation by the AMA RUC was provided to demonstrate an increase in work, and we do not believe the work has changed. Therefore, we are assigning an alternative value of 0.60 work RVUs to CPT code 88172 on an interim final basis for CY 2011.

(I) Immunization Administration (CPT Code 90460 and 90461)

The CPT Editorial Panel revised the reporting of immunization administration in the pediatric population in order to better align the service with the evolving best practice model of delivering combination vaccines. For CY 2011, the AMA RUC recommended 0.20 work RVUs for CPT code 90460 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care profession; first vaccine/toxoid component) and 0.16 work RVUs for CPT code 90461 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health profession; each additional vaccine/toxoid component (List separately in addition to code for primary procedure)). This is an increase from the current values for the predecessor services. The AMA RUC states that the increase in recommended work RVUs is due to increased time for patient education. In addition, effective January

1, 2011, reporting and payment for these services is to be structured on a per toxoid basis rather than a per vaccine (combination of toxoids) basis as it was in prior years. We disagree with the AMA RUC-recommended values for these services and are maintaining the current work RVUs for the related predecessor codes of 0.17 RVUs for CPT code 90460 and 0.15 work RVUs for CPT code 90461 since these codes would be billed on a per toxoid basis in CY 2011. Therefore, we are assigning alternative values of 0.17 work RVUs to CPT code 90460 and 0.15 work RVUs to CPT code 90461 on an interim final basis for CY 2011.

(J) Diabetic Retinopathy Imaging (CPT Code 92228)

In February, 2010 the CPT Editorial Panel established two codes for reporting remote imaging for screening retinal disease and management of active retinal disease. For CPT code 92228 (Remote imaging for monitoring and management of active retinal disease (eg, diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral), the AMA RUC recommended 0.44 work RVUs. The AMA RUC compared this service to CPT code 92250 (Fundus photography with interpretation and report) (Work RVUs = 0.44) due to similar times and believes this service is comparable to the service under review. We disagree with the reference service used by the AMA RUC and compared this code to another diagnostic service, CPT code 92135 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, (eg, scanning laser) with interpretation and report, unilateral) (Work RVUs = 0.35), which we believe is more equivalent but has more pre- and intra-service time. Upon further review of CPT code 92228 and the time and intensity needed to perform this service, we believe work RVUs of 0.30, the survey low value, are more appropriate. Therefore, we are assigning an alternative value of 0.30 work RVUs to CPT code 92228 on an interim final basis for CY 2011.

(K) Speech-Language Pathology Services (CPT Codes 92508 and 92606)

Section 143 of the MIPPA specifies that speech-language pathologists may independently report services they provide to Medicare patients. Starting in July 2009, speech-language pathologists were able to bill Medicare as independent practitioners. As a result, the American Speech-Language-Hearing Association (ASHA) requested that CMS ask the AMA RUC to review the speech-language pathology codes to newly

value the professionals' services in the work and not the practice expense. ASHA indicated that it would survey the 12 speech-language pathology codes over the course of the CPT 2010 and CPT 2011 cycles. Four of these services were reviewed by the HCPAC or the AMA RUC and were included in the CY 2010 PFS final rule with comment period (74 FR 61784 and 62146). For CY 2011, the HCPAC submitted work recommendations for the remaining eight codes.

For CPT code 92508 (Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals), the HCPAC recommended 0.43 work RVUs which was derived by dividing the value for CPT code 92507 (Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual) (work RVUs = 1.30) by 3, as the specialty society stated to the AMA RUC that there are typically 3 participants in a group. We disagree with the HCPAC-recommended value for this service and believe it is too high. We believe work RVUs of 0.33 are more appropriate, which was derived by dividing the value for CPT code 92507 by 4 participants, as we understand from providers that 4 more accurately represents the typical number of participants in a group. Additionally, the work RVUs derived from dividing the RVUs for the related individual treatment code by 4, 0.33 RVUs, are appropriate for this group treatment service relative to the work RVUs of 0.27 for CPT code 97150 (Therapeutic procedure(s), group (2 or more individuals)) which is furnished to a similar patient population, namely patients who have had a stroke.

Therefore we are assigning alternative work RVUs of 0.33 to CPT code 92508 on an interim final basis for CY 2011.

For CPT code 92606 (Therapeutic service(s) for the use of non-speech-generating device, including programming and modification), the HCPAC recommended 1.40 work RVUs, the survey median value. This service is currently bundled under the PFS and we will maintain this status for CY 2011. We are publishing the AMA RUC-recommended value in Addendum B to this final rule with comment period in accordance with our usual practice for bundled services.

(L) Sleep Testing (CPT Codes 95806 and 95807)

Sleep testing CPT codes were identified by the Five-Year Review Identification Workgroup as potentially misvalued codes through the "CMS

Fastest Growing" potentially misvalued codes screen. The CPT Editorial Panel created separate Category I CPT codes to report for unattended sleep studies. The AMA RUC recommended concurrent review of the family of sleep codes.

For CPT code 95806 (Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)), the AMA RUC recommended 1.28 work RVUs. The AMA RUC recommended 1.25 work RVUs for CPT code 95807 (Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist). Although the AMA RUC-recommended values for these codes reflect the survey 25th percentile, we disagree with the values and believe the values should be reversed because of the characteristics of the services. CPT code 95807 has 5 minutes more pre-service time but a lower AMA RUC-recommended value. Therefore, we have assigned alternative values of 1.25 work RVUs to CPT code 95806 and 1.28 work RVUs to CPT code 95807 on an interim final basis for CY 2011.

(M) Subsequent Hospital Observation Care

At the June 2009 CPT Editorial Panel meeting, three new codes were approved to report subsequent observation services in a facility setting. These codes are CPT code 99224 (Level 1 subsequent observation care, per day); CPT code 99225 (Level 2 subsequent observation care, per day); and CPT code 99226 (Level 3 subsequent observation care, per day).

The AMA RUC reviewed the survey data for CPT code 99224 and accepted the following physician times: 5 minutes of pre-service, 10 minutes of intra-service, and 5 minutes of post-service time. The AMA RUC believed this code was comparable in physician time and intensity to CPT code 99231 (Level 1 subsequent hospital care, per day, for the evaluation and management of a patient), and recommended work RVUs of 0.76. Similarly, the AMA RUC reviewed the survey data for CPT code 99225 and accepted the following physician times: 9 minutes of pre-service, 20 minutes of intra-service, and 10 minutes of post-service time. The AMA RUC believed this code was comparable in physician time and

intensity to CPT code 99232 (Level 2 subsequent hospital care, per day, for the evaluation and management of a patient), and recommended work RVUs of 1.39. Finally, the AMA RUC reviewed the survey data for CPT code 99226 and accepted the following physician times: 10 minutes of pre-service, 30 minutes of intra-service, and 15 minutes of post-service time. The AMA RUC believed this code was comparable in physician time and intensity to CPT code 99233 (Level 3 subsequent hospital care, per day, for the evaluation and management of a patient), and recommended work RVUs of 2.00.

Observation services are outpatient services ordered by a patient's treating practitioner. Admission of the patient to the hospital as an inpatient or the ending of observation services must also be ordered by the treating practitioner. CMS has stated that in only rare and exceptional cases would reasonable and necessary outpatient observation services span more than 48 hours. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. Consequently, we believe that the acuity level of the typical patient receiving outpatient observation services would generally be lower than that of the inpatient level. We believe that if the patient's acuity level is determined to be at the level of the inpatient, the patient should be admitted to the hospital as an inpatient. We note that CMS has publicly stated in a recent letter to the AHA that "it is not in the hospital's or the beneficiary's interest to extend observation care rather than either releasing the patient from the hospital or admitting the patient as an inpatient * * *"

Consequently, we are not accepting the AMA RUC's recommendation to value the subsequent observation care codes at the level of subsequent inpatient hospital care services. Instead, to recognize the differences in patient acuity between the two settings, we removed the pre- and post-services times from the AMA RUC-recommended values for subsequent observation care, reducing the values to approximately 75 percent of the values for the subsequent hospital care codes. Therefore, we are assigning alternative work RVUs of 0.54 to CPT code 99224,

0.96 to CPT code 99225, and 1.44 to CPT code 99226 on an interim final basis for CY 2011.

(2) Comprehensive Codes for a Bundle of Existing Component Services

A subset of AMA RUC work RVU recommendations addressed valuing new CY 2011 CPT codes resulting from the bundling of two or more existing component services performed together 95 percent or more of the time. We expect this bundling of component services to continue over the next several years as the AMA RUC further recognizes the work efficiencies for services commonly furnished together. Stakeholders should expect that increased bundling of services into fewer codes will result in reduced PFS payment for a comprehensive service by explicitly considering the efficiencies in work and/or PE that may occur when component services are furnished together.

For CY 2011, the AMA RUC provided CMS with recommendations for several categories of new comprehensive services that historically have been reported under multiple component codes. In some CY 2011 cases, the CPT Editorial Panel undertook relatively minor bundling, such as bundling the associated imaging with a procedure in a single new CPT code. In other cases, the CPT Editorial Panel bundled significant component codes for distinct procedures that were previously separately reported. This section focuses on the latter cases, and we note that these codes fall into three major clinical categories: Endovascular revascularization, computed tomography (CT), and diagnostic cardiac catheterization. While we acknowledge that each category of services is unique, since bundling of component services is likely to occur more often in the coming years we believe a consistent approach is especially important when valuing bundled services as part of the potentially misvalued codes initiative in order to ensure that we fully account for the resulting work efficiencies. Specifically, we recommend that the AMA RUC use, whenever possible, the building block approach, which is a consistent and transparent methodology based on the components of a code.

The new CY 2011 comprehensive codes in these three clinical categories are displayed in Table 51 and our discussion of their work values follows.

TABLE 51—NEW CY 2011 COMPREHENSIVE CODES AND WORK RVUS FOR ENDOVASCULAR REVASCLARIZATION, CT, AND DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES

CPT code	Long descriptor	AMA RUC-recommended work RVUs	CY 2011 interim final Work RVUs
Endovascular Revascularization			
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty.	8.15	8.15
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed.	10.00	10.00
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure).	3.73	3.73
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s) (List separately in addition to code for primary procedure), includes angioplasty within the same vessel, when performed.	4.25	4.25
37224	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal angioplasty.	9.00	9.00
37225	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed.	12.00	12.00
37226	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed.	10.49	10.49
37227	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed.	14.50	14.50
37228	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal angioplasty.	11.00	11.00
37229	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed.	14.05	14.05
37230	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed.	13.80	13.80
37231	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed.	15.00	15.00
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure).	4.00	4.00
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy (List separately in addition to code for primary procedure), includes angioplasty within the same vessel, when performed.	6.50	6.50
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) (List separately in addition to code for primary procedure), includes angioplasty within the same vessel, when performed.	5.50	5.50
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy (List separately in addition to code for primary procedure), includes angioplasty within the same vessel, when performed.	7.80	7.80
CT Abdomen/CT Pelvis			
74176	Computed tomography, abdomen and pelvis; without contrast material	1.74	1.74
74177	Computed tomography, abdomen and pelvis; with contrast material	1.82	1.82
74178	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with contrast material(s) and further sections in one or both body regions.	2.01	2.01
Diagnostic Cardiac Catheterization			
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed.	3.02	2.72
93452	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.	4.32	4.75
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.	5.98	6.24
93454	Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;	4.95	4.79

TABLE 51—NEW CY 2011 COMPREHENSIVE CODES AND WORK RVUS FOR ENDOVASCULAR REVASULARIZATION, CT, AND DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES—Continued

CPT code	Long descriptor	AMA RUC-recommended work RVUs	CY 2011 interim final Work RVUs
93455	with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography.	6.15	5.54
93456	with right heart catheterization	6.00	6.15
93457	with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization.	7.66	6.89
93458	with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed.	6.51	5.85
93459	with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography.	7.34	6.60
93460	with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed.	7.88	7.35
93461	with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography.	9.00	8.10
93563	Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization.	2.00	1.11
93564	for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed.	2.10	1.13
93565	for selective left ventricular or left arterial angiography	1.90	0.86
93566	for selective right ventricular or right atrial angiography	0.96	0.86
93567	for supravalvular aortography	1.08	0.97
93568	for pulmonary angiography	0.98	0.88

The AMA RUC used a variety of methodologies in developing RVUs for comprehensive codes in these three categories of bundled services. To develop the RVUs for the comprehensive endovascular revascularization services, the AMA RUC generally recommended the median work RVUs from the physician survey performed by the specialty society. The recommended values for the comprehensive services are an average of 27 percent lower than the summed RVUs of the component services (taking into consideration any MPPR that would currently apply) included in the bundle. To develop the RVUs for comprehensive CT services, the AMA RUC recommended taking the sum of 100 percent of the current work RVUs for the code with the highest RVUs and 50 percent for the second code. Under this methodology, the recommended work RVUs for the comprehensive CT codes are consistently approximately 25 percent lower than the sum of the RVUs for the component services. The approach of a uniform discount on the second CT service resembles an MPPR and, given the public concerns regarding our proposed expansion of current MPPR policies under the PFS for CY 2011 as discussed in section II.C.4. of this final

rule with comment period, we are unsure how the AMA RUC's recommended CT methodology actually considered the physician work required for the specific component services being bundled. Nevertheless, while we believe that the application of a consistent approach to valuing comprehensive services is desirable, we agree that the decreased work RVUs the AMA RUC recommended for comprehensive services in these two categories reflect a reasonable estimation of the work efficiencies created by the bundling of the component services. Therefore, we are accepting as interim final work RVUs the AMA RUC-recommended values for endovascular revascularization and CT services listed in Table 51 for CY 2011.

To develop the RVUs for comprehensive diagnostic cardiac catheterization services, the AMA RUC generally recommended the lower of either the sum of the current RVUs for the component services or the physician survey 25th percentile value. In most cases, the AMA RUC's recommendation for the comprehensive service was actually the sum of the current work RVUs for the component services and we are unsure how this approach is resource-based with respect to physician work. We are also concerned

that the physician survey appears to have overstated the work for these well-established procedures so significantly that the 25th percentile value was usually higher than the sum of the current RVUs for the component services. Under this methodology, the AMA RUC-recommended RVUs for the comprehensive codes for diagnostic cardiac catheterization are an average of only one percent lower than the sum of the RVUs for the component services (taking into consideration any MPPR that would currently apply) included in the bundle.

We do not find the AMA RUC's methodology or the resulting values in this case to be acceptable for a major code refinement exercise of this nature. If we were to accept the AMA RUC's recommended values for these cardiac catheterization codes, we essentially would be agreeing with the presumption that there are negligible work efficiencies gained in the bundling of these cardiac catheterization services. On the contrary, we believe that the AMA RUC did not fully consider or account for the efficiency gains when the component services are furnished together, including the significant reduction in service time. Rather, the AMA RUC appears to have considered only the summation of the component

services to the comprehensive service. Therefore, we are requesting that the AMA RUC reexamine these codes as quickly as possible, given the significant PFS utilization and spending for cardiac catheterization services, and put forward an alternative approach to valuing these services that would produce relative values that are resource-based and do not rely predominantly on the current component service values in a circular rationale.

Since we believe that the new comprehensive diagnostic cardiac catheterization codes would be overvalued under the AMA RUC's CY 2011 recommendations, we have employed an interim methodology to determine alternative values for these services which we are assigning as the interim final work RVUs for CY 2011. To account for efficiencies inherent in bundling, we set the work RVUs for all of the CY 2011 cardiac catheterization codes for which we received AMA RUC recommendations to 10 percent less than the sum of the current work RVUs for the component codes, taking into consideration any MPPR that would apply under current PFS policy. These values are displayed in Table 51 and in Addendum B and C to this final rule with comment period. We recognize that this interim methodology is not highly specific and further acknowledge that the use of another approach by the AMA RUC may have differential effects on the values of the new comprehensive services compared to the proportionate reduction on the sum of the RVUs for the component services that we have adopted as a temporary methodology. However, given the complexity of the component code combinations that contribute to the comprehensive cardiac catheterization codes and the apparent overstatement of physician work from the physician survey, we are unable to present a more refined, code-specific methodology for the interim final values. Instead, based upon a very

conservative estimate of the work efficiencies we would expect to be present when multiple component services are bundled together into a single comprehensive service, we have set interim final work values for the cardiac catheterization codes using a 10 percent reduction on the current values. As points of comparison, we note that the current MPPR policies under the PFS for imaging and surgical services reduce payment for the second and subsequent procedures by 50 percent on the TC and complete service, respectively, and, as discussed in detail in section II.C.4. of this final rule with comment period, we are adopting a 25 percent MPPR on the PE component of payment for therapy services in CY 2011. We further note that the service-specific work efficiencies for the other two major categories of new bundled codes for CY 2011, specifically endovascular revascularization and CT, are generally between 20 and 35 percent.

(3) Work Budget Neutrality for Clinical Categories of CPT Codes

Work budget neutrality, as a concept, is applied to hold the aggregate work RVUs constant within a set of clinically related CPT codes, while maintaining the relativity of values for the individual codes within that set. In some cases, when the CPT coding framework for a clinically related set of CPT codes is revised by the creation of new CPT codes or existing CPT codes are revalued, the aggregate work RVUs recommended by the AMA RUC within a clinical category of CPT codes may change, although the actual physician work for the services has not changed. When this occurs, work budget neutrality may be applied to adjust the work RVUs of each clinically related CPT code so that the sum of the new/ revised code work RVUs (weighted by projected utilization) for a set of CPT codes would be the same as the sum of the current work RVUs (weighted by

projected utilization) for that set of codes.

When the AMA RUC recommends work RVUs for new or revised CPT codes, we review the work RVUs and adjust or accept the recommended values as appropriate, making note of whether any estimated changes in aggregate work RVUs would result from true changes (increases or decreases) in physician work or from structural coding changes. We then determine whether the application of budget neutrality within sets of codes is appropriate. That is, if, within a set of clinically related codes, the aggregate work RVUs would increase under the RVUs we would be adopting for the upcoming year but without a corresponding true increase in physician work, we generally view this as an indication that an adjustment to ensure work budget neutrality within the set of CPT codes is warranted.

As the AMA RUC and CMS move to bundle and revalue more existing codes, creating significant structural coding changes, ensuring work budget neutrality is an important principle so that these changes are not unjustifiably redistributive among PFS services. This year, we found four sets of clinically related CPT codes where we believe the application of work budget neutrality is appropriate. That is, in these clinical areas, we believe the increases in aggregate work RVUs for the related services that would result from the work RVUs we would adopt (either the AMA RUC-recommended work RVUs or the alternative work RVUs determined by CMS) would not represent a true increase in the physician work for these services. These codes are in the areas of paraesophageal hernia procedures, obstetrical care, esophageal motility and high resolution esophageal pressure topography, and skin excision and debridement.

Table 52 lists the CPT codes that are affected by an application of work budget neutrality in CY 2011.

TABLE 52—CY 2011 WORK BUDGET NEUTRALITY (BN) FOR CLINICAL CATEGORIES OF NEW/REVISED CODES

CPT Code	Short descriptor	AMA RUC-recommended work RVUs	CMS-recommended work RVUs pre-BN	CY 2011 interim final work RVUs
Paraesophageal Hernia Procedures, BN Factor of 0.7374				
43283	Lap esoph lengthening	4.00	4.00	2.95
43327	Esoph fundoplasty lap	18.10	18.10	13.35
43328	Esoph fundoplasty thor	27.00	27.00	19.91
43332	Transab esoph hiat hern rpr	26.60	26.60	19.62
43333	Transab esoph hiat hern rpr	30.00	29.10	21.46
43334	Transhor diaphrag hern rpr	30.00	30.00	22.12
43335	Transhor diaphrag hern rpr	33.00	32.50	23.97
43336	Thorabd diaphrag hern repair	35.00	35.00	25.81

TABLE 52—CY 2011 WORK BUDGET NEUTRALITY (BN) FOR CLINICAL CATEGORIES OF NEW/REVISED CODES—Continued

CPT Code	Short descriptor	AMA RUC-recommended work RVUs	CMS-recommended work RVUs pre-BN	CY 2011 interim final work RVUs
43337	Thorabd diaphr hern repair	37.50	37.50	27.65
43338	Esoph lengthening	3.00	3.00	2.21
Obstetrical Care, BN Factor of 0.8922				
59400	Obstetrical care	32.69	32.16	28.69
59409	Obstetrical care	14.37	14.37	12.82
59410	Obstetrical care	18.54	18.01	16.07
59412	Antepartum manipulation	1.71	1.71	1.53
59414	Deliver placenta	1.61	1.61	1.44
59425	Antepartum care only	6.31	6.31	5.63
59426	Antepartum care only	11.16	11.16	9.96
59430	Care after delivery	2.47	2.47	2.20
59510	Cesarean delivery	36.17	35.64	31.80
59514	Cesarean delivery only	16.13	16.13	14.39
59515	Cesarean delivery	22.00	21.47	19.15
59610	Vbac delivery	34.40	33.87	30.22
59612	Vbac delivery only	16.09	16.09	14.35
59614	Vbac care after delivery	20.26	19.73	17.60
59618	Attempted vbac delivery	36.69	36.16	32.26
59620	Attempted vbac delivery only	16.66	16.66	14.86
59622	Attempted vbac after care	22.53	22.00	19.63
Esophageal Motility and High Resolution Esophageal Pressure Topography, BN Factor of 0.8500				
91010	Esophagus motility study	1.50	1.50	1.28
91013	Esophgl motil w/stim/perfus	0.21	0.21	0.18
Skin Excision and Debridement, BN Factor of 0.9422				
97597	Rmvl devalit tis 20 cm/<	0.54	0.54	0.51
97598	Rmvl devalit tis addl 20 cm<	0.40	0.25	0.24

For the paraesophageal hernia procedures, the CPT Editorial Panel deleted six existing CPT codes and created ten new codes to remove obsolete and duplicative codes and add new codes to report current surgical techniques for paraesophageal hernia procedures. Since in this case there would be more codes that describe the same physician work with a greater degree of precision, the aggregate increase in work RVUs that would result from our adoption of the CMS-recommended RVUs that are largely based on the AMA RUC's work RVU recommendations would not represent a true increase in physician work. Therefore, we believe it would be appropriate to apply work budget neutrality to this set of codes. After reviewing the AMA RUC-recommended work RVUs, we adjusted the work RVUs for two codes (CPT codes 43333 and 43335) as described previously in section V.C.1.b.(i)(4) of this final rule with comment period, and then applied work budget neutrality to the set of clinically related CPT codes. The work budget neutrality factor for these 12 paraesophageal hernia procedure CPT codes is 0.7374.

For the obstetrical care codes, the AMA RUC reviewed 17 existing obstetrical care codes as part of the potentially misvalued codes initiative. It recommended significant increases in the work RVUs for some of the comprehensive obstetrical care codes (incorporating more than one element of antepartum care, delivery, and/or postpartum care) largely to address the management of labor. While we generally agree with the resulting AMA RUC-recommended rank order of services in this family, the aggregate increase in work RVUs for the obstetrical services that would result from our adoption of the CMS-recommended work RVUs that are largely based on the AMA RUC work RVU recommendations is not indicative of a true increase in physician work for the services. Therefore, we believe it would be appropriate to apply work budget neutrality to this set of codes. After reviewing the AMA RUC-recommended work RVUs, we adjusted the work RVUs for several codes as described in the following section V.C.1.c.(6) of this final rule with comment period, and then applied work budget neutrality to the set of clinically

related CPT codes. The work budget neutrality factor for the 17 obstetrical care CPT codes is 0.8922.

For esophageal motility and high resolution esophageal pressure topography, two CPT codes were deleted and the services will be reported under a revalued existing CPT code and a new add-on code in CY 2011. We agree with the AMA RUC that there is compelling evidence to change the work RVUs for the existing code to account for the inclusion of procedures with higher work RVUs that would previously have been reported under the deleted codes. We also agree with the AMA RUC-recommended work RVUs for the add-on code. While we agree with the AMA RUC's recommendations for the new work RVUs for both codes, we do not believe that this structural coding change should result in an increase in aggregate physician work for the same services and, therefore, we believe it would be appropriate to apply work budget neutrality to this set of codes. The work budget neutrality factor for these 2 codes is 0.8500.

In the skin excision and debridement category, two CPT codes were deleted and the services that would previously

have been reported under these codes will be reported under two existing codes in CY 2011. However, the two existing wound management codes have been restructured from describing two distinct procedures reported based on wound surface area to describing a primary procedure and an add-on procedure that would additionally be reported in the case of a larger wound. Once again, the increase in aggregate work RVUs that would result from our adoption of the CMS-recommended work RVUs that are largely based on the AMA RUC work RVU recommendations do not represent a true increase in physician work for these procedures. Therefore, we believe it would be appropriate to apply work budget neutrality to this set of codes. After reviewing the AMA RUC-recommended work RVUs, we adjusted the work RVUs for one code (CPT code 97598) as described previously in section V.C.1.b.(i)(1) of this final rule with comment period, and then applied work budget neutrality to the set of clinically related CPT codes. The budget neutrality factor for these 2 codes is 0.9422.

c. CY 2011 Interim Final Work RVUs for Potentially Misvalued Codes

In the following section, we provide a discussion of our rationale for not accepting particular AMA RUC-recommended work RVUs for CY 2011 CPT codes that have been identified as potentially misvalued through the AMA RUC's screens and with CMS guidance. Table 53 lists all 291 CPT codes for which the AMA RUC has provided CMS with work RVU recommendations for CY 2011. Furthermore, the table displays the AMA RUC's recommended work value as well as CMS' interim final decisions for CY 2011. For CY 2011, the AMA RUC provided work RVU recommendations for a total of 82 codes identified as potentially misvalued in categories based on the screen that identified the codes, including "Harvard-Valued," "CMS Fastest Growing," and "Site-of-Service Anomalies." For CY 2011, CMS is not accepting 26 of the 82 AMA RUC-recommended work values for codes identified as potentially misvalued. We are instead providing alternative interim final work RVUs as discussed in the forthcoming section.

(1) Excision and Debridement (CPT Codes 11043 and 11044)

CPT codes 11043 (Debridement; skin, subcutaneous tissue, and muscle) and 11044 (Debridement; skin, subcutaneous tissue, muscle, and bone) were identified by the AMA RUC's Five-Year

Review Identification Workgroup through the "Site-of-Service Anomalies" potentially misvalued codes screen in September 2007. The AMA RUC recommended that the entire family of services described by CPT codes 11040 through 11044 and 97597 and 97598 be referred to the CPT Editorial Panel because the current descriptors allowed reporting of the codes for a bimodal distribution of patients and also to better define the terms excision and debridement. For CY 2011, the AMA RUC reviewed this family of codes which includes the two potentially misvalued codes, CPT codes 11043 and 11044, and provided work RVU recommendations to CMS. Since the family also included other new and revised codes, we have consolidated the discussion of Excision and Debridement codes in section V.C.1.b.(i)(1), which discusses new and revised codes. Section V.C.1.b.(i)(1) provides the complete discussion of CMS' interim final work RVU decisions for this family of codes. However, to summarize the CMS decisions in brief, we disagree with the AMA RUC's CY 2011 work RVU recommendations and are assigning alternative values for both CPT codes 11043 and 11044 on an interim final basis for CY 2011.

(2) Strapping Lower Extremity (CPT Code 29540)

CPT code 29540 (Strapping; ankle and/or foot) was identified as a potentially misvalued code through the Five-Year Review Identification Workgroup under the "Harvard Valued" codes potentially misvalued codes screen for services with utilization over 100,000. This code is also a member of a family of codes under review for CY 2011 and as such, the full discussion for the Strapping Lower Extremity family is provided in section V.C.1.b.(i)(3), which discusses new and revised codes. However, to summarize the CMS decision in brief, we disagree with the AMA RUC's CY 2011 work RVU recommendations and are assigning an alternative value of 0.32 RVUs to CPT code 29540 on an interim final basis for CY 2011.

(3) Control Nasal Hemorrhage (CPT Code 30901)

CPT code 30901 (Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method) was identified as a potentially misvalued code through the Five-Year Review Identification Workgroup under the "Harvard Valued" potentially misvalued codes screen for services with utilization over 100,000. The AMA RUC agreed with the specialty society,

stating that there is no compelling evidence to change the current work RVUs of 1.21. To support the current valuation, the AMA RUC compared CPT code 30901 to CPT code 36620 (Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous), and agreed that CPT code 30901 required slightly more total service time to perform but required comparable intensity and complexity. The AMA RUC also compared CPT code 30901 to the key reference code CPT code 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure) and agreed that code CPT code 30901 would be relatively more intense/complex. We disagree with the AMA RUC's CY 2011 work RVU recommendation to maintain the current work RVUs of 1.21 for code CPT code 30901 because the AMA RUC-recommended work value does not appropriately account for the significant reduction in intra-service time. We believe the more appropriate work RVUs are 1.10, based on the survey 25th percentile. Therefore, we are assigning an alternative value of 1.10 work RVUs to CPT code 29540 on an interim final basis for CY 2011.

(4) Cystourethroscopy (CPT Codes 52281 and 52332)

CPT codes 52281 (Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis; with or without meatotomy, with or without injection procedure for cystography, male or female) and 52332 (Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type) were identified as a potentially misvalued code through the Five-Year Review Identification Workgroup under the "Harvard Valued" potentially misvalued codes screen for services with utilization over 100,000.

The AMA RUC reviewed the survey results and determined that the physician time of 16 minutes pre-, 20 minutes intra-, and 10 minutes immediate post-service time and maintaining the current work RVUs of 2.80 appropriately account for the time and work required to perform this procedure. We disagree with the CY 2011 AMA RUC work RVU recommendation to maintain the current RVUs for this code because the physician time to perform this service (a building block of the code) has changed since the original "Harvard values" were established, as indicated by the AMA RUC-recommended reduction in pre-service time. Accounting for the reduction in pre-service time, we calculated work RVUs that are close to the survey 25th percentile. Therefore,

we are assigning 2.60 work RVUs to CPT code 52281 on an interim final basis for CY 2011.

Similarly, for CPT code 52332, we disagree with the AMA RUC's CY 2011 work RVU recommendation to maintain the current value due to the same concerns, a significant reduction in pre-service time. Based on the same building block rationale we applied to CPT code 52281, the other code within this family, we believe 1.47, which is the survey 25th percentile and maintains rank order, is a more appropriate valuation for 52332. Therefore, we are assigning an alternative value of 1.47 work RVUs to CPT code 52332 on an interim final basis for CY 2011.

(5) Vaginal Radiation Afterloading Apparatus for Clinical Brachytherapy (CPT Code 51755)

CPT code 51755 (Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy) was identified as a potentially misvalued code by the Five-Year Review Identification Workgroup through the "Site-of-Service Anomalies" potentially misvalued codes screen. This code is a member of a family of codes under review for CY 2011 and as such, the full discussion for the family is provided in section V.C.1.b.(1)(E), which discusses new and revised codes. However, to summarize the CMS decision in brief, we disagree with the AMA RUC's CY 2011 work RVU recommendations and are assigning an alternative value of 3.37 RVUs to CPT code 51755 on an interim final basis for CY 2011.

(6) Obstetrical Care Codes (CPT Codes 59440, 59410, 59510, 59515, 59610, 59614, 59618, and 59622)

As a result of being identified as potentially misvalued codes by the Five-Year Review Identification Workgroup "High IWPOT" screen for potentially misvalued codes, the AMA RUC reviewed the CPT codes that define obstetrical care (CPT codes 59400 through 59622). CPT codes 59400, 59410, 59510, 59515, 59610, 59614, 59618 and 59622 include antepartum care and/or delivery as well as postpartum care for which the AMA RUC recommended significantly increased work values. The AMA RUC recommended 32.69 work RVUs for CPT code 59400 (Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care); 18.54 work RVUs for CPT code 59410 (Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care); 36.17 work RVUs for

CPT code 59510 (Routine obstetric care including antepartum care, cesarean delivery, and postpartum care); 22.00 work RVUs for CPT code 59515 (Cesarean delivery only; including postpartum care), 34.40 work RVUs for CPT code 59610 (Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery); 20.26 work RVUs for CPT code 59614 (Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care), 36.69 work RVUs for CPT code 59618 (Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery); and 22.53 work RVUs for CPT code 59622 (Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care). For postpartum care with delivery, which is included in all of these codes, the AMA RUC recommended one CPT code 99214 (Level 4 established patient office or other outpatient visit).

We disagree with the AMA RUC-recommended work RVUs for these services and believe that one CPT code 99213 visit (Level 3 established patient office or other outpatient visit) more accurately reflects the services furnished for this postpartum care visit. Therefore, for all CPT code 99214 blocks for CPT codes that include postpartum care following delivery visits, we have converted the CPT code 99214 visit to a CPT code 99213 visit and have revised the work RVUs accordingly. Therefore, we are adopting alternative work RVUs and are assigning 32.16 work RVUs to CPT code 59400; 18.01 work RVUs to CPT code 59410; 35.64 work RVUs to CPT code 59510; 21.47 work RVUs to CPT code 59515; 33.87 work RVUs to CPT code 59610; 19.73 work RVUs to CPT code 59614; 36.16 work RVUs to CPT code 59618; and 22.00 work RVUs to CPT code 59622, prior to the work budget neutrality adjustment as discussed in section V.C.1.b.(3) of this final rule with comment period, on interim final basis for CY 2011.

(7) Vagus Nerve Stimulator (CPT Code 61885)

CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) was identified as a potentially misvalued code by the Five-Year Review Identification Workgroup under the "Site-of-Service Anomalies" screen for potential

misvalued codes. We discuss this code in the context of the Vagus Nerve Stimulator family, provided in section V.C.1.b.(i)(6), which discusses new and revised codes. However, to summarize the CMS decision in brief, we disagree with the AMA RUC's CY 2011 work RVU recommendations and are assigning an alternative value of 6.05 RVUs to CPT code 61885 on an interim final basis for CY 2011.

(8) Transforaminal Epidural Injection (CPT Code 64483)

CPT code 64483 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with image guidance (fluoroscopy or CT), lumbar or sacral; single level) was identified as a potentially misvalued code through the Five-Year Review Identification Workgroup under the "CMS Fastest Growing" potentially misvalued codes screen. The AMA RUC compared components of this code (pre-, intra-, and post-service times, in addition to intensity) to a number of other codes, although the AMA RUC's application of the crosswalk methodology was unclear to us. The AMA RUC recommended 1.90 work RVUs; however, we disagree with AMA RUC's CY 2011 work RVU recommendation and believe 1.75 work RVUs, based on the survey 25th percentile, more appropriately accounts for the significant reductions in pre-, intra-, and post-service time. Therefore, we are assigning an alternative value of 1.75 work RVUs to CPT code 64483 on an interim final basis for CY 2011.

(9) CT Thorax (CPT Code 71250)

CPT Code 71250 (Computed tomography, thorax; without contrast material) was identified as a potentially misvalued code by the Five-Year Review Identification Workgroup under the "CMS Fastest Growing" potentially misvalued codes screen. This service had never been surveyed by the AMA RUC until this review was conducted for CY 2011. The specialty recommended a pre-service time of 5 minutes based on the survey results and the AMA RUC concurred. The AMA RUC also agreed that the surveyed intra-service of 15 minutes and immediate post-service time of 5 minutes were typical for the physician work required for the service. While the AMA RUC accepted the survey results for physician times based on its comparisons to similar services and other considerations, the AMA RUC believed maintaining the code's current value of 1.16 work RVUs was more appropriate, noting that this recommended value is slightly lower than the survey 25th percentile of 1.20.

We disagree with the AMA RUC's CY 2011 work RVU recommendation to maintain the current value for CPT code 71250 and similar codes. As we have previously discussed, we are increasingly concerned over the validity of accepting work valuations based upon surveys conducted on existing codes as we have noticed a pattern of predictable survey results. That is, in providing recommendations for existing potentially misvalued codes in CY 2011, the AMA RUC often recommended maintaining the current work RVUs and supported this valuation by citing the survey results. Upon clinical review of a number of these cases, we are concerned over the validity of the survey results since the survey values often are very close to the current known value for the code. We are concerned that this may indicate a bias in the survey results since respondents would know the current value for the existing code at the time the survey is being conducted. Increasingly, rather than recommending the median survey value that has historically been most commonly used, the AMA RUC is choosing to recommend the 25th percentile value, potentially responding to the same concern we have identified. Therefore, based on our concern that CT codes would continue to be misvalued if we were to accept the AMA RUC recommendation to maintain the current value, we are assigning an alternative value of 1.00 work RVUs (the survey low value) to CPT code 71250 on an interim final basis for CY 2011.

(10) CT Spine (CPT Code 72125)

CPT codes 72125 (Computed tomography, cervical spine; without contrast material); 72128 (Computed tomography, thoracic spine; without contrast material); and 72131 (Computed tomography, lumbar spine; without contrast material) were identified as potentially misvalued codes by the Five-Year Review Workgroup under the "CMS Fastest Growing" screen for potentially misvalued codes. For CPT code 72125, the AMA RUC concurred with the specialty-recommended pre-service time of 5 minutes based on the survey results. The AMA RUC also agreed that the surveyed intra-service of 15 minutes and immediate post-service time of 5 minutes were typical for the physician work required for the service. The AMA

RUC compared this service to other comparable services and concluded that it was appropriate to maintain the current work RVUs of 1.16.

Similarly, for CPT codes 72128 and 72131, the AMA RUC accepted the survey physician times, but also disregarded the survey work RVU results. Upon clinical review of these codes in this family, we are concerned over the validity of the survey results since the survey 25th percentile values are very close to the current value of 1.16 RVUs for the code. As we stated previously, we are concerned that this pattern may indicate a bias in the survey results. Therefore, based on our concern that the CT codes would continue to be misvalued if we were to accept the AMA RUC recommendation to maintain the current values, we are assigning alternative work RVUs of 1.00 (the survey low value) to CPT codes 72125, 72128, and 72131 on an interim final basis for CY 2011.

(11) CT Upper and CT Lower Extremity (CPT Code 73200 and 73700)

CPT codes 73200 (Computed tomography, upper extremity; without contrast material) and 73700 (Computed tomography, lower extremity; without contrast material) were identified as potentially misvalued codes by the Five-Year Review Workgroup under the "CMS Fastest Growing" screen for potentially misvalued codes. Similar to the other CT codes previously discussed, the AMA RUC reviewed the survey results and accepted the survey physician times, recommending maintaining the current work RVUs of 1.09 for these services. Our clinical review of the codes, CPT codes 73200 and 73700, as with the other CT codes previously discussed, concluded that maintaining the current values would result in an overvaluing of this type of service. We remain concerned over the validity of the survey results. Therefore, based on our concern that CT codes would continue to be misvalued if we were to accept the AMA RUC recommendation to maintain the current values, we disagree with the AMA RUC's CY 2011 work RVU recommendations. We are assigning alternative work RVUs of 1.00 (the survey low RVU value) to CPT codes 73200, and 73700 on an interim final basis for CY 2011.

(12) Radiation Treatment Management (CPT Code 77427)

CPT code 77427 (Radiation treatment management, 5 treatments) was identified as a potentially misvalued code by the Five-Year Identification Workgroup's "Site-of-Service Anomalies" screen for potentially misvalued codes in 2007. For CY 2011, the AMA RUC reviewed the specialty survey results and agreed that the surveyed physician time of 7 minutes pre-service, 70 minutes intra-service, and 10 minutes immediate post-service is appropriate. The AMA RUC also used the building block approach to value the treatment visits associated with CPT code 77427. The AMA RUC averaged the number of weekly E/M visits, that is, 4 of CPT code 99214 (Level 4 established patient office or other outpatient visit) and 2 of CPT code 99213 (Level 3 established patient office or other outpatient visit) over 6 weeks to calculate an E/M building block of 1.32 RVUs. Similarly, to value the post-operative office visits associated with this code, the AMA RUC calculated a building block of 0.57 to account for the average over 6 weeks of "E/M visits after treatment planning." The AMA RUC then crosswalked the physician times for CPT code 77427 to CPT code 77315 (Teletherapy, isodose plan (whether hand or computer calculated); complex (mantle or inverted Y, tangential ports, the use of wedges, compensators, complex blocking, rotational beam, or special beam considerations)) and used the value of CPT code 77315 as the remaining building block for CPT code 77427. Accordingly, the AMA RUC calculated total work RVUs of 3.45 and recommended this value for CPT code 77427.

Upon clinical review, we modified one of the building blocks that the AMA RUC used to calculate the work RVUs associated with the treatment E/M office visits. We believe instead of the average based upon 4 units of CPT code 99214 and 2 units of CPT code 99213, a more appropriate estimation would be an average of 3 units of CPT code 99214 and 3 units of CPT code 99213. Accordingly, we are assigning an alternative value of 2.92 work RVUs to CPT code 77427 on an interim final basis for CY 2011.

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**Table 53: AMA RUC Recommendations and Interim Final Work RVUs for
CY 2011 New, Revised, and Potentially Misvalued Codes**

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
11010	Debride skin at fx site	x	4.19	Agree	4.19
11011	Debride skin musc at fx site	x	4.94	Agree	4.94
11012	Deb skin bone at fx site	x	6.87	Agree	6.87
11042	Deb subq tissue 20 sq cm/<	x	1.12	Disagree	0.80
11043	Deb musc/fascia 20 sq cm/<	x	3.00	Disagree	2.00
11044	Deb bone 20 sq cm/<	x	4.56	Disagree	3.60
11045	Deb subq tissue add-on	x	0.69	Disagree	0.33
11046	Deb musc/fascia add-on	x	1.29	Disagree	0.70
11047	Deb bone add-on	x	2.00	Disagree	1.20
11900	Injection into skin lesions	x	0.52	Agree	0.52
11901	Added skin lesions injection	x	0.80	Agree	0.80
12001	Repair superficial wound(s)	x	0.84	Agree	0.84
12002	Repair superficial wound(s)	x	1.14	Agree	1.14
12004	Repair superficial wound(s)	x	1.44	Agree	1.44
12005	Repair superficial wound(s)	x	1.97	Agree	1.97
12006	Repair superficial wound(s)	x	2.39	Agree	2.39
12007	Repair superficial wound(s)	x	2.90	Agree	2.90
12011	Repair superficial wound(s)	x	1.07	Agree	1.07
12013	Repair superficial wound(s)	x	1.22	Agree	1.22
12014	Repair superficial wound(s)	x	1.57	Agree	1.57
12015	Repair superficial wound(s)	x	1.98	Agree	1.98
12016	Repair superficial wound(s)	x	2.68	Agree	2.68
12017	Repair superficial wound(s)	x	3.18	Agree	3.18
12018	Repair superficial wound(s)	x	3.61	Agree	3.61
15823	Revision of upper eyelid	x	6.81	Agree	6.81
19357	Breast reconstruction	x	18.50	Agree	18.50
20005	I&d abscess subfascial	x	3.58	Agree	3.58
20664	Application of halo		10.06	Agree	10.06
20930	Sp bone algrft morsel add-on		0.00	Agree	0.00
20931	Sp bone algrft struct add-on		1.81	Agree	1.81
22315	Treat spinc fracture		10.11	Agree	10.11
22551	Neck spine fuse&remove addl	x	24.50	Disagree	25.00
22552	Addl neck spine fusion	x	6.50	Agree	6.50

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
22554	Neck spine fusion	x	17.69	Agree	17.69
22585	Additional spinal fusion	x	5.52	Agree	5.52
22851	Apply spine prosth device	x	6.70	Agree	6.70
23430	Repair biceps tendon	x	10.17	Agree	10.17
27065	Remove hip bone les super		6.55	Agree	6.55
27066	Remove hip bone les deep		11.20	Agree	11.20
27067	Remove/graft hip bone lesion		14.72	Agree	14.72
27070	Part remove hip bone super		11.56	Agree	11.56
27071	Part removal hip bone deep		12.39	Agree	12.39
29540	Strapping of ankle and/or ft	x	0.39	Disagree	0.32
29550	Strapping of toes	x	0.25	Disagree	0.15
29914	Hip arthro w/femoroplasty		14.67	Agree	14.67
29915	Hip arthro acetabuloplasty		15.00	Agree	15.00
29916	Hip arthro w/labral repair		15.00	Agree	15.00
30901	Control of nosebleed	x	1.21	Disagree	1.10
31256	Exploration maxillary sinus		3.29	Agree	3.29
31267	Endoscopy maxillary sinus		5.45	Agree	5.45
31276	Sinus endoscopy surgical		8.84	Agree	8.84
31287	Nasal/sinus endoscopy surg		3.91	Agree	3.91
31288	Nasal/sinus endoscopy surg		4.57	Agree	4.57
31295	Sinus endo w/balloon dil		2.70	Agree	2.70
31296	Sinus endo w/balloon dil		3.29	Agree	3.29
31297	Sinus endo w/balloon dil		2.64	Agree	2.64
31634	Bronch w/balloon occlusion		4.00	Agree	4.00
33411	Replacement of aortic valve		62.07	Agree	62.07
33620	Apply r&l pulm art bands		30.00	Agree	30.00
33621	Transhor cath for stent		16.18	Agree	16.18
33622	Redo compl cardiac anomaly		64.00	Agree	64.00
33860	Ascending aortic graft	x	59.46	Agree	59.46
33863	Ascending aortic graft	x	58.79	Agree	58.79
33864	Ascending aortic graft	x	60.08	Agree	60.08
34900	Endovasc iliac repr w/graft		16.85	Agree	16.85
35471	Repair arterial blockage	x	10.05	Agree	10.05
36410	Non-routine bl draw > 3 yrs	x	0.18	Agree	0.18
37205	Transcath iv stent percut	x	8.27	Agree	8.27
37206	Transcath iv stent/perc addl	x	4.12	Agree	4.12
37207	Transcath iv stent open	x	8.27	Agree	8.27

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
37208	Transcath iv stent/open addl	x	4.12	Agree	4.12
37220	Iliac revasc	x	8.15	Agree	8.15
37221	Iliac revasc w/stent	x	10.00	Agree	10.00
37222	Iliac revasc add-on	x	3.73	Agree	3.73
37223	Iliac revasc w/stent add-on	x	4.25	Agree	4.25
37224	Fem/popl revas w/tla	x	9.00	Agree	9.00
37225	Fem/popl revas w/ather	x	12.00	Agree	12.00
37226	Fem/popl revasc w/stent	x	10.49	Agree	10.49
37227	Fem/popl revasc stnt & ather	x	14.50	Agree	14.50
37228	Tib/per revasc w/tla	x	11.00	Agree	11.00
37229	Tib/per revasc w/ather	x	14.05	Agree	14.05
37230	Tib/per revasc w/stent	x	13.80	Agree	13.80
37231	Tib/per revasc stent & ather	x	15.00	Agree	15.00
37232	Tib/per revasc add-on	x	4.00	Agree	4.00
37233	Tibper revasc w/ather add-on	x	6.50	Agree	6.50
37234	Revasc opn/prq tib/pero stent	x	5.50	Agree	5.50
37235	Tib/per revasc stnt & ather	x	7.80	Agree	7.80
38900	lo map of sent lymph node		2.50	Agree	2.50
37765	Stab phleb veins xtr 10-20	x	7.71	Agree	7.71
37766	Phleb veins - extrem 20+	x	9.66	Agree	9.66
43283	Lap esoph lengthening ¹		4.00	Disagree	2.95
43327	Esoph fundoplasty lap ¹		18.10	Disagree	13.35
43328	Esoph fundoplasty thor ¹		27.00	Disagree	19.91
43332	Transab esoph hiat hern rpr ¹		26.60	Disagree	19.62
43333	Transab esoph hiat hern rpr ¹		30.00	Disagree	21.46
43334	Transthor diaphrag hern rpr ¹		30.00	Disagree	22.12
43335	Transthor diaphrag hern rpr ¹		33.00	Disagree	23.97
43336	Thorabd diaphr hern repair ¹		35.00	Disagree	25.81
43337	Thorabd diaphr hern repair ¹		37.50	Disagree	27.65
43338	Esoph lengthening ¹		3.00	Disagree	2.21
43605	Biopsy of stomach		13.72	Agree	13.72
43753	Tx gastro intub w/asp		0.45	Agree	0.45
43754	Dx gastr intub w/asp spec		0.45	Agree	0.45
43755	Dx gastr intub w/asp specs		0.94	Agree	0.94
43756	Dx duod intub w/asp spec		0.77	Agree	0.77
43757	Dx duod intub w/asp specs		1.26	Agree	1.26
47480	Incision of gallbladder	x	13.25	Agree	13.25

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
47490	Incision of gallbladder	x	4.76	Agree	4.76
49324	Lap insert tunnel ip cath		6.32	Agree	6.32
49327	Lap ins device for rt		2.38	Agree	2.38
49412	Ins device for rt guide open		1.50	Agree	1.50
49418	Insert tun ip cath perc	x	4.21	Agree	4.21
49419	Insert tun ip cath w/port	x	7.08	Agree	7.08
49421	Ins tun ip cath for dial opn	x	4.21	Agree	4.21
49422	Remove tunneled ip cath	x	6.29	Agree	6.29
50250	Cryoablate renal mass open		22.22	Agree	22.22
50542	Laparo ablate renal mass	x	21.36	Agree	21.36
51736	Urine flow measurement	x	0.17	Agree	0.17
51741	Electro-uroflowmetry first	x	0.17	Agree	0.17
52281	Cystoscopy and treatment	x	2.80	Disagree	2.60
52332	Cystoscopy and treatment	x	2.83	Disagree	1.47
53860	Transurethral rf treatment		3.97	Agree	3.97
55866	Laparo radical prostatectomy	x	32.06	Agree	32.06
55876	Place rt device/marker pros		1.73	Agree	1.73
57155	Insert uteri tandems/ovoids	x	5.40	Disagree	3.37
57156	Ins vag brachytx device	x	2.69	Disagree	1.87
59400	Obstetrical care ¹	x	32.69	Disagree	28.69
59409	Obstetrical care ¹	x	14.37	Disagree	12.82
59410	Obstetrical care ¹	x	18.54	Disagree	16.07
59412	Antepartum manipulation ¹	x	1.71	Disagree	1.53
59414	Deliver placenta ¹	x	1.61	Disagree	1.44
59425	Antepartum care only ¹	x	6.31	Disagree	5.63
59426	Antepartum care only ¹	x	11.16	Disagree	9.96
59430	Care after delivery ¹	x	2.47	Disagree	2.20
59510	Cesarean delivery ¹	x	36.17	Disagree	31.80
59514	Cesarean delivery only ¹	x	16.13	Disagree	14.39
59515	Cesarean delivery ¹	x	22.00	Disagree	19.15
59610	Vbac delivery ¹	x	34.40	Disagree	30.22
59612	Vbac delivery only ¹	x	16.09	Disagree	14.35
59614	Vbac care after delivery ¹	x	20.26	Disagree	17.60
59618	Attempted vbac delivery ¹	x	36.69	Disagree	32.26
59620	Attempted vbac delivery only ¹	x	16.66	Disagree	14.86
59622	Attempted vbac after care ¹	x	22.53	Disagree	19.63
61781	Scan proc cranial intra	x	3.75	Agree	3.75

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
61782	Scan proc cranial extra	x	3.18	Agree	3.18
61783	Scan proc spinal	x	3.75	Agree	3.75
61885	Insrt/redo neurostim 1 array	x	6.44	Disagree	6.05
63075	Neck spine disk surgery	x	19.60	Agree	19.60
63076	Neck spine disk surgery	x	4.04	Agree	4.04
64415	Nblock inj brachial plexus	x	1.48	Agree	1.48
64445	Nblock inj sciatic sng	x	1.48	Agree	1.48
64447	Nblock inj fem single	x	1.50	Agree	1.50
64479	Inj foramen epidural c/t	x	2.29	Agree	2.29
64480	Inj foramen epidural add-on	x	1.20	Agree	1.20
64483	Inj foramen epidural l/s	x	1.90	Agree	1.90
64484	Inj foramen epidural add-on	x	1.00	Agree	1.00
64566	Neuroeltrd stim post tibial		0.60	Agree	0.60
64568	Inc for vagus n elect impl	x	11.19	Disagree	9.00
64569	Revise/repl vagus n eltrd	x	15.00	Disagree	11.00
64570	Remove vagus n eltrd	x	13.00	Disagree	9.10
64581	Implant neuroelectrodes	x	12.20	Agree	12.20
64611	Chemodenerv saliv glands		1.03	Agree	1.03
64708	Revise arm/leg nerve	x	6.36	Agree	6.36
64712	Revision of sciatic nerve	x	8.07	Agree	8.07
64713	Revision of arm nerve(s)	x	11.40	Agree	11.40
64714	Revise low back nerve(s)	x	10.55	Agree	10.55
65778	Cover eye w/membrane		1.19	Agree	1.19
65779	Cover eye w/membrane stent		3.92	Agree	3.92
65780	Ocular reconst transplant	x	10.73	Agree	10.73
66174	Translum dil eye canal		12.85	Agree	12.85
66175	Trnslum dil eye canal w/stnt		13.60	Agree	13.60
66761	Revision of iris	x	3.00	Agree	3.00
67028	Injection eye drug	x	1.44	Agree	1.44
69801	Incise inner ear	x	2.06	Agree	2.06
69802	Incise inner ear	x	13.50	Agree	13.50
71250	Ct thorax w/o dye	x	1.16	Disagree	1.00
72125	Ct neck spine w/o dye	x	1.16	Disagree	1.00
72128	Ct chest spine w/o dye	x	1.16	Disagree	1.00
72131	Ct lumbar spine w/o dye	x	1.16	Disagree	1.00
73080	X-ray exam of elbow	x	0.17	Agree	0.17
73200	Ct upper extremity w/o dye	x	1.09	Disagree	1.00

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
73510	X-ray exam of hip	x	0.21	Agree	0.21
73610	X-ray exam of ankle	x	0.17	Agree	0.17
73630	X-ray exam of foot	x	0.17	Agree	0.17
73700	Ct lower extremity w/o dye	x	1.09	Disagree	1.00
74176	Ct abd & pelvis w/o contrast	x	1.74	Agree	1.74
74177	Ct abdomen & pelvis w/contrast	x	1.82	Agree	1.82
74178	Ct abd & pelv 1+ section/regns	x	2.01	Agree	2.01
75954	Iliac aneurysm endovas rpr		2.25	Agree	2.25
75960	Transcath iv stent rs&i	x	0.82	Agree	0.82
75962	Repair arterial blockage	x	0.54	Agree	0.54
75964	Repair artery blockage each	x	0.36	Agree	0.36
76881	Us xtr non-vasc complete	x	0.72	Disagree	0.59
76882	Us xtr non-vasc lmtd	x	0.50	Disagree	0.41
76942	Echo guide for biopsy		0.67	Agree	0.67
77003	Fluoroguide for spine inject		0.60	Agree	0.60
77012	Ct scan for needle biopsy		1.16	Agree	1.16
77427	Radiation tx management x5	x	3.35	Disagree	2.92
88120	Cytp urine 3-5 probes ea spec		1.20	Agree	1.20
88121	Cytp urine 3-5 probes cmptr		1.00	Agree	1.00
88172	Cytp dx eval fna 1st ea site		0.69	Disagree	0.60
88173	Cytopath eval fna report		1.39	Agree	1.39
88177	Cytp c/v auto thin lyr addl		0.42	Agree	0.42
88300	Surgical path gross	x	0.08	Agree	0.08
88302	Tissue exam by pathologist	x	0.13	Agree	0.13
88304	Tissue exam by pathologist	x	0.22	Agree	0.22
88305	Tissue exam by pathologist	x	0.75	Agree	0.75
88307	Tissue exam by pathologist	x	1.59	Agree	1.59
88309	Tissue exam by pathologist	x	2.80	Agree	2.80
88363	Xm archive tissue molec anal		0.37	Agree	0.37
88367	Insitu hybridization auto		1.30	Agree	1.30
88368	Insitu hybridization manual		1.40	Agree	1.40
90460	Imadm any route 1st vac/tox		0.20	Disagree	0.17
90461	Inadm any route addl vac/tox		0.16	Disagree	0.15
90870	Electroconvulsive therapy	x	2.50	Agree	2.50
90935	Hemodialysis one evaluation	x	1.48	Agree	1.48
90937	Hemodialysis repeated eval	x	2.11	Agree	2.11
90945	Dialysis one evaluation	x	1.56	Agree	1.56

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
90947	Dialysis repeated eval	x	2.52	Agree	2.52
91010	Esophagus motility study ¹		1.50	Disagree	1.28
91013	Esophagl motil w/stim/perfus ¹		0.25	Disagree	0.18
91038	Esoph impeded funct test > 1h	x	1.10	Agree	1.10
91117	Colon motility 6 hr study		2.45	Agree	2.45
91132	Electrogastrography		0.52	Agree	0.52
91133	Electrogastrography w/test		0.66	Agree	0.66
92081	Visual field examination(s)	x	0.30	Agree	0.30
92082	Visual field examination(s)	x	0.40	Agree	0.40
92132	Cmptr ophth dx img ant segmt	x	0.35	Agree	0.35
92133	Cmptr ophth img optic nerve	x	0.50	Agree	0.50
92134	Cptr ophth dx img post segmt	x	0.50	Agree	0.50
92227	Remote dx retinal imaging		0.00	Agree	0.00
92228	Remote retinal imaging mgmt		0.44	Disagree	0.30
92285	Eye photography	x	0.05	Agree	0.05
92504	Ear microscopy examination	x	0.18	Agree	0.18
92507	Speech/hearing therapy		1.30	Agree	1.30
92508	Speech/hearing therapy		0.43	Disagree	0.33
92606	Non-speech device service		1.40	Agree	1.40
92607	Ex for speech device rx 1hr		1.85	Agree	1.85
92608	Ex for speech device rx addl		0.70	Agree	0.70
92609	Use of speech device service		1.50	Agree	1.50
93040	Rhythm ecg with report	x	0.15	Agree	0.15
93042	Rhythm ecg report	x	0.15	Agree	0.15
93224	Ecg monit/reprt up to 48 hrs	x	0.52	Agree	0.52
93227	Ecg monit/reprt up to 48 hrs	x	0.52	Agree	0.52
93228	Remote 30 day ecg rev/report	x	0.52	Agree	0.52
93268	Ecg record/review	x	0.52	Agree	0.52
93272	Ecg/review interpret only	x	0.52	Agree	0.52
93451	Right heart cath	x	3.02	Disagree	2.72
93452	Left hrt cath w/ventriclgrphy	x	4.32	Disagree	4.75
93453	R&I hrt cath w/ventriclgrphy	x	5.98	Disagree	6.24
93454	Coronary artery angio s&i	x	4.95	Disagree	4.79
93455	Coronary art/grft angio s&i	x	6.15	Disagree	5.54
93456	Rhrt coronary artery angio	x	6.00	Disagree	6.15
93457	Rhrt art/grft angio	x	7.66	Disagree	6.89
93458	Lhrt artery/ventricle angio	x	6.51	Disagree	5.85

CPT Code	Short Descriptor	Valued in Relation to a Potentially Misvalued Code Screen	AMA RUC-Recommended Work RVUs	CMS Decision	CY 2011 Interim Final Work RVUs
93459	Lhrt art/grft angio	x	7.34	Disagree	6.60
93460	R&l hrt art/ventricle angio	x	7.88	Disagree	7.35
93461	R&l hrt art/ventricle angio	x	9.00	Disagree	8.10
93462	Lhrt cath trnsptl puncture	x	3.73	Agree	3.73
93463	Drug admin & hemodynamic meas	x	2.00	Agree	2.00
93464	Exercise w/hemodynamic meas	x	1.80	Agree	1.80
93563	Inject congenital card cath	x	2.00	Disagree	1.11
93564	Inject hrt congntl art/grft	x	2.10	Disagree	1.13
93565	Inject l ventr/atrial angio	x	1.90	Disagree	0.86
93566	Inject r ventr/atrial angio	x	0.96	Disagree	0.86
93567	Inject suprvlv aortography	x	0.97	Agree	0.97
93568	Inject pulm art hrt cath	x	0.98	Disagree	0.88
93652	Ablate heart dysrhythm focus	x	17.65	Agree	17.65
93922	Upr/l xtremity art 2 levels	x	0.25	Agree	0.25
93923	Upr/lxtr art stdy 3+ lvls	x	0.45	Agree	0.45
93924	Lwr xtr vasc stdy bilat	x	0.50	Agree	0.50
95800	Slp stdy unattended	x	1.05	Agree	1.05
95801	Slp stdy unatnd w/anal	x	1.00	Agree	1.00
95803	Actigraphy testing	x	0.90	Agree	0.90
95805	Multiple sleep latency test	x	1.20	Agree	1.20
95806	Sleep study unatt&resp efft	x	1.28	Disagree	1.25
95807	Sleep study attended	x	1.25	Disagree	1.28
95808	Polysomnography 1-3	x	1.74	Agree	1.74
95810	Polysomnography 4 or more	x	2.50	Agree	2.50
95811	Polysomnography w/cpap	x	2.60	Agree	2.60
95857	Cholinesterase challenge		0.53	Agree	0.53
95950	Ambulatory eeg monitoring	x	1.51	Agree	1.51
95953	Eeg monitoring/computer	x	3.08	Agree	3.08
95956	Eeg monitor technol attended	x	3.61	Agree	3.61
96105	Assessment of aphasia	x	1.75	Agree	1.75
96446	Chemotx admn prtl cavity		0.37	Agree	0.37
97597	Rmvl devital tis 20 cm< ¹	x	0.54	Disagree	0.51
97598	Rmvl devital tis addl 20 cm< ¹	x	0.40	Disagree	0.24
99224	Subsequent observation care		0.76	Disagree	0.54
99225	Subsequent observation care		1.39	Disagree	0.96
99226	Subsequent observation care		2.00	Disagree	1.44

Notes:

¹ CY 2011 interim final work RVUs reflect adjustment for work budget neutrality.

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2. Establishment of Interim Final Direct PE Inputs for CY 2011

a. Background

As we previously explained in section V.A. of this final rule with comment period, on an annual basis, the AMA RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, supplies, and equipment, for new, revised, and potentially misvalued codes. These recommendations, therefore, include inputs for all direct PE categories excluding supply prices and equipment prices and useful life inputs, which are specifically discussed in section II.A.3.e. of this final rule with comment period.

We review the AMA RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs, as clinically appropriate for the code. We determine whether we agree with the AMA RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required for the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

We received direct PE input recommendations from the AMA RUC for 325 CPT codes for CY 2011, including those CPT codes where the AMA RUC recommended no changes to the direct PE inputs of existing codes. We note that we have included in this count those recommendations received from the AMA RUC that were provided for CY 2011 and addressed in the CY 2011 PFS proposed rule. These recommendations are discussed in section II.A.3.c. of this final rule with comment period. We have accepted for CY 2011, as interim final and without refinement, the direct PE inputs based on the recommendations submitted by the AMA RUC for the 258 codes listed in Table 54.

For the remainder of the AMA RUC's direct PE recommendations for 67 codes, we have accepted the PE recommendations submitted by the AMA RUC as interim final, but with refinements. These codes and the refinements to their direct PE inputs are listed in Table 55.

Accordingly, while Table 55 details the CY 2011 refinements of the AMA RUC's direct PE recommendations at the code-specific level, we discuss the

general nature of some common refinements and the reasons for particular refinements in the following section. We note that the final CY 2011 PFS direct PE database reflects the refined direct PE inputs that we are adopting on an interim final basis for CY 2011. That database is available under downloads for the CY 2011 PFS final rule with comment period on the CMS Web site at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

b. CY 2011 Interim Final Direct PE Inputs for New, Revised, and Potentially Misvalued Codes

(1) General Equipment Time

Many of the refinements to the AMA RUC direct PE recommendations were made in the interest of promoting a transparent and consistent approach to equipment time inputs. In the past, the AMA RUC did not always provide us with recommendations regarding equipment time inputs. In CY 2010, we requested that the AMA RUC provide equipment times along with the other direct PE recommendations. Subsequent to that request, we provided the AMA RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the AMA RUC's willingness to provide us with these additional inputs as part of their direct PE recommendations.

In general, the equipment time inputs correspond to the intra-service portion of the clinical labor times. We have clarified that assumption to consider equipment time as the sum of the times within the intra-service period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. In addition, when a piece of equipment is typically used during additional visits included in a service's global period, the equipment time should also reflect that use.

Certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician over the full course of a procedure and are typically available for other patients during time that may still be in the intra-service portion of the service. We adjust those equipment times accordingly. For example, CPT code 74178 (Computed tomography, abdomen and pelvis; without contrast material in more than one body region) includes 3 minutes of intra-service clinical labor time associated with obtaining the patient's consent for the procedure. Since it would be atypical

for this activity to occur within the CT room, we believe these 3 minutes should not be attributed to the CT room.

We are refining the CY 2011 AMA RUC direct PE recommendations to conform to these equipment time policies. These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 55.

(2) Equipment Time and Clinical Labor for Conscious Sedation

In services that include conscious sedation recovery, clinical labor and equipment time inputs are generally established using a distinctive logic. In the case of these services, clinical labor time is based on 15 minutes of registered nurse (RN) recovery monitoring for each hour monitored following the procedure to account for a typical 1:4 nurse to patient ratio. Times for equipment used during the recovery monitoring period, therefore, are equal to four times the number of RN minutes during the recovery monitoring period.

Equipment time for pieces of equipment used in conscious sedation should generally include time to administer the anesthesia, time for the procedure, and time to monitor the patient following the procedures. Standard equipment and supplies for conscious sedation include: EQ011 (ECG, 3-channel (with SpO₂, NIBP, temp, resp)); EF019 (stretcher chair); EQ032 (IV infusion pump); and SA044 (pack, conscious sedation).

We are refining the CY 2011 AMA RUC direct PE recommendations to conform to these policies. These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 55.

(3) Equipment Time for Add-On Codes

For add-on codes, only minutes allocated to the procedure itself are added to the time for the equipment, since any additional minutes would duplicate the equipment time already accounted for in the primary procedure that accompanies the add-on code.

We are refining the CY 2011 AMA RUC PFS direct PE recommendations to conform to this policy. These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 55.

(4) Changes in Standard Uses of Certain Supplies

As discussed in section II.A.3.b.(1) of this final rule with comment period, we are finalizing our proposal to remove the supply item "biohazard bag" from the direct PE database because the item is considered an indirect practice

expense. Additionally, as discussed in section II.A.3.b.(6) of this final rule with comment period, we are finalizing our CY 2011 proposal to remove the pulse oximeter with printer (CMS Equipment Code EQ211) as an input for the 118 codes that also contain the ECG, 3-channel (with SpO₂, NIBP, temp, resp) (CMS Equipment Code EQ011).

We are refining the CY 2011 AMA RUC PFS direct PE recommendations to conform to these policies. These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 55.

(5) New Supply and Equipment Items

When clinically appropriate, the AMA RUC generally recommends the use of supply and equipment items that already exist in the direct PE database for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE database. In these cases, the AMA RUC has historically recommended a new item be created and has facilitated CMS' pricing of that item by working with the specialty societies to provide sales invoices to us. We appreciate the contributions of the AMA RUC in that process.

Despite the assistance of the AMA RUC for CY 2011, we did not receive adequate information for pricing the following new supply items included in the AMA RUC's CY 2011 direct PE recommendations: SC333 (Catheter, angiographic, Berman); SD251 (Sheath Shuttle (Cook)); SD255 (Reentry Device (Frontier, Outback, Pioneer)); SD257 (Tunneler); and SD258 (Vacuum Bottle). We agree with the AMA RUC that these supply items are appropriate direct PE inputs for the associated procedures. However, because these items do not resemble current supplies in the PE database, we were unable to identify existing supplies with input prices to substitute for the AMA RUC-recommended direct PE inputs. We were also unable to estimate the prices for these new supply items based on analogy to existing supplies in the direct PE database because, as stated previously, they are not clinically similar to existing items in the direct PE database and we do not have information on the pricing of the new supply items. Therefore, our only alternative for these supply items for CY 2011 was to accept them as direct PE inputs for the associated services based on the AMA RUC recommendations, but to price them at \$0 for CY 2011. For CY 2012, we will consider the prices for these supply items eligible to be updated through the process we are

finalizing for CY 2011 that is described in section II.A.3.e. of this final rule with comment period.

In the case of certain other direct PE recommendations for CY 2011, the AMA RUC has recommended new supply or equipment items that we believe to be already described by existing items in the direct PE database. Therefore, we are refining the AMA RUC CY 2011 direct PE recommendations to utilize existing supply and equipment items in the PE database where appropriate. These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 55.

(6) Endovascular Revascularization Stents

In reviewing the supply input recommendations from the AMA RUC for CPT codes describing certain endovascular revascularization services, we considered the quantity of high-cost stents associated with some of the codes. The recommendations included two or three stents for each of the following six CPT codes: 37226 (Revascularization, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s)); 37227 (Revascularization, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy); 37230 (Revascularization, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s)); 37231 (Revascularization, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy); 37234 (Revascularization, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) (List separately in addition to code for primary procedure)); and 37235 (Revascularization, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy (List separately in addition to code for primary procedure)).

Given the complex clinical nature of these services, their new pricing in the nonfacility setting under the PFS, and the high cost of each stent, we were concerned that two or three stents could overestimate the number of stents used in the typical office procedure that would be reported under one of the CPT code. Therefore, we examined CY 2009 hospital OPFS claims data for the combinations of predecessor codes that would have historically been reported for each case reported in under CY 2011 under a single comprehensive code. Because of the OPFS device-to-procedure claims processing edits, all

prior cases would have included HCPCS C-code for at least one stent on the claim for the case. Based on our analysis of these data, we determined that for each new CY 2011 comprehensive code, the predecessor code combinations would have used only one stent in 65 percent or more of the cases. We have no reason to believe that when these new CPT codes are reported for procedures performed in the nonfacility setting, patients would receive more than the one stent typically used in the hospital outpatient setting. Therefore, we are refining the CY 2011 AMA RUC recommendations to include one stent in the direct PE inputs for each of the six endovascular revascularization stent insertion codes, including the add-on codes. These refinements are reflected in the final CY 2011 PFS direct PE database.

(7) Nasal/Sinus Endoscopy Supply and Equipment Items

The AMA RUC recommendation for direct PE inputs for CPT code 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa), included irregular supply and equipment inputs. The AMA RUC recommended two similar, new supply items, specifically "kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)" and "kit, sinus surgery, balloon (maxillary)" as supply inputs with a quantity of one-half for each item. We believe that this recommendation was intended to reflect an assumption that each of these distinct supplies is used in approximately half of the cases when the service is furnished. In general, the direct PE inputs should reflect the items used when the service is furnished in the typical case. Therefore, the quantity of supply items associated with a code should reflect the actual units of the item used in the typical case, and not be reflective of any estimate of the proportion of cases in which any supply item is used. We note, however, that fractional inputs are appropriate when fractional quantities of a supply item are typically used, as is commonly the case when the unit of a particular supply reflects the volume of a liquid supply item instead of quantity. Additionally, in the case of certain services with global service periods, fractional quantities of supplies may be appropriate when fractional numbers of post-service office visits are associated with a code.

Upon receipt of these recommendations, we requested that the AMA RUC clarify the initial recommendation by determining which

of these supply items would be used in the typical case. The AMA RUC recommended that the supply item "kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)" be included in the inputs for the code. We considered that recommendation, but we believe that the item "kit, sinus surgery, balloon (maxillary)" is more clinically appropriate based on the description of CPT code 32195.

The AMA RUC recommendation for equipment inputs for the same code (CPT code 31295) included a parallel irregularity by distributing half of the equipment minutes to each of two similar pieces of equipment, one existing and one new: "Endoscope, rigid, sinuscopy" (ES013) and "fiberscope, flexible, sinuscopy" (new). We believe that this recommendation was intended to reflect an assumption that each of these distinct pieces of equipment is used in approximately half of the cases in which the service is furnished. In general, the direct PE inputs should reflect the items used when the service is furnished in the typical case. Therefore, the equipment time inputs associated with a code should reflect the number of minutes an equipment item is used in the typical case, and not be distributed among a set of equipment items to reflect an estimate of the proportion of cases in which a particular equipment item might be used. However, we note that in the case of certain services with global service periods, distribution of equipment minutes among similar equipment items may be appropriate when fractional numbers of post-service office visits are associated with a code. Upon review of these items, we believe that the new piece of equipment, "fiberscope, flexible, sinuscopy," is more clinically appropriate based on the description of CPT code 32195.

We are refining the CY 2011 AMA RUC direct PE recommendations to conform to these determinations. These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 55.

TABLE 54—CPT CODES WITH ACCEPTED AMA RUC DIRECT PE RECOMMENDATIONS FOR CY 2011 CODES

CPT Code	Short descriptor
11010	Debride skin at fx site
11011	Debride skin musc at fx site
11012	Deb skin bone at fx site
11045	Deb subq tissue add-on
11046	Deb musc/fascia add-on
11047	Deb bone add-on

TABLE 54—CPT CODES WITH ACCEPTED AMA RUC DIRECT PE RECOMMENDATIONS FOR CY 2011 CODES—Continued

CPT Code	Short descriptor
11900	Injection into skin lesions
11901	Added skin lesions injection
12001	Repair superficial wound(s)
12002	Repair superficial wound(s)
12004	Repair superficial wound(s)
12005	Repair superficial wound(s)
12006	Repair superficial wound(s)
12007	Repair superficial wound(s)
12011	Repair superficial wound(s)
12013	Repair superficial wound(s)
12014	Repair superficial wound(s)
12015	Repair superficial wound(s)
12016	Repair superficial wound(s)
12017	Repair superficial wound(s)
12018	Repair superficial wound(s)
15823	Revision of upper eyelid
19357	Breast reconstruction
20005	I&d abscess subfascial
20664	Application of halo
20930	Sp bone algrft morsel add-on
20931	Sp bone algrft struct add-on
22315	Treat spine fracture
22552	Addl neck spine fusion
22554	Neck spine fusion
22585	Additional spinal fusion
22851	Apply spine prosth device
23430	Repair biceps tendon
27065	Remove hip bone les super
27066	Remove hip bone les deep
27067	Remove/graft hip bone lesion
27070	Part remove hip bone super
27071	Part removal hip bone deep
29540	Strapping of ankle and/or ft
29550	Strapping of toes
29914	Hip arthro w/femoroplasty
29915	Hip arthro acetabuloplasty
29916	Hip arthro w/labral repair
30901	Control of nosebleed
31256	Exploration maxillary sinus
31267	Endoscopy maxillary sinus
31276	Sinus endoscopy surgical
31287	Nasal/sinus endoscopy surg
31288	Nasal/sinus endoscopy surg
33411	Replacement of aortic valve
33620	Apply r&l pulm art bands
33621	Transthor cath for stent
33622	Redo compl cardiac anomaly
33860	Ascending aortic graft
33863	Ascending aortic graft
33864	Ascending aortic graft
34900	Endovasc iliac repr w/graft
35471	Repair arterial blockage
36410	Non-routine bl draw > 3 yrs
37205	Transcath iv stent percut
37206	Transcath iv stent/perc addl
37207	Transcath iv stent open
37208	Transcath iv stent/open addl
37222	Iliac revasc add-on
37223	Iliac revasc w/stent add-on
37232	Tib/per revasc add-on
37233	Tibper revasc w/ather add-on
37765	Stab phleb veins xtr 10-20
37766	Phleb veins—extrem 20+
38900	Io map of sent lymph node
43283	Lap esoph lengthening
43327	Esoph fundoplasty lap
43328	Esoph fundoplasty thor

TABLE 54—CPT CODES WITH ACCEPTED AMA RUC DIRECT PE RECOMMENDATIONS FOR CY 2011 CODES—Continued

CPT Code	Short descriptor
43332	Transab esoph hiat hern rpr
43333	Transab esoph hiat hern rpr
43334	Transthor diaphrag hern rpr
43335	Transthor diaphrag hern rpr
43336	Thorabd diaphr hern repair
43337	Thorabd diaphr hern repair
43338	Esoph lengthening
43605	Biopsy of stomach
43753	Tx gastro intub w/asp
47480	Incision of gallbladder
47490	Incision of gallbladder
49324	Lap insert tunnel ip cath
49327	Lap ins device for rt
49400	Air injection into abdomen
49412	Ins device for rt guide open
49419	Insert tun ip cath w/port
49421	Ins tun ip cath for dial opn
49422	Remove tunneled ip cath
50250	Cryoablate renal mass open
50542	Laparo ablate renal mass
50590	Fragmenting of kidney stone
50684	Injection for ureter x-ray
*51725	Simple cystometrogram
*51726	Complex cystometrogram
*51727	Cystometrogram w/up
*51728	Cystometrogram w/vp
*51729	Cystometrogram w/vp&up
51736	Urine flow measurement
51741	Electro-uroflowmetry first
52281	Cystoscopy and treatment
52332	Cystoscopy and treatment
55866	Laparo radical prostatectomy
55876	Place rt device/marker pros
59400	Obstetrical care
59409	Obstetrical care
59410	Obstetrical care
59412	Antepartum manipulation
59414	Deliver placenta
59425	Antepartum care only
59426	Antepartum care only
59430	Care after delivery
59510	Cesarean delivery
59514	Cesarean delivery only
59515	Cesarean delivery
59610	Vbac delivery
59612	Vbac delivery only
59614	Vbac care after delivery
59618	Attempted vbac delivery
59620	Attempted vbac delivery only
59622	Attempted vbac after care
61781	Scan proc cranial intra
61782	Scan proc cranial extra
61783	Scan proc spinal
61885	Insrt/redu neurostim 1 array
62268	Drain spinal cord cyst
62269	Needle biopsy spinal cord
62281	Treat spinal cord lesion
62319	Inject spine w/cath l/s (cd)
63075	Neck spine disk surgery
63076	Neck spine disk surgery
63610	Stimulation of spinal cord
*64420	Nblock inj intercost sng
*64421	Nblock inj intercost mlt
64480	Inj foramen epidural add-on
64484	Inj foramen epidural add-on
64508	Nblock carotid sinus s/p
64561	Implant neuroelectrodes

TABLE 54—CPT CODES WITH ACCEPTED AMA RUC DIRECT PE RECOMMENDATIONS FOR CY 2011 CODES—Continued

CPT Code	Short descriptor
64566	Neuroeltrd stim post tibial
64568	Inc for vagus n elect impl
64569	Revise/repl vagus n eltrd
64570	Remove vagus n eltrd
64581	Implant neuroelectrodes
64611	Chemodenerv saliv glands
*64620	Injection treatment of nerve
64708	Revise arm/leg nerve
64712	Revision of sciatic nerve
64713	Revision of arm nerve(s)
64714	Revise low back nerve(s)
65778	Cover eye w/membrane
65780	Ocular reconstr transplant
66761	Revision of iris
67028	Injection eye drug
69802	Incise inner ear
70010	Contrast x-ray of brain
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
73080	X-ray exam of elbow
73200	Ct upper extremity w/o dye
73510	X-ray exam of hip
73610	X-ray exam of ankle
73630	X-ray exam of foot
73700	Ct lower extremity w/o dye
74430	Contrast x-ray bladder
*75571	Ct hrt w/o dye w/ca test
*75572	Ct hrt w/3d image
*75573	Ct hrt w/3d image congen
*75574	Ct angio hrt w/3d image
75954	Iliac aneurysm endovas rpr
75960	Transcath iv stent rs&i
75962	Repair arterial blockage
75964	Repair artery blockage each
76000	Fluoroscope examination
76942	Echo guide for biopsy
77003	Fluoroguide for spine inject
*77011	Ct scan for localization
77012	Ct scan for needle biopsy

TABLE 54—CPT CODES WITH ACCEPTED AMA RUC DIRECT PE RECOMMENDATIONS FOR CY 2011 CODES—Continued

CPT Code	Short descriptor
*77301	Radiotherapy dose plan imrt
77427	Radiation tx management x5
88120	Cytp urine 3-5 probes ea spec
88121	Cytp urine 3-5 probes cmptr
88172	Cytp dx eval fna 1st ea site
88173	Cytopath eval fna report
88177	Cytp c/v auto thin lyr addl
88300	Surgical path gross
88302	Tissue exam by pathologist
88304	Tissue exam by pathologist
88305	Tissue exam by pathologist
88307	Tissue exam by pathologist
88309	Tissue exam by pathologist
88363	Xm archive tissue molec anal
88367	Insitu hybridization auto
88368	Insitu hybridization manual
90460	Imadm any route 1st vac/tox.
90461	Imadm any route addl vac/tox
90870	Electroconvulsive therapy
90935	Hemodialysis one evaluation
90937	Hemodialysis repeated eval
90945	Dialysis one evaluation
90947	Dialysis repeated eval
91013	Esophgl motil w/stim/perfus
*91038	Esoph imped funct test > 1h
91117	Colon motility 6 hr study
*91132	Electrogastrography
*91133	Electrogastrography w/test
92081	Visual field examination(s)
92082	Visual field examination(s)
92132	Cmptr ophth dx img ant segmt
92133	Cmptr ophth img optic nerve
92134	Cptr ophth dx img post segmt
92504	Ear microscopy examination
92507	Speech/hearing therapy
92508	Speech/hearing therapy
92606	Non-speech device service
92607	Ex for speech device rx 1hr
92608	Ex for speech device rx addl
92609	Use of speech device service
93040	Rhythm ecg with report

TABLE 54—CPT CODES WITH ACCEPTED AMA RUC DIRECT PE RECOMMENDATIONS FOR CY 2011 CODES—Continued

CPT Code	Short descriptor
93041	Rhythm ecg tracing
93042	Rhythm ecg report
93224	Ecg monit/reprt up to 48 hrs
93225	Ecg monit/reprt up to 48 hrs
93226	Ecg monit/reprt up to 48 hrs
93227	Ecg monit/reprt up to 48 hrs
93228	Remote 30 day ecg rev/report
93270	Remote 30 day ecg rev/report
93271	Ecg/monitoring and analysis
93272	Ecg/review interpret only
93462	L hrt cath trnsptl puncture
93463	Drug admin & hemodynamic meas
93563	Inject congenital card cath
93564	Inject hrt congntl art/grft
93565	Inject l ventr/atrial angio
93652	Ablate heart dysrhythm focus
93922	Upr/l xtremity art 2 levels
93923	Upr/lxtr art stdy 3+ lvls
93924	Lwr xtr vasc stdy bilat
95800	Slp stdy unattended
95801	Slp stdy unatnd w/anal
95803	Actigraphy testing
95805	Multiple sleep latency test
95806	Sleep study unatt&resp efft
95807	Sleep study attended
95808	Polysomnography 1-3
95810	Polysomnography 4 or more
95811	Polysomnography w/cpap
95857	Cholinesterase challenge
95950	Ambulatory eeg monitoring
95953	Eeg monitoring/computer
96105	Assessment of aphasia
97598	Rmvl devital tis addl 20 cm<
99224	Subsequent observation care
99225	Subsequent observation care
99226	Subsequent observation care

*CPT codes discussed in more detail in section II.A.3.c. of this final rule with comment period.

Table 55: CPT Codes with Refined AMA RUC Direct PE Recommendations for CY 2011 Codes

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
11042	Deb subq tissue 20 sq cm/<	Sedate/apply anesthesia EQ137	2 min	0 min	Anesthesia is not used for this code.
11043	Deb musc/fascia 20 sq cm/<	EQ138	54 min	51 min	Instrument pack is allocated the total service period time less the time to clean the room (basic instrument pack).
11044	Deb bone 20 sq cm/<	EQ138	76 min	73 min	Instrument pack is allocated the total service period time less the time to clean the room (medium instrument pack).
22551	Neck spine fuse&remove addl	Other clin activity: coordination of care	91 min	88 min	Instrument pack is allocated the total service period time less the time to clean the room (medium instrument pack).
		Clean scope, L037D	15 min	0 min	The additional minutes of 15 pre-service minutes for coordination of care is redundant with description of other pre-service clinical labor times.
		kit, sinus surgery, balloon (maxillary, frontal or sphenoid)	10 min	30 min	The standard time to clean a flexible scope is 30 minutes.
		kit, sinus surgery, balloon (maxillary)	0.5 kit	Delete	See comments for kit, sinus surgery, balloon (maxillary) below.
31295	Sinus endo w/balloon dil	ES013	0.5 kit	1 kit	1 surgical kit is allocated rather than splitting two kits.
		new equipment, fiberscope, flexible, sinoscopy	31.5 min	Delete	The rigid endoscope time is not accepted by CMS. See comments for new equipment, fiberscope, flexible, bioscopy below.
31296	Sinus endo w/balloon dil	ES013	31.5 min	80 min	Scope allocated total service time less time to clean the room. CMS is accepting the new scope rather than splitting time between the rigid endoscope (see above) and the flexible fiberscope.
31297	Sinus endo w/balloon dil	ES013	73 min	70 min	Rigid endoscope allocated total service time less time to clean the room.
			71 min	68 min	Rigid endoscope allocated total service time less time to clean the room.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
31634	Bronch w/balloon occlusion	EQ211	85 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EF031	85 min	74 min	Table - Apply service period time less time to clean the scope, and monitoring patient post-op.
		EQ011	85 min	147 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	85 min	147 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ235	85 min	74 min	Suction machine - Apply service period time less time to clean the scope, and monitoring patient post-op.
		ER031	85 min	74 min	Fluoroscopic system - Apply service period time less time to clean the scope, and monitoring patient post-op.
		ES017	112 min	104 min	Fiberscope - Apply service period time less time to monitor the patient post-op.
		ES031	85 min	74 min	Video system, endoscopy - Apply service period time less time to clean the scope, and monitoring patient post-op.
		EF018	0 min	147 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		37220	Iliac revasc	EL011	90 min
EQ088	90 min			77 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
ER029	90 min			77 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EQ032	153 min	302 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	153 min	302 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	153 min	302 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EL011	120 min	107 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	120 min	107 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	120 min	107 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
37221	Iliac revasc w/stent	EQ032	183 min	332 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	183 min	332 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	183 min	332 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
37224	Fem/popl revas w/tia	EL011	110 min	97 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	110 min	97 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	110 min	97 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
37225	Fem/popl revas w/ather	EQ032	173 min	322 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	173 min	322 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	173 min	322 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EL011	148 min	135 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	148 min	135 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	148 min	135 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		EQ032	211 min	360 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	211 min	360 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	211 min	360 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		37226	Fem/popl revas w/stent	SD254	3
EL011	120 min			107 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
EQ088	120 min			107 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		ER029	120 min	107 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		EQ032	183 min	332 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	183 min	332 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	183 min	332 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SD254	3	1	Reduce quantity to reflect typical use.
		EL011	155 min	142 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	155 min	142 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	155 min	142 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
37227	Fem/popl revasc stnt & ather	EQ032	218 min	367 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	218 min	367 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	218 min	367 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
37228	Tib/per revasc w/tla	EL011	120 min	107 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EQ088	120 min	107 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	120 min	107 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		EQ032	183 min	332 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	183 min	332 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	183 min	332 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EL011	150 min	137 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	150 min	137 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	150 min	137 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
37229	Tib/per revasc w/ather	EQ032	213 min	362 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	213 min	362 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	213 min	362 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
37230	Tib/per revasc w/stent	SD266	2	1	Reduce quantity to reflect typical use.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
37231	Tib/per revasc stent & ather	EL011	150 min	137 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	150 min	137 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	150 min	137 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		EQ032	213 min	362 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	213 min	362 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ011	213 min	362 min	EKG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SD266	2	1	Reduce quantity to reflect typical use.
		EL011	165 min	152 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	165 min	152 min	Contrast media - Refined equipment time to reflect typical use exclusive to patient.
		ER029	165 min	152 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
EQ032	228 min	377 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.		
EF018	228 min	377 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.		

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EQ011	228 min	377 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
37234	Revsd opa/prq tib/pero stent	SD266	2	1	Reduce quantity to reflect typical use.
37235	Tib/per revasc stnt & ather	SD266	2	1	Reduce quantity to reflect typical use.
43754	Dx gastr intub w/asp spec	SM004	1	Delete	Biohazard bags are no longer recognized as direct inputs.
43755	Dx gastr intub w/asp specs	SM004	1	Delete	Biohazard bags are no longer recognized as direct inputs.
		EQ168	48 min	35 min	Exam light - Refined equipment time to reflect typical use exclusive to patient.
		EQ235	48 min	35 min	Suction machine - Refined equipment time to reflect typical use exclusive to patient.
		EQ269	48 min	35 min	Blood pressure monitor - Refined equipment time to reflect typical use exclusive to patient.
43756	Dx duod intub w/asp spec	EL014	48 min	35 min	Radiographic - Fluoroscopic room - Refined equipment time to reflect typical use exclusive to patient.
		EP030	48 min	35 min	pH conductivity meter - Refined equipment time to reflect typical use exclusive to patient.
		EF024	48 min	35 min	Fluoroscopy table - Refined equipment time to reflect typical use exclusive to patient.
		EF027	48 min	35 min	Table for equipment - Refined equipment time to reflect typical use exclusive to patient.
		SM004	1	Delete	Biohazard bags are no longer recognized as direct inputs.
43757	Dx duod intub w/asp specs	EQ168	65 min	52 min	Exam light - Refined equipment time to reflect typical use exclusive to patient.
		EQ235	65 min	52 min	Suction machine - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EQ269	65 min	52 min	Blood pressure monitor - Refined equipment time to reflect typical use exclusive to patient.
		EL014	65 min	52 min	Radiographic - Fluoroscopic room - Refined equipment time to reflect typical use exclusive to patient.
		EP030	65 min	52 min	pH conductivity meter - Refined equipment time to reflect typical use exclusive to patient.
		EF024	65 min	52 min	Fluoroscopy table - Refined equipment time to reflect typical use exclusive to patient.
		EF027	65 min	52 min	Table for equipment - Refined equipment time to reflect typical use exclusive to patient.
		SM004	1	Delete	Biohazard bags are no longer recognized as direct inputs.
		Film jacket	1	Delete	Film jackets are not disposable/consumable supplies.
		EF031	0 min	71 min	RUC recommendation missing table for procedure. Power table - Refined equipment time to reflect typical use exclusive to patient.
		EF015	136 min	71 min	Mayo stand - Refined equipment time to reflect typical use exclusive to patient.
		EQ168	136 min	71 min	Exam light - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	136 min	282 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		New Code	136 min	71 min	Appropriate equipment item already in database: EQ250 (portable ultrasound machine); Refined equipment time to reflect typical use exclusive to patient. Refined equipment time to reflect typical use exclusive to patient.
		EL014	76 min	71 min	Radiographic - Fluoroscopic room - Refined equipment time to reflect typical use exclusive to patient.
49418	Insert tun ip cath perc				

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		ER029	55 min	2 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		ED024	55 min	2 min	Film processor - Refined equipment time to reflect typical use exclusive to patient
		ED032	9 min	2 min	Laser printer - Refined equipment time to reflect typical use exclusive to patient.
		EF018	0 min	282 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	0 min	282 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
53860	Transurethral rf treatment	Renessa Generator and accessories (new equipment)	\$10,330	\$9,995	Generator only (the generator itself includes accessories).
		New equipment - T&P Applicator Set	80 min	77 min	Allocated total service period less time to clean the room.
		EQ137	80 min	77 min	Surgical instrument pack - Allocated total service period less time to clean the room.
57155	Insert uteri tandems/ovoids	EQ011	70 min	122 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	70 min	122 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EF018	70 min	122 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
57156	Ins vag brachytx device	New equipment - Vaginal Applicator Kit	53 min	50 min	Allocated total service period less time to clean the room.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
64415	Nblock inj brachial plexus	EQ184	8 min	36 min	Nerve stimulator should be allocated total service period time.
64445	Nblock inj sciatic sng	EQ184	8 min	37 min	Nerve stimulator should be allocated total service period time.
64447	Nblock inj fem single	EQ184	8 min	36 min	Nerve stimulator should be allocated total service period time.
		Greet patient	5 min	3 min	Standard time is 3 minutes.
		RT to prep IV	2 min	0 min	Redundant time (time is already allocated to RN).
		EF018	40 min	43 min	Stretcher is allocated total service period less time to clean the room.
64479	Inj foramen epidural c/t	EL014	27 min	22 min	Radiographic - Fluoroscopic room - Refined equipment time to reflect typical use exclusive to patient.
		ER067	27 min	22 min	X-ray view box - Refined equipment time to reflect typical use exclusive to patient.
		ED031	27 min	2 min	Printer, dye sublimation - Refined equipment time to reflect typical use exclusive to patient.
		Greet patient	5 min	3 min	Standard time is 3 minutes.
		RT to prep IV	2 min	0 min	Redundant time (time is already allocated to RN).
		EF018	40 min	43 min	Stretcher is allocated total service period less time to clean the room.
64483	Inj foramen epidural l/s	EL014	27 min	22 min	Radiographic - Fluoroscopic room - Refined equipment time to reflect typical use exclusive to patient.
		ER067	27 min	22 min	X-ray view box - Refined equipment time to reflect typical use exclusive to patient.
		ED031	27 min	2 min	Printer, dye sublimation - Refined equipment time to reflect typical use exclusive to patient.
65779	Cover eye w/membrane stent	EQ137	28 min	46 min	Instrument pack is allocated the total service period time less the time to clean the room.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
66174	Translum dil eye canal	EQ183	24 min	39 min	Operating microscope is allocated total service period less time to clean the instrument pack.
66175	Translum dil eye canal w/stnt	EL005	72 min	180 min	Exam lane should be allocated total office visit time.
69801	Incise inner ear	EL005	72 min	180 min	Exam lane should be allocated total office visit time.
74176	Ct abd & pelvis w/o contrast	EQ138	64 min	61 min	Instrument pack is allocated the total service period time less the time to clean the room.
		EL007	32 min	27 min	CT room - Refined equipment time to reflect typical use exclusive to patient.
		ER029	32 min	27 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		ED032	32 min	8 min	Laser printer - Refined equipment time to reflect typical use exclusive to patient.
74177	Ct abdomen & pelvis w/contrast	EL007	48 min	42 min	CT room - Refined equipment time to reflect typical use exclusive to patient.
		ER029	48 min	42 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		ED032	48 min	10 min	Laser printer - Refined equipment time to reflect typical use exclusive to patient.
74178	Ct abd & pelv 1+ section/regns	EL007	68 min	57 min	CT room - Refined equipment time to reflect typical use exclusive to patient.
		ER029	68 min	57 min	Film alternator - Refined equipment time to reflect typical use exclusive to patient.
		ED032	68 min	20 min	Laser printer - Refined equipment time to reflect typical use exclusive to patient.
76881	Us xtr non-vasc complete	Processor chemicals	1	Delete	Processor chemicals are not a valid supply input.
		Film jacket	1	Delete	Film jackets are not disposable/consumable supplies.
76882	Us xtr non-vasc limtd	New Code	16 min	16 min	Appropriate equipment item already in database: EQ250 (portable ultrasound machine).

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
91010	Esophagus motility study	EF014	63 min	56 min	Surgical light allocated total service period less time to clean manometry equipment.
		New equipment, Manometry accessory cable	50 min	60 min	Manometry cable allocated total service period less time to clean the room.
		New equipment, Manometry system	50 min	60 min	Manometry system allocated total service period less time to clean the room.
		EF015	63 min	56 min	Mayo stand allocated total service time less time to clean the manometry equipment.
*91065	Breath hydrogen test	EF023	63 min	56 min	Exam table allocated total service time less time to clean the manometry equipment
		New equipment, BreathTrackerDigital SC Instrument stand, drying tube	3 separate pieces	Summed equipment	Equipment inputs summed into one line-item since these items are only used together
92227	Remote dx retinal imaging	EL005	0 min	53 min	used 53 minutes as the total time for all equipment items consistent with our general policy for establishing equipment times
92228	Remote retinal imaging mgmt	EL005	0 min	12 min	Ophthalmology exam lane typical for the procedure.
92285	Eye photography	New equipment - Printer, color, photographic	10 min	10 min	Ophthalmology exam lane typical for the procedure.
93229	Remote 30 day ecg tech supp	The AMA RUC recommended that the current inputs for this service be maintained. We address, in detail, our refinements of previous AMA RUC-recommended direct PE inputs associated with this code in section III.J. of this final rule with comment period.			
93268	Ecg record/review	The AMA RUC recommended that the current inputs for this service be maintained. We address, in detail, the direct PE inputs associated with this code in section II.A.3.b.(2) of this final rule with comment period.			
93451	Right heart cath	SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	82 min	44 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
93452	Left hrt cath w/ventriclgrphy	EQ088	82 min	44 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	82 min	152 min	ECC used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	82 min	152 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	82 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	82 min	44 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	82 min	152 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	112 min	44 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	112 min	44 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	112 min	272 min	ECC used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	112 min	272 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	112 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
93453	R&L hrt cath w/ventriclgrphy	EL011	112 min	44 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	112 min	272 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	127 min	59 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	127 min	59 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	127 min	287 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	127 min	287 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	127 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	127 min	59 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	127 min	287 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
93454	Coronary artery angio s&i	SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	112 min	44 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	112 min	44 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
93455	Coronary art/grft, angio &i	EQ011	112 min	272 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	112 min	272 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	112 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	112 min	44 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	112 min	272 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	122 min	54 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	122 min	54 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	122 min	282 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	122 min	282 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	122 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	122 min	54 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
93456	Rhrt coronary artery angio	EF018	122 min	282 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs
		ED018	122 min	54 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	122 min	54 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	122 min	282 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	122 min	282 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	122 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	122 min	54 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	122 min	282 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
93457	Rhrt art/grft angio	ED018	132 min	64 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	132 min	64 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EQ011	132 min	292 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	132 min	292 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	132 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	132 min	64 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	132 min	292 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
93458	Lhrt artery/ventricle angio	SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	127 min	59 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	127 min	59 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	127 min	287 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	127 min	287 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	127 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	127 min	59 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EF018	127 min	287 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	132 min	64 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	132 min	64 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	132 min	292 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
93459	Lhrt art/grft angio	EQ032	132 min	292 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	132 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	132 min	64 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	132 min	292 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
93460	R&l hrt art/ventricle angio	SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	132 min	64 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	132 min	64 min	Contrast media warmer -- Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EQ011	132 min	292 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	132 min	292 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	132 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	132 min	64 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.
		EF018	132 min	292 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
93461	R&I hrt art/ventricle angio	SM004	2	Delete	Biohazard bags are no longer recognized as direct inputs.
		ED018	147 min	69 min	Computer workstation, cath monitoring - Refined equipment time to reflect typical use exclusive to patient.
		EQ088	147 min	69 min	Contrast media warmer - Refined equipment time to reflect typical use exclusive to patient.
		EQ011	147 min	307 min	ECG used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	147 min	307 min	IV pump used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ211	147 min	Delete	Pulse oximeters are no longer standard equipment for conscious sedation.
		EL011	147 min	69 min	Angiography room - Refined equipment time to reflect typical use exclusive to patient.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
93464	Exercise w/hemodynamic meas	EF018	147 min	307 min	Stretcher used in conscious sedation - Time includes administering anesthesia, procedure time, and monitoring patient.
93566	Inject r ventr/atrial angio	EL011	29 min	26 min	This is an add-on code and the cleaning time for the angiography room is accounted for in the base code.
		Prepare equipment	3 min	0 min	This is an add-on code and the time to prepare equipment is accounted for in the base code.
		Clean imaging equipment	3 min	0 min	This is an add-on code and the time to clean imaging equipment is accounted for in the base code.
		ED018	23 min	17 min	Computer workstation - This is an add-on code and the time to clean and prepare equipment is in the base code.
		EQ088	20 min	15 min	Contrast media warmer - This is an add-on code and the time to clean and prepare equipment is in the base code.
		EQ011	20 min	15 min	ECG - This is an add-on code and the only time allocated to the equipment is the procedure time.
		EQ032	20 min	15 min	IV Pump - This is an add-on code and the only time allocated to the equipment is the procedure time.
93567	Inject suprv/iv aortography	EL011	23 min	15 min	Angiography room - This is an add-on code and the only time allocated to the equipment is the procedure time.
		EF018	0 min	15 min	The stretcher is a standard piece of equipment used in conscious sedation. This is an add-on code and the only time allocated to the equipment is the procedure time.
		Prepare equipment	3 min	0 min	This is an add-on code and the time to prepare equipment is accounted for in the base code.
		Clean imaging equipment	3 min	0 min	This is an add-on code and the time to clean imaging equipment is accounted for in the base code.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
93568	Inject pulm art hrt cath	ED018	18 min	12 min	Computer workstation - This is an add-on code and the time to clean and prepare equipment is in the base code.
		EQ088	15 min	10 min	Contrast media warmer - This is an add-on code and the time to clean and prepare equipment is in the base code.
		EQ011	15 min	10 min	ECG - This is an add-on code and the only time allocated to the equipment is the procedure time.
		EQ032	15 min	10 min	IV Pump - This is an add-on code and the only time allocated to the equipment is the procedure time.
		EL011	18 min	10 min	Angiography room - This is an add-on code and the only time allocated to the equipment is the procedure time.
		EF018	0 min	10 min	The stretcher is a standard piece of equipment used in conscious sedation. This is an add-on code and the only time allocated to the equipment is the procedure time.
		Prepare equipment	3 min	0 min	This is an add-on code and the time to prepare equipment is accounted for in the base code.
		Clean imaging equipment	3 min	0 min	This is an add-on code and the time to clean imaging equipment is accounted for in the base code.
		ED018	23 min	17 min	Computer workstation - This is an add-on code and the time to clean and prepare equipment is in the base code.
		EQ088	20 min	15 min	Contrast media warmer - This is an add-on code and the time to clean and prepare equipment is in the base code.
		EQ011	20 min	15 min	ECG - This is an add-on code and the only time allocated to the equipment is the procedure time.
		EQ032	20 min	15 min	IV Pump - This is an add-on code and the only time allocated to the equipment is the procedure time.

CPT Code	Short Descriptor	CMS Code/Description	AMA RUC Recommendation	CMS Refinement	Comment
		EL011	23 min	15 min	Angiography room - This is an add-on code and the only time allocated to the equipment is the procedure time.
		EF018	0 min	15 min	The stretcher is a standard piece of equipment used in conscious sedation. This is an add-on code and the only time allocated to the equipment is the procedure time.
95956	Eeg monitor technol attended	EF009	52 min	Delete	Medical recliner is redundant to other equipment package.
		EQ017	771 min	772 min	ECG should be allocated total service period time.
96446	Chemotx admn prtl cavity	EF002	101 min	104 min	Hospital bed allocated total service time less time to mix chemotherapy.
		EQ032	101 min	104 min	IV pump allocated total service time less time to mix chemotherapy.
97597	Rmvl devital tis 20 cm/<	EL005	47 min	44 min	Instrument pack is allocated the total service period time less the time to clean the room.

* CPT codes discussed in more detail in section II.A.3.c. of this final rule with comment period.

3. Establishment of Interim Final Malpractice RVUs for CY 2011

According to our final policy as discussed in section II.B.2. of this CY 2011 final rule with comment period, we have assigned malpractice RVUs for CY 2011 new and revised codes by a crosswalk to a similar source code. We have reviewed the malpractice source code AMA RUC recommendations for 224 CY 2011 new and revised codes and we are accepting them all for CY 2011. According to our policy, we have adjusted the malpractice RVUs of the CY 2011 new/revised codes for differences in work RVUs (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source code and the new/revised code to reflect the specific risk-of-service for the new/revised code. The source code crosswalks for the CY 2011 new/revised codes are subject to public comment on this CY 2011 final rule with comment period, as well as the CY 2011 malpractice RVUs of the new/revised codes that are listed in Addendum C to this final rule with comment period.

Table 8 lists the CY 2011 new/revised codes and their respective source codes for determining the interim final CY 2011 malpractice RVUs. We are also posting the crosswalk on the CMS Web site under the downloads for the CY 2011 PFS final rule with comment period at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

VI. Provisions of the Affordable Care Act

The following section addresses certain provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) enacted on March 30, 2010 (collectively known as the Affordable Care Act (ACA)).

A. Section 3002: Improvements to the Physician Quality Reporting System

Section 3002 of the ACA makes a number of changes to the Physician Quality Reporting System (previously referred to as the Physician Quality Reporting Initiative, or PQRI), including authorizing incentive payments through 2014, and requiring a payment adjustment beginning in 2015, for eligible professionals who do not satisfactorily submit quality data. For a more detailed discussion of the provisions of section 3002 of the ACA, please refer to section VII.F.1. of this final rule with comment period.

B. Section 3003: Improvements to the Physician Feedback Program and Section 3007: Value-Based Payment Modifier Under the Physician Fee Schedule

1. Background

As required under section 1848 (n) of the Act, as added by section 131(c) of MIPPA, we established and implemented by January 1, 2009, the Physician Resource Use Measurement & Reporting (RUR) Program (now referred to as the Physician Feedback Program) for purposes of providing confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. Section 1848(n) of the Act also authorizes us to include information on the quality of care furnished to Medicare beneficiaries by a physician or group of physicians.

We are continuing a phased implementation of the Physician Feedback Program. Phase I was discussed in the CY 2010 proposed and final rules (74 FR 33589, and 74 FR 61844, respectively), and has been completed. Phase I consisted of several activities including extensive data analysis to inform decisions about topics such as measures, attribution, and risk adjustment and formative testing of report design with practicing physicians. We concluded Phase I by sending to individual practicing physicians in 12 geographic areas⁴ several hundred reports that contained per capita and episode-based cost information.

Phase I of the Physician Feedback Program focused on providing confidential feedback on resource use measures. Section 1848 (n)(1)(A)(iii) of the Act states that the Secretary may also include information on the quality of care furnished to Medicare beneficiaries by physicians (or groups of physicians) in the feedback reports. We believe that providing physicians with feedback on both quality and cost is consistent with the direction of other CMS value-based purchasing (VBP) initiatives. As a result, we decided to include quality measures in Phase II of the Physician Feedback Program and, in particular, we considered measures used in the Physician Quality Reporting System (previously referred to as the Physician Quality Reporting Initiative (PQRI)) and claims-based measures such as the measures used in the Generating Medicare Physician Quality

Performance Measurement Results (GEM) project (74 FR 61846).

Section 1848 (n)(1)(A)(ii) of the Act also states that the Secretary may provide reports at the physician group level. Accordingly, as part of Phase II of the Physician Feedback Program, we will also include reporting to group practices, defined as more than one physician practicing medicine together (74 FR 61846). In addition, we noted that the definition applies to the following types of physician groups: (1) Formally established single or multi-specialty group practices; (2) physicians practicing in defined geographic regions; and (3) physicians practicing within facilities or larger systems of care (74 FR 61846). As we continue with Phase II, we plan to report to both physician group practices and their affiliated practitioners, recognizing that many physicians practice in arrangements other than solo practices. We believe that using both group and individual level reporting will also allow us to gain experience with the sample size issues that arise when individual physicians have too few Medicare beneficiaries with specific conditions to generate reliable information. (See the CY 2010 final rule with comment period (74 FR 61844) for a detailed discussion of plans for Phase II.)

2. Effect of the ACA of 2010 on the Program

The ACA contains two provisions relevant to the Physician Feedback Program. Section 3003 of the ACA continues the confidential feedback program and requires the Secretary, beginning in 2012, to provide reports that compare patterns of resource use of individual physicians to other physicians. In addition, section 3007 of the ACA requires the Secretary to apply a separate, budget-neutral payment modifier to the Fee-For-Service PFS payment formula. The value-based payment modifier, which will be phased in beginning January 1, 2015 through January 1, 2017, will provide for differential payment under the fee schedule to a physician or groups of physicians, and later, possibly to other eligible professionals, based upon the relative quality and cost of care of their Medicare beneficiaries. Accordingly, our goal is to have Medicare physicians receive a confidential feedback report prior to implementation of the value-based payment modifier. We view these two provisions as complementary, as we expect the work done for the Physician Feedback Program under section 3003 of the ACA will inform our implementation of the value-based

⁴The 12 geographic areas are: Boston, MA, Syracuse, NY, Northern New Jersey, Greenville, SC, Miami, FL, Little Rock, AR, Indianapolis, IN, Cleveland, OH, Lansing, MI, Phoenix, AZ, Seattle, WA, and Orange County, CA.

payment modifier under section 3007 of the ACA. The approach used for performance assessment in the confidential feedback reports will serve as the foundation for implementing the value-based payment modifier.

Specifically, throughout future phases of reports under the Physician Feedback Program, we will continue to enhance our measures and methods and improve the content of the reports based on both our research and the feedback of stakeholders before the value-based payment modifier begins to affect physician payments in 2015.

We plan to engage in a large-scale effort to garner widespread stakeholder involvement with regard to how we continue to build and expand the confidential feedback program and transition to implementation of the value-based payment modifier. We recognize that such a payment modifier may have an impact on the delivery of care to Medicare beneficiaries. Reports that will be produced in the future based on changes as a result of section 3003 of the ACA will contain both cost and quality data, and work done to improve these reports with regard to fair and actionable measures in each of these domains will aid our decision making in how to apply the value-based payment modifier. We intend to seek stakeholder input on various aspects of program design, including cost and quality measures, methodologies for composing measures, and feedback report content and delivery. Such feedback may be gathered through rulemaking, open door forums, or other mechanisms. Below we summarize the public comments received on the changes we proposed to make to Phase II of the Physician Feedback Program.

3. Summary of Comments and Phase II Proposed Changes

a. Episode Groupers

We intend that reports in Phase II of the Physician Feedback Program will be distributed in the fall of 2010. However, we proposed several changes to the program parameters for Phase II that were finalized in prior rules (75 FR 40114). First, we proposed to discontinue our use of commercially-available proprietary episode grouping software given limitations we noted in proprietary episode grouping software we used in previous phases of the program. In addition, we noted that section 3003 of the ACA requires that the Secretary develop a Medicare-specific episode grouper by January 1, 2012, and make the details of the episode grouper available to the public. It is our intent that the Medicare-

specific episode grouper will address the limitations we found in the proprietary software.

We recognize that, because of its disease/condition-specific focus, episode-based cost information can be more meaningful and actionable for physicians than per capita information. We plan to provide such information in feedback reports after public grouper software is developed. Prior to that, we may consider other potential interim options for episode grouping to provide such information. As we indicated, we believe that our use of proprietary episode grouping software in the previous phases of the program had certain limitations (75 FR 40114). These software products were not intended for use with Medicare claims data, and we discovered several problems with the data outputs. Specifically, the groupers do not work well to create episodes for beneficiaries with multiple chronic conditions, which is a significant portion of Medicare beneficiaries.

For example, when a beneficiary with a chronic disease is hospitalized for an acute condition, that beneficiary most likely also receives treatments unrelated to the condition for which he or she is hospitalized, but related to the chronic disease. The groupers, which are proprietary and often referred to as "black boxes," do not enable users to understand the coding to determine how to accommodate these issues. Therefore, we had to make several decisions about how to pre-process the claims data so that the groupers could recognize and attempt to deal with these issues in the clinical grouping logic. After report production in Phase I, we discovered several problems with the pre-processing, which resulted in inaccurate episode cost information being disseminated.

Until a Medicare-specific episode grouping software is developed, we plan to produce reports for Phase II that contain annualized per capita cost information. More specifically, instead of episode-specific cost information, we plan to provide all patient per capita cost information, as well as per capita cost information for those beneficiaries with five common chronic diseases: (1) Diabetes; (2) congestive heart failure; (3) coronary artery disease; (4) chronic obstructive pulmonary disease; and (5) prostate cancer. This information will not be limited to the cost of treating the disease itself, but will provide total Part A/B per capita cost information, as well as service category breakdowns, for the care received by the subset of attributed beneficiaries with that disease.

Comment: Many commenters were supportive of CMS' decision to

discontinue using the proprietary episode grouper software in Phase II and instead to develop a Medicare-specific grouper available to the public. Several of these commenters discussed the specific limitations of proprietary groupers and also the importance of developing and utilizing a Medicare-specific episode grouper available to the public. Many commenters urged CMS to include extensive testing and stakeholder input while developing the Medicare-specific grouper. These commenters asserted that it was important that the process to develop a Medicare-specific grouper be available to the public, as well as the methodology such a grouper will employ, remain transparent, and open for public review and recommendation. A few commenters expressed concern about CMS' ability to create a fair and accurate Medicare-specific episode grouper in the timeline allotted for its implementation. One commenter specifically requested that CMS, to the extent possible, express concern about the timeline enacted by Congress. Another commenter opposed dropping the episode grouper in Phase II and requested that CMS use this time to test and explore different episode grouping methodologies.

Response: We appreciate these comments in support of our proposal to discontinue our use of commercially-available proprietary episode grouping software due to concerns over their suitability for use with Medicare claims and the pending development of a Medicare-specific episode grouper. Our research has documented that the currently available episode groupers, as they are now configured, present significant challenges to their use with our highly complex patient population. Therefore, we believe it is appropriate to discontinue use of the commercially available episode groupers for the Phase II reports and until a Medicare-specific episode grouper is available. We acknowledge the suggestion, however, that CMS test and explore different episode grouping methodologies. We are bound by statute to make the details of the developed Medicare-specific episode grouper available to the public and intend to do so. We also intend to involve the stakeholder community and to receive their input during the testing stage. We acknowledge that there are many challenges involved in deciding on the methodologies to utilize in developing the episode grouper. We also acknowledge that the statutory required timeframe for development of the grouper is one of those challenges. We believe that the episode grouper is

a useful element in appropriately providing effective and actionable cost measures for physician feedback. We intend to research and test many different methodologies in order to create a fair and appropriate episode grouper for the Medicare population and will incorporate episode-based cost measures into the physician feedback reports as early as possible.

After considering all of the public comments received regarding this issue and for the reasons we explained above, we are finalizing our proposal to discontinue use of the commercially-available proprietary episode grouping software for Phase II reports.

b. Quality Measures

We proposed to exclude data from the Physician Quality Reporting System in the Physician Feedback Program reports even though commenters have been generally supportive of including Physician Quality Reporting System measures in the reports (75 FR 40114).

The first year of the Physician Quality Reporting System was 2007, participation was still quite low, and the first round of Physician Quality Reporting feedback reports contained errors that necessitated correction. To date, work by CMS' Physician Feedback Program support contractor has been based upon claims data from 2007. Because of the low number of physicians reporting under the Physician Quality Reporting System in 2007, and because providers have the flexibility to choose which measures to report under the Physician Quality Reporting System, we believe the resulting small numbers of physicians reporting an individual measure would greatly limit meaningful peer comparisons, and thus the number of providers who would receive a feedback report. Therefore for Phase II, we proposed to use the claims-based measures developed by CMS in the GEM project (75 FR 40115).⁵ This is a core set of 12 process quality measures developed by HEDIS that can be calculated using only administrative claims data. Several chronic conditions that are prevalent in the Medicare population are captured by this set of measures. However, in future phases of the program, we intend to explore the possibility of linking the Physician Feedback Program to the Electronic Health Record (EHR) incentive program for meaningful use of EHR technology (as added by the Health Information Technology for Economic and Clinical Health Act (Title IV of Division B of the Recovery Act, together with Title XIII of

Division A of the Recovery Act) (HITECH)), and the group practice reporting option (GPRO) in the Physician Quality Reporting System. Both of these programs offer measures and measure sets, as well as methods of reporting data which would be conducive to meaningful peer comparisons among physicians.

Comment: Several commenters agreed with our proposal to not use Physician Quality Reporting System measures during Phase II. These commenters argued that the Physician Quality Reporting System measures are voluntarily reported, some reports have contained errors, and therefore, these data are inadequate for assessing quality for many providers. Several commenters voiced concerns and/or disagreement with using GEM measures as an alternative to the Physician Quality Reporting System measures. These commenters claimed that the GEM measures are too focused on primary care and prevention, are limited in scope (for example, do not contain any measures for prostate cancer, and breast and colorectal cancer measures are only related to screening), and have few, if any, measures pertaining to some specialties. Some commenters advocated for the future use of Physician Quality Reporting System measures claiming that more eligible professionals are participating in the program now. Several commenters agreed with CMS' decision to explore linking the Physician Feedback Program with the EHR incentive program.

Response: We appreciate these comments and we understand the commenters' concern that the 12 core GEM measures may not fully measure the broad scope of care delivered to Medicare beneficiaries. However, the GEM measures serve as an initial core measure set, upon which a larger set can be built for purposes of including in future reports. We also believe that the GEM measures will yield sufficient information to allow peer group comparisons. In contrast, the Physician Quality Reporting System data available to us for the Phase II reports were very limited and would not provide sufficient data for the minimum case size and number of peers needed to report data for many physicians. We plan to take into account the limitations commenters raised as we explore our options for choosing and developing measures for subsequent phases of the Physician Feedback Program and the development of the value-based payment modifier. As part of this process, we fully intend to explore the possibility of linking this program to the EHR incentive program for meaningful

use of electronic health records, and the GPRO option in the Physician Quality Reporting System. We recognize the need to develop a comprehensive measure set that will fairly measure both quality and resource use. We intend to work with the stakeholder community to create a fair, reasonable, and actionable set of measures that we expect to publish not later than January 1, 2012 for future use in determining the value-based payment modifier.

After considering all of the comments we received and for the reasons discussed above, we are finalizing our proposal to not include Physician Quality Reporting System data in the Phase II reports.

c. Report Distribution

We proposed to distribute reports electronically in Phase II, by leveraging the infrastructure used to distribute Physician Quality Reporting System feedback reports (75 FR 40155). We believe this infrastructure will enable groups to utilize an electronic portal to download their Phase II reports. Individual practitioners will be able to contact their MACs/fiscal intermediaries to receive an e-mailed copy of their reports. We have received feedback from physicians that the reports distributed in Phase I were too long and cumbersome to manage in hard copy. We proposed consolidating the report and disseminating it electronically for easier navigation. Below we summarize our responses to public comments we received regarding this proposal.

Comment: Most commenters generally expressed support for our proposal to distribute reports electronically in Phase II utilizing the existing infrastructure that is used to distribute Physician Quality Reporting System feedback reports. One commenter in particular, noted that the Physician Quality Reporting System portal was cumbersome and that security issues created access problems. Many commenters stressed that the reports need to be easy to navigate and need to be easily understood.

Response: We agree that electronic delivery is a desirable means of distribution for these reports and are continuing to evaluate and develop methods to make future reports easily accessible, user friendly and informative. We appreciate all of the feedback from commenters regarding this proposal. While we acknowledge that users have expressed difficulty in using the Physician Quality Reporting System portal, it was the best option for electronic dissemination of the Phase II reports. In the future we will consider all of the potential options available to

⁵ <http://www.cms.gov/GEM>.

us and will take these suggestions into account when developing future means of report distribution. After taking into consideration the comments summarized above, we are finalizing our proposal to distribute Phase II reports electronically utilizing the existing infrastructure used to distribute Physician Quality Reporting System feedback reports. In the future, as we disseminate increasing numbers of reports, we will provide information regarding how individuals and groups can access their reports through sub-regulatory guidance and other means of notification.

4. Implementation of Sections 3003 and 3007 of the ACA

Sections 3003 and 3007 of the ACA contain several important implementation dates. In addition to developing an episode grouper by January 1, 2012, we are required by the same date to publish the cost and quality measures we intend to use for purposes of the value-based payment modifier. The payment modifier will become effective for certain physicians and groups of physicians on January 1, 2015, with a phased implementation so that all physicians paid under the PFS will be subject to the value-based payment modifier by January 1, 2017. On or after January 1, 2017, we have the authority to also apply the payment modifier to other eligible professionals. Through the rulemaking process in 2013, we will begin implementing the program parameters for the value-based payment modifier.

In anticipation of implementing sections 3003 and 3007 of the ACA, we intend to perform extensive data analysis and research, and to seek stakeholder input on issues related to cost and quality measures so that we can be prepared to publish, by January 1, 2012, measures we intend to use for purposes of the value-based payment modifier. We intend for the work done in establishing cost and quality measures for purposes of the payment modifier to inform the continued dissemination of confidential feedback reports to both individual physicians and physician groups. Specifically, the measures chosen for purposes of the value-based payment modifier will be included in future phases of the confidential feedback reports.

As noted previously, Phase I included reports to several hundred physicians. In Phase II, during Fall 2010, we anticipate disseminating reports to about 40 large physician groups and the approximately 2,000 physicians affiliated with those groups. We anticipate future phases of the reports to

include additional dissemination to increasing numbers of practitioners and groups such that virtually every applicable Medicare practitioner receives a report prior to implementation of the value-based payment modifier.

5. Summary of Comments Sought on Specific Statistical Issues Related to the ACA Sections 3003 and 3007

We recognize that there are many important decisions to be made when implementing a program that compares physicians to their peers, especially when such information can lead to differential payment. Since the inception of the Physician Feedback program, all data have been price standardized which includes accounting for geographic adjustments. We have identified important statistical issues in previous rules, and as we have done in previous rules, we sought input on several of these topics as they relate to future phases of reports. These include, but are not limited to: risk adjustment; attribution; benchmarking; peer groups; minimum case sizes; cost and quality measures; and compositing methods. Specific parameters of the Physician Feedback Program are based on the most current information we have available to us. These parameters will continue to evolve and we will continue to evaluate them as the state of the art in these areas continues to improve. Therefore, in the proposed rule, we solicited public comment on the following statistical and methodological issues (75 FR 40115).

a. Risk Adjustment

The cost data used in Phase I were risk adjusted. For the per capita costs, we used CMS' Hierarchical Condition Categories (HCC) model developed for risk adjustment in Medicare Advantage plans. This model takes into account beneficiary characteristics such as age, sex, and Medicaid status, and then predicts costs for beneficiaries based on their unique mix of health conditions. Several other socioeconomic factors, such as the median income per capita in the county where the physician practices, were used. For the episode-based costs, we used the risk adjustment method built into the proprietary grouper software. Regression analyses indicated that these additional socioeconomic factors did little to improve the fit of the model.

The cost data in Phase II are risk adjusted using the HCC model, but excluding the additional socioeconomic factors such as the median income per capita in the county where the physician practices, that had been used

in Phase I. And since there are no episode-based costs in Phase II—only annual per capita costs—the HCC model will be the only method used. Other methods of risk adjustment, such as the CC (complications and co-morbidities) and MCC (major complications and co-morbidities) indicators implemented in the 2008 MS-DRG system, were considered but not employed.

The quality data included in Phase II will not be risk adjusted because the GEM measures are all clinical process measures, measure specifications provided detailed inclusion/exclusion criteria, and it is generally accepted that such measures need not be risk adjusted. Beneficiaries should receive the indicated preventive services (for example, breast cancer screening) regardless of their demographic characteristics or presence or absence of health conditions.

We solicited comment on the appropriate method for risk adjusting cost data, as well as our reasoning for not risk adjusting clinical process quality measures (75 FR 40115) and the comments we received are summarized below.

Comment: There were a number of comments regarding the need to risk adjust for socioeconomic and cultural differences (including English proficiency, literacy, poverty, and family structure) and multiple co-morbidities in order to avoid creating a disincentive for physicians who treat disadvantaged or complex patient populations. If socioeconomic factors are not added to the HCC model, commenters suggested using an alternative method to account for these factors such as a stratified analysis and comparison among similar providers and/or similar patient groups. Similarly, some commenters suggested that patients with substance abuse and mental health co-morbidities should be stratified into a distinct cohort. Other commenters suggested that exclusions be allowed for patient non-adherence or for cases of terminal illness. While there was general agreement that process measures do not require risk adjustment, several of the commenters pointed out that socioeconomic factors can also impact process and claims-based measures and risk adjustment of these measures should be considered on a measure by measure basis. Commenters asserted that outcome measures should be risk adjusted and some suggested that CMS use publically available risk models developed by specialty societies. Some commenters suggested that CMS provide evidence of the utility and reliability of using HCC to risk adjust per capita measures.

Several commenters suggested that CMS test multiple methodologies for risk adjustment and perform appropriate statistical analyses to determine variability among the different methodologies. Commenters emphasized the need to implement a methodology that would be transparent to the public and all stakeholders.

Response: We thank the commenters for their thoughtful input. In Phase II reports, we will employ the same method of risk adjustment for per capita cost measures as we use in our Medicare Advantage (MA) program, that is, the hierarchical condition category (HCC) model. We will continue to seek stakeholder input as we consider these comments and ways to improve our risk adjustment methodology.

b. Attribution

Deciding which physician(s) is/are responsible for the care of which beneficiaries is an important aspect of measurement. We must strike a balance between only attributing cost information to physicians for the services they personally delivered, and attributing costs to physicians based on a more encompassing view of the services provided to each beneficiary so as to encourage better care coordination and accountability for patient outcomes.

There are several methods that are generally used for attributing beneficiaries' costs to physicians for the purposes of measuring and comparing performance. In Phase I, we used two different attribution methodologies. Half of the reports used the multiple-proportional attribution, in which a beneficiary's costs were summed, and then divided among the physicians who treated that beneficiary in the same proportion as their share of evaluation and management (E&M) services provided. The other half of the reports used the plurality-minimum method, in which a beneficiary's entire cost (either for the episode or for the year) was attributed to the physician who performed the plurality of the E&M services, subject to a minimum percentage (in that case, 10 percent).

In Phase II reports, we plan to use the plurality-minimum method with a minimum percentage threshold of E&M services of 20 percent for individual physicians and a minimum percentage threshold of E&M services of 30 percent of the E&M services for physician group level reports (75 FR 40116). These minimum threshold determinations were based on our analysis of the claims data. We recognize that other attribution methods exist, which may be either more or less appropriate given the aspect of care one is measuring. For

example, it may be desirable to attribute the entire cost of a surgical episode to the performing surgeon. Another method for attributing costs is referred to as multiple-even, in which the entire beneficiary's cost is attributed to multiple physicians who treated the beneficiary.

We sought comment on the topic of attribution methodologies, including both of those we have already used in the program, as well as others. The comments we received are summarized below.

Comment: Many commenters voiced concern about the plurality minimum attribution method that CMS has planned to use in its Phase II feedback reports. A number of commenters asked that we ensure that the plurality minimum method does not penalize primary care doctors by holding them accountable for all the services beneficiaries receive, since they only deliver a subset of all of the care a beneficiary receives. Other commenters were concerned that if there were too many visits to a specialist, the specialist might get penalized. Many commenters were opposed to the plurality minimum model, not wanting to be held accountable for care they do not influence. Others expressed concern that costs could be attributed incorrectly and also that unintended changes in referral patterns might result, as physicians might be influenced by the cost of care without regard to quality. One commenter requested that CMS consider attribution options built on threshold concepts or specific agreement between a physician/medical group and patient on responsibility for management of a specific condition with the goal of focusing measurement and attribution assignment on those patients who are truly under the care of the physician or group for the condition. Another commenter asked CMS to ensure that the same patient is attributed for resource use and quality, and additionally to clarify if patients will be attributed to primary care and specialists. Generally, specialty physician associations supported the multiple-proportional attribution method, pointing out that there is shared accountability in delivering preventive and many other services. One commenter believed that the multiple-even method should be used, and in the case of surgical episodes, the entire cost should be attributed to the performing surgeon.

Other commenters believed that the plurality minimum method was acceptable, but strongly urged CMS to continually analyze whether this methodology results in fair and accurate

reports under different clinical scenarios, especially those where multiple co-morbidities are present. In addition, these commenters urged CMS to statistically examine the impact of changing the minimum thresholds. Several commenters recommended that CMS test multiple attribution models and evaluate the results. Another commenter recommended extensive chart reviews in order to ensure that the claims data supports the attribution model used. Several commenters pointed out that the choice of attribution method will not influence patient behavior and suggested incorporating patient accountability, including compliance. There were several comments about hospital costs being attributed to physicians that suggested alignment with other programs such as Hospital Value-Based Purchasing. One commenter suggested using multiple models and not a single model of attribution. One commenter noted that the problem of small numbers may make it difficult to fairly assess the costs at the individual level. Overall, commenters pointed out that the method(s) used should be accurate, transparent, and not disadvantage small or rural practices.

Response: We appreciate the input from commenters. We will continue to consider and evaluate how to apply attribution methods to physician feedback reports and seek stakeholder input. In Phase II reports, we plan to use the plurality-minimum method with a minimum percentage threshold of E&M services of 20 percent for individual physicians and a minimum percentage threshold of E&M services of 30 percent of the E&M services for physician group level reports.

c. Benchmarking and Peer Groups

Determining how to most relevantly compare physicians to a standard or to their peers is also an important policy aspect of the program. CMS' research conducted in Phase I of the program indicated that physicians prefer to be compared only to those physicians most like them (that is, the narrowest peer group). We recognize the importance of fair comparison, but are also faced with the challenge that very narrow peer groups, especially among specialist and subspecialists are most often not large enough to make statistically significant comparisons.

The individual-level reports in both phases of the program have contained, or will contain, two peer group comparisons: (1) Physicians in the same specialty in the same geographic area; and (2) physicians in the same specialty across all 12 geographic areas. In each

of these peer groups, a physician is shown where he or she falls on a distribution that specifically identified the 10th, 50th, and 90th percentiles. These benchmarks were finalized on an interim basis in the CY 2010 proposed rule (74 FR 33589).

In determining differences among providers for episode-based measures in Phase I, we used a minimum frequency test. For per capita measures in Phase I, a physician had to have a case size of 20 or more beneficiaries to be measured and compared. There was no minimum peer group size requirement.

The original MIPPA mandate requires us to make comparisons among physicians on cost, and gives the Secretary the authority to include comparisons on quality. The use of quality measures in the program was finalized in the CY 2010 final rule (74 FR 61846). In Phase II, comparisons with appropriate peer groups will be made for both measures of cost and quality. Phase II reports will be provided only to those physicians that have 30 or more patients for each of the cost measures. For the quality measures, we plan to use the measure specifications in the GEM project to define minimum case sizes, which are at least 11 beneficiaries. We also plan to impose a minimum peer group size of 30 in Phase II for each of the cost and quality measures. A minimum sample size of 30 is generally accepted in the research community as the minimum sample size to represent a group and make comparisons.

We solicited comment on the most appropriate and relevant peer groups for comparison, including the appropriate minimum case sizes and minimum peer group sizes. We were also interested in suggested methodologies that could be applied to small case sizes. The comments we received are summarized below.

Comment: Several commenters recommended that CMS establish separate benchmark measures for teaching medical facilities. These commenters argued that the proposed methodology should take into account the multiple missions of academic clinical facilities because their cases are often more complex. Other commenters recommended that CMS establish benchmarks that compared physicians to other physicians with similar practices and/or who perform similar procedures and additionally take into account sub-specialties and geography as peer groups will vary. These commenters suggested that CMS work with specialty groups and communities to develop the best comparisons. Other commenters noted that CMS needs to

account for issues such as the difference between a practicing surgeon and a surgeon who does little surgery but acts more as a manager of care. These commenters asserted that this type of differentiation can be identified through review of claims history and data accessible through specialty organizations. Several commenters recommended that hospitalists and hospital groups be benchmarked against other hospital-based physicians or groups, preferably in similar practice settings, for example, emergency departments. A number of commenters suggested that CMS use metrics such as measures of statistical precision, multiple metrics including mean, median, percentiles in defining parameters for peer groups rather than use arbitrary numbers for minimum sample size. One commenter recommended that a power analysis be conducted to identify an appropriate sample size to be used for benchmarking.

Response: We appreciate the feedback we received from commenters and will take these into consideration for the future. While we will continue to explore these issues, in Phase II reports, we will use the peer group and minimum case size of 30 as outlined above and in the proposed rule.

d. Cost and Quality Measures and Compositing Methods

As mentioned above, and in previous rules, section 1848(n)(1)(A)(ii) of the Act gives the Secretary the authority to include both cost and quality information in the feedback reports. In Phase I, we chose to use only cost information, and used both per capita and episode cost measurements. As mentioned above, we previously finalized the use of quality measures in Phase II (74 FR 61846), but finalized our proposal to discontinue our use of episode cost measurements. Accordingly, we have yet to include any composite measures of cost or quality in the feedback reports.

Section 3007 of the ACA requires us to establish a value-based payment modifier to pay physicians differentially based both on their quality of care and their costs of care using composites of both quality and cost measures. Accordingly, we will need to devise a methodology in the future for compositing cost measures and quality measures, including considering, among other things, possible methodologies to develop the value-based payment modifier. In the future, episode-based cost measures developed using the Medicare-specific episode grouper software also may be considered in

developing a composite of cost measures. Other domains of measures that may be considered include patient-level utilization statistics (for example, emergency department visits per 1,000 patients) and structural measures such as whether a provider has adopted an electronic health record. We recognized that measure composites are methodologically and operationally complex and, therefore, we sought early comments on this topic (75 FR 40116). The comments we received are summarized below.

Comment: Many commenters stressed the importance of measuring both quality and cost of care to ensure useful and meaningful comparisons of physician work. Several commenters asserted that focusing on cost measures alone was insufficient and urged CMS to include quality measures in the comparison to resource utilization feedback reports. These commenters asserted that composite measures of cost and quality provide the most meaningful context to capture and review resource utilization. Several comments focused on the challenge of measuring quality at the physician level and the importance that the measures be fair, meaningful and actionable, and accurately applied. Incorporation of standards and measures endorsed by the National Quality Forum (NQF) was also recommended as well as annual measure updates of quality measures. A number of commenters stressed the importance of maintaining the focus on quality and outcomes measurement. Types of quality measures suggested for inclusion in the reports included structure, patient safety, clinical processes of care, patient experience, care coordination and clinical outcomes, weighted toward clinical outcomes, care coordination, and patient experience. Several commenters remarked on the limitation of claims-based measures for quality and one recommended that outcomes measures be based on clinical rather than administrative data. One commenter stated that ICD-10 will enhance evaluation of physician performance and suggested evaluation of quality be delayed until ICD-10 is implemented. One commenter suggested a disease focus on peripheral vascular disease. Several commenters suggested that CMS work with specialty societies on using available registries of physician level data as a source of physician quality performance. Many commenters stated that quality should be weighted higher than cost, but agreed both need to be reported. Many commenters encouraged CMS to work expeditiously with

stakeholders to improve quality measures for inclusion in the value-based payment modifier. Some commenters acknowledged CMS' recognition that measure composites are methodologically and operationally complex and urged CMS to carefully test and evaluate different composite methodologies before implementing the value-based payment modifier. These commenters argued that the first step in creating a composite measure is to identify the individual components (for example, individual measures) that should go into the composite, and therefore CMS should ensure that a reliable Medicare-specific episode grouper is in place as it would be essential to this initial process. One commenter suggested any composite measures developed by CMS should be reviewed by the multi-stakeholder consultative partnership defined in section 3014 of the ACA prior to any adoption into the physician payment program.

Some commenters mentioned that the National Quality Forum and the American Medical Association's Physician Consortium for Performance Improvement (PCPI) had developed guidance on creating composite measures. These commenters argued that CMS needed to engage in more empirical work on creating composite measures before implementing a modifier for physician payment. These commenters expressed concern that an accurate value-based payment modifier based on resource use would be ready for 2015, given the substantial statistical and methodological hurdles that must be overcome in creating cost and quality composites and a single cost and quality index. They concluded by saying that CMS should continue to seek stakeholder comment throughout the composite measure development process. One commenter urged CMS to ensure that compliance with preventive health service measurements be taken into account when developing the composite measures.

Response: As required under the statute, we plan to identify the measures of resource use and quality that will comprise composites of cost and quality for the physician feedback reports and for the value-based payment modifier by January 1, 2012. We thank the commenters for their many thoughtful suggestions and recommendations on cost and quality measures and compositing methods. As we stated above, we solicited public comment to inform potential future policies on these issues, and the Physician Feedback Program in general. We thank the public for their thoughtful comments and

appreciate the feedback received from stakeholders. In addition, a number of societies and organizations volunteered support and also volunteered to share research findings that they believe is applicable to this program.

We fully expect to draw on the expertise of stakeholders as we continue to work on implementing the physician feedback program and implementation of the value-based payment modifier. Moreover, we plan to engage in open and continuing dialogue with stakeholders on both the Physician Feedback Program and value-based payment modifier.

In addition to the comments we solicited and received on specific methodological issues related to production of the feedback reports, we also received a number of general comments and suggestions regarding the development of reports to ensure access, utility, and relevance.

Comment: A number of commenters suggested that the reports be: Interactive, easy to understand, timely, actionable, inclusive of sufficient detail, inclusive of data on cost categories (for example, imaging use, prescriptions, hospitalizations, etc.) and impactful. Some commenters requested the capability to drill down on data, especially if a physician is shown to be a high cost outlier. One commenter requested that the physicians have the ability to review the reports and correct any data that they believe is inaccurate. Others reiterated that all methodologies and algorithms should be in the public domain along with clear plans for evaluating the viability and impact of the reports and reporting mechanisms. We received more than one suggestion for alignment with the HITECH payment incentive program and other programs, in order to alleviate reporting burden and variation. Another commenter supported the creation of group reports, but suggested CMS explore alternative ways to define and determine affiliation with a medical practice group rather than relying solely on tax identification numbers' (TINs). Many strongly encouraged CMS to engage public stakeholders intensely and specifically mentioned the importance of working with specialists, specialty societies, clinical experts, treatment guideline developers, and manufacturers on the issues that specifically pertain to their respective interests and expertise in creating measures, composite measures, and performance reporting. Finally, a commenter requested that the reports include graphical and numerical illustrations of data.

In addition, we received a number of comments on the value-based payment

modifier although we did not solicit specific comments or make proposals. Our summary of these comments follows:

Comment: A number of commenters supported the idea of a value-based payment modifier using the confidential feedback reports as the foundation and applauded CMS' intentions for a transparent process seeking stakeholder input on the methodology through rulemaking and other public forums. However, other commenters expressed caution in proceeding given the lack of experience with the quality and resource measures which are yet to be published, and the evolutionary nature of the methodology to develop quality and resource scores that will comprise the value-based payment modifier. Several commenters recommended that the value-based payment modifier program be delayed until CMS could demonstrate that it has in place reliable and accurate methodologies for implementation. Several of these commenters urged CMS to thoroughly test out multiple models and methodologies and discuss advantages and disadvantages with the multiple stakeholders.

Response: We appreciate the above input from stakeholders. We will continue to seek further stakeholder input and comment through future rulemaking and other venues, such as open door forums and listening sessions, as we continue to implement the Physician Feedback Program and develop the specifications to implement the value-based payment modifier.

C. Section 3102: Extension of the Work Geographic Index Floor and Revisions to the Practice Expense Geographic Adjustment Under the Medicare Physician Fee Schedule, and Protections for Frontier States as Amended by Section 10324

Section 1848(e)(1)(E) of the Act (as amended by section 3102(a) of the ACA) extended application of the 1.0 work GPCI floor for services furnished through December 31, 2010. In addition, section 1848(e)(1) of the Act (as amended by section 3102(b) of the ACA) specified that for CY 2010 and CY 2011, the employee wage and rent portions of the PE GPCI must reflect only one-half of the relative cost differences for each locality compared to the national average and includes a "hold harmless" provision for any PFS locality that would receive a reduction to its PE GPCI resulting from the limited recognition of cost differences. Section 1848(e)(1) of the Act (as amended by section 3102(b) of the ACA) also required an analysis of the current methods and data sources

used to determine the relative cost differences in office rent and employee wages compared to the national average and the cost share weights assigned to each PE GPCI component: employee wages, office rent, and supplies. Finally, section 1848(e)(1) of the Act (as amended by section 3102(b) of the ACA) required the Secretary to make appropriate adjustments to the PE GPCI by no later than January 1, 2012. In addition, section 1848(e)(1) of the Act (as amended by section 10324(c) of the ACA) established a 1.0 PE GPCI floor for services furnished in frontier states effective January 1, 2011. The provisions of the ACA related to the GPCIs are discussed in detail in section II.D. of this final rule with comment period.

D. Section 3103: Extension of Exceptions Process for Medicare Therapy Caps

Section 1833(g)(5) of the Act (as amended by section 3103 of the ACA) extended the exceptions process for spending limitations on therapy services in certain outpatient settings through December 31, 2010. Therapy caps are discussed in detail in section III.A. of this final rule with comment period.

E. Section 3104: Extension of Payment for Technical Component of Certain Physician Pathology Services

Section 542(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), as amended by section 732 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), section 104 of division B of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), section 104 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), and section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) was amended by section 3104 of the ACA to continue payment to independent laboratories for the TC of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital through CY 2010. The technical component (TC) of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist interprets. The professional component (PC) of physician pathology services refers to the pathologist's interpretation of the slide.

When the hospital pathologist furnishes the PC service for a hospital patient, the PC service is separately

billable by the pathologist. When an independent laboratory's pathologist furnishes the PC service, the PC service is usually billed with the TC service as a combined service.

Historically, any independent laboratory could bill the Medicare contractor under the PFS for the TC of physician pathology services for hospital patients even though the payment for the costs of furnishing the pathology service (but not its interpretation) was already included in the bundled inpatient stay payment to the hospital. In the CY 2000 PFS final rule with comment period (64 FR 59408 through 59409), we stated that this policy has contributed to the Medicare program paying twice for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) to the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service. While the policy also permits the independent laboratory to bill for the TC of physician pathology services for hospital outpatients, in this case, there generally would not be duplicate payment because we would expect the hospital to not also bill for the pathology service, which would be paid separately to the hospital only if the hospital were to specifically bill for it. We further indicated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to its inpatients.

Therefore, in the CY 2000 PFS final rule with comment period, we revised § 415.130(c) to state that for physician pathology services furnished on or after January 1, 2001 by an independent laboratory, payment is made only to the hospital for the TC furnished to a hospital inpatient. Ordinarily, the provisions in the PFS final rule with comment period are implemented in the following year. However, the change to § 415.130 was delayed 1 year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

Full implementation of § 415.130 was further delayed by section 542 of the BIPA and section 732 of the MMA, which directed us to continue payment to independent laboratories for the TC of physician pathology services for hospital patients for a 2-year period beginning on January 1, 2001 and for CYs 2005 and 2006, respectively. In the CY 2007 MPFS final rule with comment period (71 FR 69624 and 69788), we amended § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may

not bill the carrier for the TC of physician pathology services furnished to a hospital inpatient or outpatient. However, section 104 of the MIEA-TRHCA continued payment to independent laboratories for the TC of physician pathology services for hospital patients through CY 2007, and section 104 of the MMSEA further extended such payment through the first 6 months of CY 2008.

Section 136 of the MIPPA extended the payment through CY 2009. Most recently, section 3104 of the ACA amended the prior legislation to extend the payment through CY 2010.

Consistent with this legislative change, we proposed to revise § 415.130(d) to: (1) Amend the effective date of our payment policy to reflect that for services furnished after December 31, 2010, an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished to a hospital inpatient or outpatient; and (2) reformat this subsection into paragraphs.

Comment: One commenter urged CMS to implement the provision to continue to pay independent laboratories for the TC of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital on a permanent basis which would eliminate the potential for complicated billing that occurs each time the provision is set to expire and is subsequently extended by.

Response: Payment for the costs of furnishing the pathology service (but not its interpretation) is already included in the bundled inpatient stay payment to the hospital. We continue to believe that this payment provision represents a duplicate payment for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) to the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service.

After consideration of the public comment we received we are finalizing the proposed policy to continue payment to independent laboratories for the TC of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for CY 2010. Absent legislation that extends this provision, for services furnished after December 31, 2010, an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered

hospital. Accordingly, we are finalizing the proposed revisions to § 415.130(d) to reflect this change.

F. Sections 3105 and 10311: Extension of Ambulance Add-Ons

1. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the MIPPA amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports which originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports which do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the ACA further amend section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2010 and before January 1, 2011. We stated in the CY 2011 PFS proposed rule (75 FR 40117) that we are revising § 414.610(c)(1)(i) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of these payment add-ons, please see Transmittal 706 (Change Request 6972) dated May 21, 2010.

2. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of rural areas for payment of air ambulance services. The statute specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, shall continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009. Sections

3105(b) and 10311(b) of the ACA amend section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010.

Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the "rural" indicator on the ZIP Code file for air ambulance services, effective January 1, 2010 through December 31, 2010. We stated in the CY 2011 PFS proposed rule (75 FR 40118) that we are revising § 414.610(h) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of this MIPPA provision, please see Transmittal 706 (Change Request 6972) dated May 21, 2010.

3. Amendment to Section 1834(l)(12) of the Act

Section 414 of the MMA added paragraph (12) to section 1834(l) of the Act, which specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a "qualified rural area," that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). Sections 3105(c) and 10311(c) of the ACA amend section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. Therefore, as directed by the ACA, we are

continuing to apply the rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2010 and before January 1, 2011 where transportation originates in a qualified rural area.

We stated in the CY 2011 PFS proposed rule (75 FR 40118) that we are revising § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. The statute requires a 1-year extension of the rural bonus (which was previously established by the Secretary), and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of this rural bonus, please see Transmittal 706 (Change Request 6972) dated May 21, 2010.

A summary of the comments we received and our responses are included below.

Comment: Despite the extension of the ambulance payment add-ons under the ACA as discussed above, one commenter stated that "it has become increasingly difficult to continue to operate with the reimbursement cuts that went into effect January 1, 2010". They expressed concern that Medicare payment rates for ambulance services are not keeping up with inflation in the industry. They were also concerned that this is the first time in nearly a decade that the ambulance industry will be experiencing negative growth.

Response: We are not sure what reimbursement cuts the commenter is referring to in 2010. As discussed above, pursuant to sections 3105 and 10311 of the ACA, we are required to extend certain ambulance payment add-ons through December 31, 2010. Thus, as discussed above, we are revising our regulations to conform the regulations to these statutory requirements. To date, Congress has not extended these payment add-ons beyond December 31, 2010, and thus we are not authorized to provide these add-ons beyond December 31, 2010.

Comment: One commenter stated that CMS must provide instructions to its contractors that direct them to reprocess claims paid at the original 2010 rates.

Response: Several provisions of the ACA require retroactive adjustments to Medicare claims, including claims for ambulance services, because these provisions have effective dates prior to the ACA's enactment or shortly thereafter. We are currently developing the best course of action for addressing past claims that were processed under pre-ACA rules. The volume of claims that must be adjusted is unprecedented

and a careful process must be deployed to ensure that new claims coming into the Medicare program are processed timely and accurately, even as we address making retroactive adjustments. Once this process has been developed, we will provide instructions to our contractors regarding adjusting ambulance claims that were paid under the pre-ACA rules in order to apply the payment add-ons required by the ACA.

In this final rule with comment period, we are finalizing the revisions to § 414.610(c)(1)(i), (c)(5)(ii), and (h), as discussed above and in the CY 2011 PFS proposed rule, in order to conform the

regulations to the requirements set forth in sections 3105 and 10311 of the ACA. We note that in § 414.610(c)(1), we have made minor formatting revisions for clarification purposes. In addition, in § 414.610(c)(1)(i), we have corrected a typographical error that appeared in the CY 2011 PFS proposed rule (75 FR 40258) by changing "December 21" to "December 31" to conform with the ACA requirements. As we discuss above, sections 3105 and 10311 of the ACA are self-implementing and do not require any substantive exercise of discretion by the Secretary.

G. Section 3107: Extension of Physician Fee Schedule Mental Health Add-On

Section 3107 of the ACA amended section 138(a)(1) of the MIPPA to continue the 5 percent increase in Medicare payment for specified mental health services through December 31, 2010. This payment increase was originally authorized under section 138 of the MIPPA from July 1, 2008 until December 31, 2009. Accordingly, payment for the 24 psychiatry CPT codes in Table 56, representing "specified services," remains increased by 5 percent through December 31, 2010.

TABLE 56—SPECIFIED MENTAL HEALTH SERVICES SUBJECT TO THE FIVE PERCENT INCREASE IN MEDICARE PAYMENT THROUGH DECEMBER 31, 2010

Office or Other Outpatient Facility

Insight Oriented, Behavior Modifying and/or Supportive Psychotherapy:

- 90804 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient;)
- 90805 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services)
- 90806 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient;)
- 90807 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services)
- 90808 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient;)
- 90809 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services)

Interactive Psychotherapy:

- 90810 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient;)
- 90811 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services)
- 90812 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient;)
- 90813 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services)
- 90814 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient;)
- 90815 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services)

Inpatient Hospital, Partial Hospital or Residential Care Facility

Insight Oriented, Behavior Modifying and/or Supportive Psychotherapy:

- 90816 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient;)
- 90817 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services)
- 90818 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient;)
- 90819 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services)
- 90821 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient;)
- 90822 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services)

Interactive Psychotherapy:

- 90823 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient;)

TABLE 56—SPECIFIED MENTAL HEALTH SERVICES SUBJECT TO THE FIVE PERCENT INCREASE IN MEDICARE PAYMENT THROUGH DECEMBER 31, 2010—Continued

90824	(Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services)
90826	(Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient;)
90827	(Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services)
90828	(Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient;)
90829	(Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services).

Comment: One commenter supported CMS' proposal to continue the current 5 percent increase in Medicare payment for specified mental health services through December 31, 2010.

Response: We appreciate the support of our efforts to implement this mandated mental health add-on provision that extends the expiration of the 5 percent increase in payment for specified outpatient mental health services from January 1, 2010 to December 31, 2010.

After consideration of the public comment we received, we are finalizing the extension of the 5 percent increase in Medicare payment under the PFS from January 1, 2010 to December 31, 2010.

H. Section 3108: Permitting Physician Assistants To Order Post-Hospital Extended Care Services

The ACA included a self-implementing provision relating to SNFs. Section 3108 of the ACA adds physician assistants (PAs) to the list of practitioners (that is, physicians, nurse practitioners (NPs), and clinical nurse specialists) that can perform the required initial certification and periodic recertification under section 1814(a)(2)(B) of the Act with respect to the SNF level of care. Accordingly, we proposed to make appropriate revisions to include PAs in § 424.20(e)(2), in which we refer to NPs, clinical nurse specialists, and PAs collectively as "physician extenders."

We received no comments on this proposal and, therefore, are finalizing this provision as proposed without further modification.

I. Section 3111: Payment for Bone Density Tests

Section 1848(b) of the Act (as amended by section 3111 of the ACA) changed the payment calculation for dual-energy x-ray absorptiometry (DXA)

services described by two specified DXA CPT codes for CYs 2010 and 2011. This provision required payment for these services at 70 percent of the product of the CY 2006 RVUs for these DXA codes, the CY 2006 conversion factor (CF), and the geographic adjustment for the relevant payment year.

Effective January 1, 2007, the CPT codes for DXA services were revised. The former DXA CPT codes 76075 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (eg, hips, pelvis, spine)); 76076 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; appendicular skeleton (peripheral) (for example, radius, wrist, heel)); and 76077 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; vertebral fracture assessment) were deleted and replaced with new CPT codes 77080, 77081, and 77082 that have the same respective code descriptors as the predecessor codes. Section 1848(b) of the Act (as amended by section 3111 of the ACA) specifies that the revised payment applies to two of the predecessor codes (CPT codes 76075 and 76077) and "any succeeding codes," which are, in this case, CPT codes 77080 and 77082.

Section 1848(b) (as amended by section 3111 of the ACA) revised the payment for CPT codes 77080 and 77082 during CY 2010 and CY 2011. We have provided payment in CY 2010 under the PFS for CPT codes 77080 and 77082 at the specified rates. (Additional information regarding the CY 2010 payment rates for these services is available in CR 6973, published May 10, 2010.)

Because the statute specifies a payment amount for these services as described previously, we proposed to impute RVUs for CY 2011 that would provide the specified payment amount

for these services when multiplied by the CY 2011 CF. Specifically, we divided the payment amount based on the statutory requirements by the CY 2011 CF for the proposed rule and distributed the imputed total RVUs across the work, PE, and malpractice components proportionately to their CY 2006 distribution. Therefore, these imputed RVUs for CPT codes 77080 and 77082 were displayed in Addendum B to the CY 2011 proposed rule.

Comment: Many commenters supported the ACA provision requiring a specific payment amount for DXA services. Several commenters requested that CMS include in the final rule a sample payment calculation for CPT codes 77080 and 77082 to clarify the calculation for these two codes and to facilitate proper processing of claims by Medicare contractors. In addition, one commenter requested that CMS recalculate any imputed RVUs for DXA services based on the final conversion factor reflected in the CY 2011 PFS final rule with comment period.

Response: We appreciate the comments we received on our proposal. We note that any changes to the proposed rule calculation that resulted from changes between proposed rule values and final rule values have been incorporated in the final determination of the RVUs for these codes upon which PFS payment is based. That said, we are updating our calculation for this final rule with comment period to reflect the final CY 2011 conversion factor applicable under current law that is discussed in section II.H.1.b. of this final rule with comment period. A sample payment calculation for CPT code 77080 is included below.

Sample CY 2011 Calculation of Medicare Payment Rates for CPT Code 77080 (CY 2006 CPT Code 76075)

As discussed above, section 1848(b) of the Act (as amended by section 3111 of

the ACA) required us to provide payment for CPT code 77080 at 70 percent of the product of the CY 2006 RVUs for the specified DXA code, the

CY 2006 CF, and the geographic adjustment for the relevant payment year in which the service is furnished.

The CY 2006 RVUs for CPT code 76075 (77080) can be found in Table 57 below.

TABLE 57—CY 2006 RVUS FOR CPT CODE 77080 (CY 2006 CPT CODE 76075)

CY 2006 CPT Code	Mod	CY 2006 Short descriptor	2006 Physician work RVUs	2006 Nonfacility PE RVUs	2006 Facility PE RVUs	2006 Malpractice RVUs
76075	26 ..	Dxa bone density, axial	0.30	0.10	0.10	0.04
76075	TC	Dxa bone density, axial	0.00	3.10	NA	0.17
76075	Dxa bone density, axial	0.30	3.20	NA	0.18

First, we multiplied the CY 2006 RVUs listed in Table 57 above by the CY 2006 CF, which was \$37.8975. These results are shown in Table 58 below.

TABLE 58—CY 2006 RVUS FOR CPT CODE 77080 MULTIPLIED BY THE CY 2006 CF

CY 2006 CPT Code	Mod	CY 2006 Physician work RVUs* 2006 CF	CY 2006 Nonfacility PE RVUs* 2006 CF	CY 2006 Facility PE RVUs* 2006 CF	CY 2006 Malpractice RVUs* 2006 CF
76075	26 ..	\$11.37	\$3.79	\$3.79	\$0.38
76075	TC	NA	117.48	NA	6.44
76075	11.37	121.27	NA	6.82

Second, we took 70 percent of the result to arrive at the CY 2011 national payment amounts for each component of the CPT code. These results are shown in Table 59 below.

TABLE 59—CY 2011 NATIONAL PAYMENT AMOUNTS FOR CPT CODE 77080

CY 2006 CPT Code	Mod	CY 2011 Physician work payment amount	CY 2011 Nonfacility PE payment amount	CY 2011 Facility PE payment amount	CY 2011 Malpractice payment amount
76075	26 ..	\$7.96	\$2.65	\$2.65	\$0.27
76075	TC	NA	82.24	NA	4.51
76075	7.96	84.89	NA	4.78

Third, in order to determine the CY 2011 RVUs for CPT code 77080 (76075) that are displayed in Addendum B to this final rule with comment period, we divided the CY 2011 national payment amounts shown in Table 59 by the CY 2011 CF (discussed in section II.G.1. of this final rule with comment period) of \$25.5217. These results are shown in

Table 60 and in Addendum B to this final rule with comment period. We note that RVUs under the PFS are generally resource-based and, therefore, are typically unaffected by changes to the CF. However, because the statute essentially sets a fixed payment amount for DXA services, the CF directly determines the RVUs for CPT code 77080 as we must impute RVUs for the

DXA services in CY 2011. Therefore, when there are changes to the PFS CF, we must make corresponding changes to the RVUs for CPT codes 77080 and 77082 for CY 2010 and CY 2011 in order to maintain the fixed national payment amount specified in the statute, which is then subject to geographic adjustment as indicated below.

TABLE 60—CY 2011 RVUS FOR CPT CODE 77080
(NOTE: Calculated using the current law CY 2011 CF of \$25.5217)

CY 2011 CPT Code	Mod	CY 2011 Physician work RVUs	CY 2011 Nonfacility PE RVUs	CY 2011 Facility PE RVUs	CY 2011 Malpractice RVUs
77080	26 ..	0.31	0.10	0.10	0.01
77080	TC	0.00	3.22	NA	0.18
77080	0.31	3.32	NA	0.19

Finally, in order to provide payment for a specific DXA service furnished by a practitioner, the RVUs listed in Table 60 would be multiplied by the CY 2011 CF and subject to geographic adjustment based on the CY 2011 GPCIs that apply

to the location where the service is furnished.

In summary, after consideration of the public comments we received, we are finalizing our proposed CY 2011 payment methodology for CPT codes 77080 and 77082 in accordance with the section 1848(b) of the Act (as amended by section 3111 of the ACA). In CY 2011, payment for CPT codes 77080 and 77082 will be made at 70 percent of the product of the CY 2006 RVUs for the specified DXA codes, the CY 2006 CF, and the CY 2011 geographic adjustment.

J. Section 3114: Improved Access for Certified Nurse-Midwife Services

Section 1833(a)(1)(K) of the Act (as amended by section 3114 of the ACA) increased the amount of Medicare payment made under the PFS for certified nurse-midwife (CNM) services. Currently, section 1833(a)(1)(K) of the Act specifies that the payment amount for CNM services is 80 percent of the lesser of the actual charge or 65 percent of the PFS amount for the same service furnished by a physician. Under section 1833(a)(1)(K) of the Act (as amended by section 3114 of the ACA), effective for services furnished on or after January 1, 2011, Medicare payment for CNM services is increased to 100 percent of the PFS amount for the same service furnished by a physician (or 80 percent of the actual charge if that is less). We proposed to revise our regulations at § 414.54 (Payment for certified nurse-midwives' services) accordingly to reflect the increased payment for CNM services effective for services furnished on or after January 1, 2011.

Although CNMs are currently paid under Medicare Part B for their professional services, there is no mention of CNMs under the regulatory provision that lists the providers and suppliers of services to whom payment is made under the Medicare Part B program. Accordingly, we proposed to make a technical revision to § 410.150 (To whom payment is made) to specify that Medicare Part B pays CNMs for professional services in all settings, as well as services and supplies furnished incident to those services.

CNMs are authorized under the statute to be paid directly for services that they are legally authorized to furnish under State law and that are of the type that would otherwise be covered if furnished by a physician or incident to a physician's services. Additionally, there is no requirement for physician oversight or supervision of CNMs. Accordingly, CNMs are authorized to personally furnish diagnostic tests that fall under their State scope of practice without regard to

the levels of physician supervision required under the diagnostic tests benefit. Therefore, we proposed to revise § 410.32(b)(2) (Exceptions to the levels of physician supervision required for diagnostic tests) to include CNMs who furnish diagnostic tests that fall within their State scope of practice.

Comment: Several commenters welcomed the proposed increase in Medicare payment for CNM services effective January 1, 2011, stating that this policy would provide equitable payment under Medicare to CNMs. These commenters claimed that Medicare payment to GNMs at 100 percent of the Medicare Part B PFS amount that would be paid to a physician (or 80 percent of the actual charge if that is less) represents policy reform resulting from advocacy over a number of years. The commenters believe that the Medicare payment increase will enable CNMs across the nation to expand services to women with disabilities of childbearing age, as well as to senior women who are Medicare patients. The commenters noted that previously the 35 percent payment differential between CNMs and other health professionals furnishing similar services limited the expansion of CNM services to Medicare patients. Additionally, the commenters asserted that CNMs serve a critical role as primary care providers for women throughout their lifespan and claimed that regulatory changes to unleash the potential of this group of providers were critically needed to fill the gaps in primary care.

The commenters also supported CMS' proposed technical revisions to § 410.150 and § 410.32. The proposed changes to § 410.150 would include CNMs as a supplier of services to whom Medicare payment can directly be made for their professional services in all settings and for services and supplies furnished incident to their professional services. Additionally, the commenters believe that the proposed changes to § 410.32 would clarify that when CNMs personally perform diagnostic tests, these health professionals are not subject to physician supervision for payment of diagnostic tests.

Response: We appreciate the commenters' support for implementing the new statutory provision that increases Medicare Part B payment for CNM services, effective January 1, 2011, from 80 percent of the lesser of the actual charge or 65 percent of the PFS amount that would be paid to a physician to 100 percent of the Medicare Part B PFS amount that would be paid to a physician or 80 percent of the actual charge if that is less.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to increase the Medicare Part B payment amount for CNM services under the PFS from 65 percent of the PFS amount that would be paid to a physician to 100 percent of the PFS amount that would be paid to a physician, or 80 percent of the actual charge if that is less. We are also finalizing our proposed modification to § 414.54 to reflect this statutory change, with clarification to state that the amount paid to a CNM may not exceed 100 percent of the PFS amount that would be paid to a physician for the same service furnished on or after January 1, 2011. In addition, we are finalizing, without modification, our proposed revisions to § 410.32 and § 410.150.

K. Section 3122: Extension of Medicare Reasonable Costs Payments for Certain Clinical Diagnostic Laboratory Tests Furnished to Hospital Patients in Certain Rural Areas

Section 416 of the MMA established a reasonable cost payment for outpatient clinical diagnostic laboratory tests furnished by hospitals with fewer than 50 beds that are located in qualified rural areas for cost reporting periods beginning during the 2-year period beginning on July 1, 2004.

Section 105 of the Tax Relief and Health Care Act of 2006 (Pub. L. 109-432) (TRHCA) extended the 2-year period in section 416(b) of the MMA for an additional cost-reporting year.

Section 107 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173) (MMSEA) extended the time period for cost reporting periods beginning on July 1, 2004 and ending on June 30, 2008. For some hospitals with cost reports that began as late as June 30, 2008, this extension affected services performed as late as June 29, 2009, because this was the date those cost reports would have closed.

Section 3122 of the ACA reinstates reasonable cost payment for clinical diagnostic laboratory tests performed by hospitals with fewer than 50 beds that are located in qualified rural areas as part of their outpatient services for cost reporting periods beginning on or after July 1, 2010 through June 30, 2011. For some hospitals with cost reports that begin as late as June 30, 2011, this reinstatement of reasonable cost payment could affect services performed as late as June 29, 2012, because this is the date those cost reports will close.

We received no comments on this proposal and therefore are finalizing this provision without modification.

L. Section 3134: Misvalued Codes Under the Physician Fee Schedule

Section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) required the Secretary to periodically review and identify potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being potentially misvalued. Section 1848(c)(2)(K) of the Act (as added by section 3134 of the ACA) further specified that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services, as well as conduct surveys or implement other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the review and appropriate adjustment of the relative values of potentially misvalued codes. Finally, section 1848(c)(2)(L) of the Act (as added by section 3134 of the ACA) provided that the Secretary shall establish a process to validate relative value units under the PFS.

We note that over the past several years, we have been working with the AMA RUC to identify approaches to addressing the issue of potentially misvalued services. Our CY 2011 approaches to categories of potentially misvalued codes are discussed in section II.C. of this final rule with comment period.

M. Section 3135: Modification of Equipment Utilization Factor for Advanced Imaging Services

1. Adjustment in Practice Expense To Reflect Higher Presumed Utilization

Section 1848(b)(4)(C) of the Act (as added by section 3135(a) of the ACA) adjusted the utilization rate beginning in CY 2011 for expensive diagnostic imaging equipment to a 75 percent assumption in the methodology for establishing the PE of the RVUs of procedures that use this equipment.

In the CY 2010 PFS final rule with comment period (74 FR 61755), we finalized a policy to increase the utilization rate to 90 percent for expensive diagnostic equipment priced at more than \$1 million (CT and MRI scanners), providing for a 4-year transition to the 90 percent utilization rate from the CY 2009 utilization rate of 50 percent. Therefore, in CY 2010 we were transitioning to a 90 percent equipment utilization rate assumption, applying a 25/75 blend of the new and old PE RVUs, respectively, for the associated procedures. Section 1848(b)(4)(C) of the Act (as added by section 3135(a) of the ACA) does not

provide for any further transition and, therefore, we are assigning a 75 percent equipment utilization rate assumption to CT and MRI scanners, effective January 1, 2011. Under section 1848(b)(4) of the Act (as amended by section 3135(a) of the ACA), this change in the equipment utilization rate assumption from CY 2010 to CY 2011 is not budget neutral under the PFS. The equipment utilization rate assumption remains at 50 percent for all other equipment included in the PFS PE methodology. Further discussion of our final CY 2011 policies regarding the equipment utilization rate assumption can be found in section II.A.3.a. of this final rule with comment period.

2. Adjustment in Technical Component "Discount" on Single-Session Imaging to Consecutive Body Parts

Section 1848(b)(4)(D) of the Act (as added by section 3135(a) of the ACA) increased the established PFS multiple procedure payment reduction (MPPR) for the TC of certain single-session imaging services to consecutive body areas from 25 to 50 percent, effective July 1, 2010, and section 1848(c)(2)(B)(v)(VI) of the Act (as added by section 3135(b) of the ACA) exempted this percent change from the PFS budget neutrality provision. This policy is discussed in detail in section II.C.4 of this final rule with comment period.

Effective January 1, 2006, we adopted an MPPR of 25 percent for the TC of certain diagnostic imaging procedures, applied to the second and subsequent services when more than one service in one of 11 imaging families, defined by imaging modality and contiguous body area, is furnished in a single session (70 FR 70261 through 70263). The established imaging MPPR applies to TC services and to the TC of global services. It does not apply to PC services or to the PC of global services. Under this policy, full payment was made for the TC of the highest priced procedure, while payment was made at 75 percent of the TC for each additional procedure. As of July 1, 2010 and continuing in CY 2011, payment is made at full payment for the TC of the highest paying procedure, while at 50 percent of the TC for each additional procedure, consistent with the new statutory provision. Further discussion of the MPPR policies affecting nonsurgical PFS services can be found in section II.C.4. of this final rule with comment period.

N. Section 3136: Revision for Payment for Power-Driven Wheelchairs

1. Payment Rules for Power Wheelchairs

Durable medical equipment (DME) is defined at section 1861(n) of the Act and includes wheelchairs necessary for use in the patient's home. Section 1861(n) of the Act provides that wheelchairs included in the definition of DME "may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition." The general Medicare payment rules for DME are set forth in section 1834(a) of the Act and 42 CFR part 414, subpart D of our regulations. Section 1834(a)(1) of the Act and § 414.210(a) of our regulations establish that the Medicare payment for a DME item is generally equal to 80 percent of either the lower of the actual charge or the fee schedule amount for the item less any unmet Part B deductible. The beneficiary coinsurance is generally equal to 20 percent of either the lower of the actual charge or the fee schedule amount for the item once the deductible is met.

For Medicare payment purposes, power wheelchairs or power-driven wheelchairs are classified under various HCPCS codes based on the level of performance and functional characteristics of each power wheelchair that accommodate the specific needs of patients. Power wheelchairs classified under performance Groups 1 through 3 are covered under Medicare for use in the patient's home. Power wheelchair groups were established in 2006 with the release of the Power Mobility Device Coding Guidelines published by the Durable Medical Equipment Regional Carriers (DMERCs) currently called the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The DMEPOS quality standards define certain power wheelchairs falling as "complex, rehabilitative" power wheelchairs, and these "complex, rehabilitative" power wheelchairs are treated as a separate product category for the purpose of implementing the DMEPOS Competitive Bidding Program (CBP) mandated by section 1847(a) of the Act. In both the quality standards and the DMEPOS CBP, complex, rehabilitative power wheelchairs are defined or identified as power wheelchairs classified as Group 2 power wheelchairs with power options that can accommodate rehabilitative features (for example, tilt in space) or Group 3 power wheelchairs. Section

1847(a)(2)(A) of the Act, as amended by section 154(a)(1)(B) of MIPPA, excludes complex, rehabilitative power wheelchairs classified within Group 3 from the DMEPOS CBP.

With the exception of power wheelchairs furnished during calendar year 1990, power wheelchairs have been paid under the capped rental category of DME since January 1, 1989. The payment rules for capped rental DME are provided at section 1834(a)(7) of the Act and § 414.229 of our regulations. Payment for these items is generally on a monthly rental basis, with rental payments capped at 13 months. After a 13-month period of continuous use during which rental payments are made, the statute and regulations require that the supplier transfer title to the wheelchair to the beneficiary. In addition, effective for power wheelchairs furnished on or after January 1, 1991, section 1834(a)(7) of the Act, as amended by section 4152(c)(2)(D) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508), mandates that the supplier of the power wheelchair offer the patient the option to purchase rather than rent the item. Since 1991, over 95 percent of Medicare beneficiaries have exercised this lump-sum purchase option for power wheelchairs.

Consistent with payment for other DMEPOS items, § 414.210(f)(1) permits payment for replacement of capped rental DME if the item has been in continuous use for the equipment's reasonable useful lifetime or is lost, stolen, or irreparably damaged. Section 414.210(f)(1) states the reasonable useful lifetime for equipment is determined through program instructions. In the absence of CMS program instructions, the carrier may determine the reasonable useful lifetime for equipment, but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment. If the beneficiary elects to obtain a new capped rental item after the reasonable useful lifetime, a new 13-month rental payment period would begin for the new equipment in accordance with the requirements of § 414.229.

Pursuant to section 1834(a)(7)(A)(i)(II) of the Act and § 414.229(b), the current capped rental fee schedule amounts applicable to wheelchairs for months 1 thru 3 of the 13-month capped rental period are calculated to pay 10 percent of the purchase price recognized in the statute for the item. The rental fee schedule amounts for months 4 through 13 of the 13-month capped rental period are calculated to pay 7.5 percent of the

purchase price for the item. The purchase price is determined consistent with section 1834(a)(8) of the Act and § 414.229(c) and § 414.220(e) and (f) and is calculated based on average allowed payments for the purchase of new items, and is updated by the covered item update, as required by section 1834(a)(14) of the Act and § 414.229(d). The purchase fee schedule amount for new power wheelchairs acquired on a lump sum purchase basis is 100 percent of the purchase price calculated for the item, as discussed above.

2. Revision of Payment Amounts for Power Wheelchairs

Section 3136(a) of the ACA made several changes to section 1834(a)(7)(A) of the Act. Section 3136(a)(1) of the ACA amends section 1834(a)(7)(A) of the Act by adding a new subclause (III) to section 1834(a)(7)(A)(i) of the Act. Subclause (III) revises the capped rental fee schedule amounts for all power wheelchairs, modifying the current payment structure of 10 percent of the purchase price for months 1 through 3 and 7.5 percent of that purchase price for months 4 through 13 that was previously discussed.

The rental fee schedule amount for months 1 through 3 of the 13-month capped rental period for power wheelchairs is revised to 15 percent of the purchase price for the item. The rental fee schedule amounts for months 4 through 13 of the 13-month capped rental period for power wheelchairs is revised to 6 percent of the purchase price for the item. The statutory provision does not change the methodologies used to calculate and subsequently update the purchase price of power wheelchairs. Therefore, the methodology described previously for determining the purchase price amounts will continue to apply.

Pursuant to section 3136(c) of the ACA, the changes made by section 3136(a) of the ACA apply to power-driven wheelchairs furnished on or after January 1, 2011. Furthermore, as discussed previously, section 3136(c)(2) of the ACA states that the changes made by section 3136(a) of the ACA, including the new payment structure for power wheelchairs, do not apply to payment made for items and services furnished pursuant to contracts entered into under section 1847 of the Act for the DMEPOS CBP prior to January 1, 2011, which applies to the implementation of the first round of the DMEPOS CBP. As a result, contract suppliers furnishing power wheelchairs in competitive bidding areas (CBA) pursuant to contracts entered into prior to January 1, 2011, as part of Round 1

of the DMEPOS CBP will continue to be paid based under the current regulations using 10 percent of the purchase price for months 1 through 3 and 7.5 percent for each of the remaining months. We did not receive public comment on our proposed changes to § 414.202, § 414.229, and § 414.408, and therefore we are finalizing our proposals without modification.

3. Elimination of Lump Sum Payment for Standard Power Wheelchairs

Section 3136(a)(2) of the ACA further amends section 1834(a)(7)(A)(iii) of the Act by inserting the term "complex, rehabilitative" before the term "power-driven wheelchairs." As a result, section 1834(a)(7)(A)(iii) of the Act now extends the lump sum purchase option only to complex, rehabilitative power wheelchairs. As discussed above, "complex, rehabilitative" power wheelchairs are power wheelchairs that are classified as: (1) Group 2 power wheelchairs with power options that can accommodate rehabilitative features (for example, tilt in space), or (2) Group 3 power wheelchairs. We consider all other power wheelchairs to be standard power wheelchairs. Therefore, we proposed to interpret the language "complex, rehabilitative" in section 1834(a)(7)(A) of the Act consistent with this longstanding classification. As a result, the changes made by section 3136 of the ACA to section 1834(a)(7)(A)(iii) of the Act eliminate the lump sum purchase option for standard power wheelchairs.

Pursuant to section 3136(c) of the ACA, the changes made to section 1834(a)(7)(A)(iii) of the Act apply to power-driven wheelchairs furnished on or after January 1, 2011. The lump sum purchase payment option will no longer extend to standard power driven wheelchairs furnished on or after January 1, 2011.

Furthermore, section 3136(c)(2) of the ACA states that the changes made by section 3136(a) of the ACA, including the limitation of the lump sum purchase payment option to complex, rehabilitative power wheelchairs, do not apply to payment made for items and services furnished pursuant to contracts entered into under section 1847 of the Act for the DMEPOS CBP prior to January 1, 2011, pursuant to the implementation of the first round of the DMEPOS CBP. As a result, contract suppliers furnishing power wheelchairs in CBAs in accordance with contracts entered into prior to January 1, 2011 as part of Round 1 of the DMEPOS CBP must continue to offer beneficiaries the lump sum purchase option for all power wheelchairs.

We proposed changes to § 414.229 and § 414.408 to reflect our interpretation of these statutory requirements.

Comment: Several commenters stated that the changes regarding the lump sum payment option will make it more difficult for many suppliers to furnish standard power wheelchairs because suppliers usually purchase wheelchairs from manufacturers using the full lump sum payments. One commenter stated that some homecare providers will need to arrange for loans to obtain sufficient finances to purchase wheelchairs that are then paid for by the Medicare program and beneficiaries over the longer 1-month payment period and if the recent capital markets for loans do not improve, CMS should consider a delay in implementing our regulations.

Response: While we recognize that the regulatory changes require adjustments by standard power wheelchair suppliers, we do not believe that section 3136(a)(2) of the ACA provides flexibility to delay the implementation of this provision. Moreover, these concerns are related to the financial relationships developed by manufacturers of standard power wheelchairs with the suppliers who furnish patients with wheelchairs, which is not within the purview of our regulations. As we explained in the proposed rule (75 FR 40121), power wheelchairs have been paid under the capped rental category of DME since 1989, and the option to purchase in addition to the rental payment method was established in 1991. Thus, section 3136(a)(2) of the ACA and the regulatory changes implementing that provision are not establishing a new rental payment methodology. We expect suppliers will be able to adapt expeditiously to furnishing standard power wheelchairs under a rental payment structure. Finally, we believe that there may be some financial benefit to suppliers as a result of this change. As is the case for manual wheelchairs furnished to Medicare beneficiaries, suppliers of standard power wheelchairs furnished to Medicare beneficiaries on or after January 1, 2011, may be able to rent these items to multiple beneficiaries if the beneficiaries use the items for fewer than 13 continuous months. In many cases where a power wheelchair is rented to multiple beneficiaries, the supplier will receive more than 13 monthly payments for the item, including payments based on 15 percent of the statutory purchase price for the first 3 months that each beneficiary rents the item.

Comment: Several commenters raised a concern that the elimination of the lump sum payment method will cause a significant increase in monthly rental claims submitted for standard power wheelchairs; thereby, increasing administrative claims processing costs. One commenter noted that in the event claims processing contractors have difficulty processing claims, we did not discuss how to apply interest rates for Medicare overpayments or underpayments.

Response: We appreciate this comment regarding the efficient implementation of the provision of section 3136 of the ACA, which includes a requirement that payment for all standard power wheelchairs be made on a monthly rental basis effective January 1, 2011. We are working with our contractors to make the necessary changes to the claims processing systems in order to be ready to process additional standard power wheelchair rental claims with dates of service on or after January 1, 2011. Also, we have coordinated within CMS and our partners to update educational materials for our beneficiaries. With regard to overpayments or underpayments, these issues will be handled in the same manner as overpayments or underpayments are handled for capped rental DME in general.

Comment: Several commenters stressed the need to clarify the conditions of payment requirements for power wheelchairs that are rented after a break in service or change in patient condition. These commenters stated that because the majority of power wheelchairs have been paid under the lump sum purchase payment method, physicians and suppliers performed the documentation requirements set forth in § 410.38(c)(2) prior to initial delivery of the standard power wheelchairs. These documentation requirements specify the physician or treating practitioner must conduct a face-to-face examination of the patient to determine that the power wheelchair is medically necessary before it is dispensed to the beneficiary. In addition, the supplier must perform an on-site evaluation of the patient's home to develop supporting documentation for the initial delivery and payment for a power wheelchair. As a result of the elimination of the lump sum purchase option for standard power wheelchairs, more power wheelchairs will be paid under the rental payment method after January 1, 2011. Thus, the commenters urged that the regulations should clarify whether a new face-to-face examination and home evaluation must be performed when a break in service of greater than 60 days occurs.

Response: This comment is outside the scope of the CY 2011 PFS proposed rule. We did not propose any changes to the conditions of payment set forth in § 410.28(c)(2). We again note, however, that payments on a rental basis for capped rental items, including power wheelchairs, have been made since January 1, 1989. The payment and coverage requirements identified by the commenters for power mobility devices (PMDs), including power-operated vehicles or scooters and standard and complex, rehabilitative power wheelchairs, must be met before the item is furnished to the beneficiary on either a purchase or rental basis. Section 3136 of the ACA, which in part eliminates the purchase option for standard power wheelchairs furnished on or after January 1, 2011, has no impact on these requirements. They remain in effect for all PMDs furnished to Medicare beneficiaries on a purchase or rental basis, including rented power wheelchairs. Payment for capped rental items is limited to 13 months of continuous use, defined at § 414.230. Section 414.230(d) sets forth the criteria for a new rental period: during this 13-month capped rental period, a break in use of the equipment for more than 60 continuous days, plus the days remaining in the rental month in which use ceases, would result in the start of a new period of continuous use and a new 13-month capped rental period if the supplier submits a new prescription, new medical necessity documentation, and documentation that describes the reason for the interruption in use and documents that medical necessity in the prior rental episode ended. Section 3136 of the ACA has no impact on the requirements set forth in § 414.230 regarding continuous use of capped rental items.

Comment: One commenter requested a revision to the billing modifiers for Advance Beneficiary Notice of Noncoverage (ABN) to utilize when a supplier bills for furnishing a wheelchair that has features beyond what is covered by Medicare.

Response: This comment is outside the scope of the CY 2011 PFS proposed rule because we did not propose any changes to the billing modifiers for ABNs. Nevertheless, we encourage interested parties to follow our HCPCS editorial process and submit coding recommendations by following the instructions found at our Web site at <http://www.cms.gov/MedHCPCSGenInfo>.

Comment: One commenter requested clarification on whether the beneficiary retains ownership of power wheelchair associated accessories (for example

elevated leg rests or adjustable height arms rests) during or after the rental period. These associated accessories are not included with the rental of the standard power wheelchair base equipment.

Response: Payment for accessories for power wheelchairs that are not included in the basic equipment package for the wheelchair and are separately payable items under the inexpensive or routinely purchased (IRP) DME category is made on either a rental or lump sum purchase basis. If payment is made on a lump sum basis to the supplier for an associated accessory, then the beneficiary owns the accessory for use with the standard power wheelchair during and after the 13-month wheelchair rental period. If payment is made on a rental basis for an accessory in the IRP category and it appears that the beneficiary will use the wheelchair for the full 13-month capped rental period, the beneficiary may elect to purchase the accessory, and the Medicare allowed payment for purchase of the accessory would be equal to the lower of the actual charge or the purchase fee schedule amount, less cumulative paid rental amounts. Title to an accessory for a power wheelchair that is not included in the basic equipment package for the wheelchair and is a separately payable item under the capped rental DME category is transferred to the beneficiary following the 13-month capped rental period.

Comment: One commenter requested information on how to apply the calculation of the reasonable useful lifetime to a standard power wheelchair which had been in continuous use for 10 months prior to being returned to a supplier and then after appropriate cleaning and servicing is placed with a different beneficiary. Also, the commenter requested how to apply the calculation of the reasonable useful lifetime if the standard power wheelchair is assigned to several beneficiaries under similar circumstances and remains in continuous use beyond 13 months because of use by multiple beneficiaries prior to title being transferred to the last beneficiary.

Response: The regulations applicable to calculation of the reasonable useful lifetime are located at § 414.210(f) and state that computation of the reasonable useful lifetime of equipment is based on when the equipment is delivered to the beneficiary, not the age of the equipment. At the end of 13 months rental use of a DME item, the supplier must transfer title to the item, such as a power wheelchair, to the beneficiary in accordance with § 414.229(f)(2). If,

following transfer of title, it is determined that the power wheelchair will not last for the entire reasonable useful lifetime, the supplier is required by § 414.210(e)(4) to replace the equipment at no cost to the beneficiary or the Medicare program.

Comment: One commenter expressed concern that the proposed changes to § 414.408(f)(1) will force suppliers to convert to a rental payment model of furnishing standard power wheelchairs prior to the end of the 3 year contract period for DMEPOS Round 1 Rebid CBAs although their bids included an assumption that the lump sum payment method would continue into subsequent years. Another commenter believed inequalities occur by continuing the option of a lump sum payment method for standard power wheelchairs in Round 1 Rebid CBAs but not in other geographic areas.

Response: Section 3136(c)(2) of the ACA states that the change made by section 3136(a) of the ACA, eliminating the lump sum payment method for standard power wheelchairs, does not apply to payment made for items and services furnished pursuant to contracts entered into under section 1847 of the Act for the DMEPOS CBP prior to January 1, 2011 pursuant to the implementation of the first round of the DMEPOS competitive bidding program (CBP). We noted that although these changes will not apply to payment made for items and services furnished pursuant to the contracts awarded following the Round 1 Rebid, contract suppliers must prepare for the elimination of the lump sum payment method for standard power wheelchairs that will take effect at the end of the 3 year contract period. When the Round 1 contracts are recompeted, suppliers will submit bids for furnishing power wheelchairs on a rental only basis.

Comment: One commenter suggested Medicare should consider implementing a serial number tracking program for power wheelchairs to improve anti-fraud efforts.

Response: This comment is outside the scope of the CY 2011 PFS proposed rule. We appreciate the commenter's suggestion and will consider studying the feasibility of a nationwide serial tracking program for power wheelchairs for future rulemaking efforts. We were informed that nationwide there are more than 106 styles of power wheelchairs available from 22 manufacturers. A nationwide serial tracking program would require significant program resources and stakeholder input which we would need to conduct prior to rulemaking.

After considering the comments received, we are adopting, without modification, our proposed changes to § 414.229 and § 414.408 that eliminate the lump sum payment option for standard power wheelchairs.

O. Section 3139: Payment for Biosimilar Biological Products

Section 3139 of the ACA amends section 1847A of the Act to provide for Medicare payment of biosimilar biological products using the average sale price (ASP) methodology.

Section 1847A(c)(6)(H) of the Act, as added by the ACA, defines a biosimilar biological product as a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). The reference biological product for a biosimilar biological product is defined by the statute as the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product.

The ACA also amends section 1847A(b) of the Act by adding paragraph 8 to specify that the payment amount for a biosimilar biological product will be the sum of the following two amounts: The ASP of all NDCs assigned to the biosimilar biological product determined using the methodology in section 1847A(b)(6) of the Act, and 6 percent of the payment amount determined using the methodology in section 1847A(b)(4) of the Act for the corresponding reference biological product. Sections 7001 to 7003 of the ACA also established a licensing pathway for biosimilar biological products, and in accordance with the statute, the effective date for Medicare ASP statutory provisions is July 1, 2010. We proposed to make conforming regulation text changes at § 414.902 and § 414.904 and we solicited comments regarding our conforming changes.

We anticipate that as biosimilar biological drug products are approved, we will receive ASP sales data through the ASP data submission process and publish national payment amounts in a manner that is consistent with our current approach to other drugs and biologicals that are paid under section 1847A of the Act and set forth in 42 CFR part 414 subpart J. Until we have collected sufficient sales data as reported by manufacturers, payment limits will be determined in accordance with the provisions in section

1847A(c)(4) of the Act. If no manufacturer data is collected, prices will be determined by local contractors using any available pricing information, including provider invoices. More information about the ASP payment methodology and the data submission process may be found on the CMS Web site at http://www.cms.gov/McrPartBDrugAvgSalesPrice/01_overview.asp and in section VII.A.1., "Carry Over ASP," of this final rule with comment period.

Comment: Several commenters supported the proposed regulation text changes.

Response: Based on the comments that we received, we are finalizing our proposal and regulation text without additional modification.

Comment: Several commenters requested that CMS assign biosimilars and other brand name drugs and biologicals separate HCPCS codes in order to facilitate the tracking of items paid under section 3139 of the ACA, as well as branded drugs and biologicals subject to fees under section 9008 of the ACA.

Response: We appreciate the comments; however, our proposal did not address procedures for assignment of HCPCS codes, and so these comments are outside the scope of this rule. For more information about the HCPCS coding process, we refer you to <http://www.cms.gov/MedHCPCSGenInfo/>.

In summary, we are finalizing our proposed definitions of biosimilar biological, reference biological and our proposed payment methodology without additional modification.

P. Section 3401: Revision of Certain Market Basket Updates and Incorporation of Productivity Improvements Into Market Basket Updates That Do Not Already Incorporate Such Improvements

1. ESRD Market Basket Discussion

Section 3401(h) of the ACA amended section 1881(b)(14)(F) of the Act and directs the Secretary to annually increase payment amounts established under the ESRD market basket. Please see section VII.E. of this final rule with comment for a detailed description of these provisions.

2. Productivity Adjustment Regarding the Ambulatory Surgical Center Payment System, and the Ambulance, Clinical Laboratory and DMEPOS Fee Schedules

Section 3401 of the ACA requires that the update factor under certain payment systems be annually adjusted by changes in economy-wide productivity.

The year that the productivity adjustment is effective varies by payment system. Specifically, section 3401 of the ACA requires that, in CY 2011 (and in subsequent years) update factors under the ambulatory surgical center (ASC) payment system, the ambulance fee schedule (AFS), the clinical laboratory fee schedule (CLFS), and the DMEPOS fee schedules be adjusted by changes in economy-wide productivity. Section 3401(a) of the ACA amends section 1886(b)(3)(B) of the Act to add clause (xi)(II) which sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private non-farm business MFP. Please see <http://www.bls.gov/mfp> which is the link to the BLS historical published data on the measure of MFP.

As stated in the PFS proposed rule (75 FR 40123), the projection of MFP is currently produced by IHS Global Insight (IGI), an economic forecasting firm. As described in the CY 2011 PFS proposed rule, in order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from the IGI US Macro-economic models. These models take into account a very broad range of factors that influence the total U.S. economy. IGI forecasts the underlying proxy components such as Gross Domestic Product (GDP), capital, and labor inputs required to estimate MFP and then combines those projections according to the BLS methodology.

In Table 34 of the proposed rule (75 FR 40123), we identified each of the MFP component series employed by the BLS and the corresponding concepts estimated by IGI that appeared to be the best measure at the time of the proposed rule. IGI found that the historical growth rates of the BLS components used to calculate MFP and the IGI components identified and listed in the PFS proposed rule (75 FR 40123) were consistent across all series and therefore suitable proxies for calculating MFP. We proposed a method in which IGI uses the growth rates of the forecasted IGI concepts to project BLS' components of MFP. The resulting MFP adjustment derived from using this method was proposed to be used under section 3401

of the ACA to adjust the updates for the ASC payment system, the AFS, the CLFS, and the DMEPOS fee schedules.

Since the proposed rule, BLS issued revised estimates of private nonfarm business MFP (released on August 24, 2010). We also received public comments on the proposed calculation of the MFP adjustment. We summarize these comments and our responses below.

Comment: Several commenters stated that CMS provided no details in the proposed rule on the data and calculations that it used in making the MFP estimates, instead referring readers to the BLS, which only provides historical data. The commenters stated that this level of information is insufficient for public comment. The commenters requested that CMS fully disclose the methods and data sources used for the MFP estimate for public comment before implementing the multifactor productivity adjustment to the ASC payment system and to the other payment systems. Another commenter stated that transparency is needed concerning the assumptions underlying the projection of MFP and the commenter asked that CMS address this in the final rule so a better understanding can be gained about how CMS arrived at its MFP adjustment.

Response: The CY 2011 PFS proposed rule included a citation to the BLS Web site. This link provided a lengthy detailed description of the methodology that is used by the BLS to construct an estimate of MFP for the private nonfarm business sector, including a discussion of the underlying series used in the MFP calculation. For the forecasted estimate of MFP, we then identified in Table 34 in the CY 2011 PFS proposed rule (75 FR 40123) the forecasted series that closely align to the series used by BLS. The data source for these forecasted series is IGI, an economic forecasting firm. Following the methodology as described in the BLS documentation that we provided in the CY 2011 PFS proposed rule, a forecast of MFP was created using the IGI series. Given the information that was presented in the CY 2011 PFS proposed rule, we believe that we provided adequate information regarding the methods, calculations, and data sources used for the MFP estimate. In this final rule with comment period, we have included below a more detailed description of this methodology for even greater transparency.

In response to the public comments we received requesting additional information on the assumptions underlying the projection of MFP, we note that the projection of MFP is not driven by specific assumptions. The

underlying series forecasted by IGI are derived from a set of complex economic forecasting models that project various components of the total U.S. economy. These models are intended to capture many drivers of economic growth in the U.S. economy. Therefore, the underlying series that IGI uses, to calculate a forecast of MFP are products of this economy-wide macroeconomic model as opposed to being based on a specific set of assumptions.

Comment: Several commenters expressed concern that current economic conditions are distorting the factor used for the productivity adjustment, potentially leading to unintended consequences. These commenters claim that the original intent of the productivity adjustment was to hold providers to a standard of productivity improvement achieved by the rest of the economy. However, the commenters stated that when productivity gains are driven by undesirable trends in the economy, this adjustment could lead to excessive cuts. The current "jobless recovery" is inflating productivity as output increases but a key input—employment—continues to stagnate. The commenters claim that cutting

Medicare payments by this inflated figure could hurt hospitals and other health care providers and suppliers that have been one of the few sources of continued job growth in this economy.

Response: We are required by law to implement section 3401 of the ACA, which requires that in CY 2011 (and in subsequent years) update factors under the ASC payment system, the AFS, the CLFS, and the DMEPOS fee schedules be adjusted by the 10-year moving average of changes in annual economy-wide multi-factor productivity for the private non-farm business sector.

Although we believe that the IGI method of calculating a forecast of MFP discussed in the CY 2011 PFS proposed rule (75 FR 40123) is appropriate and accurately reflects the 10-year moving average of changes in annual economy-wide multi-factor productivity, in response to this comment, CMS and IGI reevaluated the series that are used to calculate MFP to ensure that the underlying components that are ultimately selected are those that will produce a measure of MFP that most closely tracks the official measure of MFP as published by BLS. While the concepts listed in Table 34 of the CY 2011 PFS proposed rule were similar to the underlying concepts used by BLS (as

discussed in the proposed rule), CMS and IGI subsequently determined that there are technically superior IGI series for output and labor that can be used to derive a calculation of MFP (still using the method as described in the proposed rule), that will ultimately result in a more appropriate forecast of MFP. The IGI method is described in more detail below and we note that the methodology is the same methodology as was described in the CY 2011 PFS proposed rule, which is aligned closely with the methodology employed by the BLS. For more information regarding the BLS method for estimating productivity we refer the commenter to the following link: <http://www.bls.gov/mfp/mpprtech.pdf>.

Table 61 lists the MFP component series employed by the BLS and the corresponding concepts estimated by IGI as specified in Table 34 of the CY 2011 PFS proposed rule and in this final rule. Please note that, in BLS' revised MFP estimates published on August 24, 2010, the index series was rebased from 2000=100 to 2005=100. Thus, Table 61 refers to the BLS series in 2005 dollars whereas Table 34 of the CY 2011 PFS proposed rule referred to the BLS series in 2000 dollars.

TABLE 61—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT

BLS series	IGI series—proposed rule	IGI series—final rule
Real value-added output, constant 2005 dollars	Real gross non-farm value added output, chained 2005 dollar billions.	Non-housing non-government non-farm real GDP, Billions of chained 2005 dollars—annual rate.
Private non-farm business sector labor input; 2005=100.00.	Hours of all persons—private nonfarm business sector; 1992=1.0.	Man-hours in private nonfarm establishments, Billions of hours—annual rate.
Aggregate capital inputs; 2005=100.00	Real effective capital stock used for full employment GDP, chained 2005 dollar billions.	Real effective capital stock used for full employment GDP, Billions of chained 2005 dollars.

In this final rule with comment period, we are finalizing the same IGI method as described in the CY 2011 PFS proposed rule, with minor technical improvements to the underlying concepts used to calculate MFP. We have also included a more detailed description below of the methodology (which was described in the proposed rule and which we are finalizing in this final rule with comment period) used to calculate MFP in response to the public comments we received.

To create a forecast of BLS' MFP index, the forecasted annual growth rates of the "non-housing, non-government, non-farm, real GDP", "man-hours in private nonfarm establishments", and "real effective capital stock" series (ranging from 2009

to 2020) are used to "grow" the levels of the "real value-added output," "private non-farm business sector labor input," and "aggregate capital input" series published by the BLS. Using these three key concepts, MFP is derived by subtracting the contribution of labor and capital inputs from output growth.

However, in order to estimate MFP, we need to understand the relative contributions of labor and capital to total output growth. Therefore, two additional measures are needed to operationalize the estimation of the IGI MFP projection: Labor compensation and capital income. The sum of labor compensation and capital income represents total income. The BLS calculates labor compensation and capital income (in current dollar terms)

to derive the nominal values of labor and capital inputs. IGI uses the "non-government total compensation" and "flow of capital services from the total private non-residential capital stock" series as proxies for the BLS' income measures. These two proxy measures for income are divided by total income to obtain the shares of labor compensation and capital income to total income.

In order to estimate labor's contribution and capital's contribution to the growth in total output, the growth rates of the proxy variables for labor and capital inputs are multiplied by their respective shares of total income. These contributions of labor and capital to output growth are subtracted from total output growth to calculate the "change

in the growth rates of multifactor productivity”:

$$\text{MFP} = \text{Total output growth} - \{(\text{labor input growth} * \text{labor compensation share}) + (\text{capital input growth} * \text{capital income share})\}$$

The change in the growth rates (also referred to as the compound growth rates) of the IGI MFP are multiplied by 100 in order to calculate the percent change in growth rates (the percent change in growth rates are published by the BLS for its historical MFP measure). Finally, the growth rates of the IGI MFP are converted to index levels based to 2005 to be consistent with the BLS’ methodology.

For benchmarking purposes, the historical growth rates of IGI’s proxy variables were used to estimate a historical measure of MFP, which was compared to the historical MFP estimate published by the BLS. The comparison revealed that the growth rates of the components were consistent across all series, and therefore validated the use of the proxy variables in generating the IGI MFP projections.

The resulting MFP index was then interpolated to a quarterly frequency using the Bassie method for temporal disaggregation. The Bassie technique utilizes an indicator (pattern) series for its calculations. IGI uses the index of output per hour (published by the BLS) as an indicator when interpolating the MFP index.

As discussed below, for each of these payment systems, the update factor is the percentage increase (or percentage decrease for the CLFS) in the consumer price index for all urban consumers (CPI-U) (referred to as the “CPI-U update factor”).

For all four payment systems, section 3401 of the ACA generally states that the Secretary shall reduce the CPI-U adjustment by the MFP adjustment. In order to calculate the MFP-adjusted updates to these payment systems, we proposed that the MFP percentage adjustment would be subtracted from the CPI-U update factor. For example, if the update factor (CPI-U) is 4.0 percent, and the projected MFP is 1.3 percent, the MFP-Adjusted update factor (or MFP-Adjusted CPI-U for these payment systems) would be a 2.7 percent increase.

We proposed that the end of the 10-year moving average of changes in the MFP should coincide with the end of this CPI-U timeframe (75 FR 40123). Since the CPI-U update factor is reduced by the MFP adjustment to determine the annual update for these payment systems, we stated that we believe it is appropriate for the numbers associated with both parts of the

calculation to be projected as of the same end date. In this way, changes in market conditions are aligned.

In this final rule with comment period, we wanted to further clarify how for each payment system, the end of the 10-year moving average of changes in the MFP will coincide with the period on which the CPI-U is calculated. In the case of the ASC payment system, the CPI-U projected for the 12-month period ending with the midpoint of the year involved, which is CY 2011 for this final rule with comment period. Therefore, the end of the 10-year moving average of changes in the MFP is projected so that it ends with the midpoint of the year involved, which is CY 2011 for this final rule with comment period. In the case of the AFS, CLFS, and DMEPOS fee schedules, the CPI-U is estimated for the period ending June 30th of the year preceding the update year itself, which is CY 2010 for this final rule with comment period. Therefore, the end of the 10-year moving average of changes in the MFP is estimated so that it ends June 30th of the year preceding the update year itself, which is CY 2010 for this final rule with comment period.

We proposed to round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules (that is, if the number we are rounding is followed by 5, 6, 7, 8, or 9, we will round the number up; if the number we are rounding is followed by 0, 1, 2, 3, or 4, we will round the number down).

In the following sections, we provide more information on the statutory requirements and proposals for each of the four payment systems. The statutory requirements for the ASC payment system were also addressed in the CY 2011 OPPI/ASC final rule with comment period. We note that, in the CY 2011 PFS proposed rule (75 FR 40123 through 40125), we described the legislative provision and outlined the methodology used to calculate and apply the MFP adjustment to determine the annual updates for ASC payment system, the AFS, the CLFS, and the DMEPOS fee schedules for CY 2011 and each subsequent year. We stated that we would set forth the final MFP adjustment for CY 2011 in this final rule with comment period. Also, we stated in the CY 2011 PFS proposed rule (75 FR 40123) that once we finalize the methodology for determining and applying the MFP adjustment to the CPI-U update factors for these payment systems, for subsequent calendar years, as we have done in the past, we would notify the general public of the annual

update to the AFS, CLFS, and DMEPOS fee schedules via CMS instruction and on the CMS Web site. These notifications would set forth both the CPI-U percentage increase (or, for the CLFS, the percentage decrease) and the MFP adjustment for the applicable year. For ASCs, for subsequent calendar years, as we have done in the past, we stated that we would continue to notify the general public of the annual update to the ASC payment amount via the annual OPPI/ASC rulemaking process.

In summary, as discussed previously, we are finalizing the same IGI method as described in the CY 2011 proposed rule to calculate the MFP adjustment, with minor technical improvements to the underlying concepts used to calculate the MFP adjustment. Furthermore, as proposed, the MFP adjustment is calculated so that the end of the 10-year moving average of changes in the MFP will coincide with the end of the CPI-U timeframe for each of the four payment systems (that is, the ASC payment system, AFS, CLFS, and DMEPOS fee schedules) so that market conditions are aligned. Also, as proposed, we will round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules. Using the methodology finalized previously, the final MFP adjustment for CY 2011 is 1.3 percent for the ASC payment system, and 1.2 percent for the AFS, CLFS, and DMEPOS fee schedules. We are also finalizing our proposal to calculate the MFP-adjusted updates for the ASC payment system, the AFS, the CLFS and the DMEPOS fee schedules for CY 2011 and each subsequent year by subtracting the MFP adjustment from each payment system’s CPI-U update factor, as further described in the following sections.

a. Ambulatory Surgical Centers (ASCs)

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated the ASC payment amounts in a calendar year, the payment amounts “shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.” Because the Secretary does update the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor). Section 3401(k) of the ACA amends section

1833(i)(2)(D) of the Act by adding a new clause (v) which requires that "any annual update under [the ASC payment] system for the year [after application of any reduction in any update for failure to report on quality measures, if the Secretary implements a quality reporting program for ASCs] shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act" (which we refer to as the MFP adjustment) effective with the calendar year beginning January 1, 2011. Section 3401(k) of the ACA states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the "percentage increase" in the CPI-U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI-U for a year is negative, we proposed to hold the CPI-U update factor for the ASC payment system to zero. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the ACA, then requires that the Secretary reduce the CPI-U update factor (which would be held to zero if the CPI-U percentage change is negative) by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage change below zero. If the application of the MFP adjustment to the CPI-U percentage increase would result in an MFP-adjusted CPI-U update factor that is less than zero, then the annual update to the ASC payment rates would be negative and payments would decrease relative to the prior year.

Table 62 provides illustrative examples of how we proposed the MFP adjustment would be applied to the ASC payment system. These examples show the implication of a positive CPI-U update factor with a smaller MFP adjustment, a positive CPI-U update factor with a large MFP adjustment, and a CPI-U update factor of zero. We discussed the application of the MFP adjustment to the CPI-U update factor for the ASC payment system under the OPPTS/ASC CY 2011 proposed rule (75 FR 46359). We solicited comment on the specific mathematical calculation of the MFP adjustment and noted that comments on the application of the MFP adjustment to the CPI-U update factor under the ASC payment system should be made to the OPPTS/ASC CY

2011 proposed rule (75 FR 46359). As discussed previously, we received and responded to comments on the calculation of the MFP adjustment and have finalized this methodology as described above. In the CY 2011 OPPTS/ASC final rule with comment period, we respond to any comments received and finalize the methodology for applying the MFP adjustment to the CPI-U update factor for ASCs.

TABLE 62—MULTIFACTOR PRODUCTIVITY ADJUSTED PAYMENT UPDATE: ILLUSTRATIVE EXAMPLE

CPI-U (percent)	MFP Adjustment (percent)	MFP-Adjusted CPI-U update factor (percent)
4.0	1.3	2.7
4.0	4.7	-0.7
0.0	0.2	-0.2

b. Ambulance Fee Schedule (AFS)

In accordance with section 1834(l)(3)(B) of the Act, the AFS rates are required to be increased each year by the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. We refer to this update as the Ambulance Inflation Factor (AIF). Section 3401(j) of the ACA amends section 1834(l)(3) of the Act to add a new subclause (C) which states that, for CY 2011 and each subsequent year, after determining the percentage increase under section 1834(l)(3)(B) of the Act (that is, the CPI-U percentage increase, or AIF), the Secretary shall reduce such percentage increase by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (as discussed previously). Section 3401(j) of the ACA further amends section 1834(l)(3) of the Act to state that the application of subclause (C) (that is, the reduction of the CPI-U percentage increase by the MFP adjustment) may result in that percentage increase being less than zero for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

In accordance with section 1834(l)(3) of the Act as amended by section 3401(j) of the ACA, before applying the MFP adjustment, the Secretary first determines the "percentage increase" in the CPI-U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI-U for a year is negative, we proposed to hold the AIF to zero. The statute then requires that the Secretary reduce the CPI-U percentage increase

(which would be held to zero if the CPI-U percentage change is negative) by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage increase below zero. If the application of the MFP adjustment to the CPI-U percentage increase would result in an MFP-adjusted AIF that is less than zero, then the annual update to the AFS would be negative and payments would decrease relative to the prior year.

Table 63 provides illustrative examples of how we proposed the MFP adjustment would be applied to the AFS. Finally, we proposed to revise § 414.610(f) to require that the AIF be reduced by the MFP adjustment as required by the statute in determining the annual update under the ambulance fee schedule for CY 2011 and each subsequent year, and to revise § 414.620 to state that changes in payment rates resulting from the incorporation of the AIF and the MFP adjustment will be announced by CMS by instruction and on the CMS Web site, as we previously discussed.

TABLE 63—EXAMPLES OF THE APPLICATION OF THE MULTIFACTOR PRODUCTIVITY ADJUSTMENT TO THE AMBULANCE FEE SCHEDULE

[In percent]

A CPI-U	B AIF	C MFP Adjustment	D Final update rounded
2.0	2.0	1.3	0.7
0.0	0.0	1.3	-1.3
-2.0	0.0	1.3	-1.3
1.0	1.0	1.3	-0.3

Comment: A few commenters stated that the payment rates for ambulances have consistently fallen further behind the actual cost of providing the service. One commenter stated that the annual update as adjusted by the MFP adjustment would create a permanent disparity between future increases in Medicare's reimbursement for ambulance services and the increased costs of providing those services. The commenter stated that the two largest operational costs for ambulance services are personnel and fuel, neither of which readily lends itself to operational efficiencies. In particular, they claim that small and rural providers lack the volume of transports needed to obtain any meaningful economies of scale. These commenters acknowledge that the MFP adjustment is mandated by law, but they state that it will likely result in a net decrease in the already insufficient base reimbursement rate for air

ambulances. One commenter urged CMS to take whatever steps are within its authority to mitigate the potentially devastating effects of this new requirement.

Response: As discussed previously and in the CY 2011 PFS proposed rule (75 FR 40124), we are required by law to implement section 3401(j) of the ACA, which requires that for CY 2011 and each subsequent year, after determining the percentage increase under section 1834(l)(3)(B) of the Act (that is, the CPI-U percentage increase, or AIF), the Secretary shall reduce such percentage increase by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In response to the request that we "mitigate" any potentially negative effects of the MFP adjustment, we reiterate that we are required to apply the MFP adjustment to the AIF in the manner specified by the ACA, and we are not authorized by statute to implement measures to mitigate the effects of this adjustment. We note that certain temporary payment add-ons, currently codified at section 1834(l)(12) and (13) of the Act and at section 146(b)(1) of the MIPAA, were extended by the ACA through December 31, 2010 (see section VI.F(1) and (3), of this final rule). To date, Congress has not extended these payment add-ons beyond December 31, 2010. Therefore, we are finalizing the methodology for applying the MFP adjustment to the AIF for the AFS as described in the

proposed rule. We did not receive any comments regarding the proposed changes to § 414.610(f) and § 414.620 as discussed above. Therefore, we are revising the regulation text in § 414.610(f) and § 414.620 as proposed, with the following minor technical change. In § 414.610(f), for clarification purposes, we have made a technical revision to refer to the definition of the productivity adjustment in section 1886(b)(3)(B)(xi)(II) of the Act.

c. Clinical Laboratory Fee Schedule

Section 1833(h)(2)(A)(i) of the Act, as amended by section 3401(l) of the ACA, states that the Secretary shall set the CLFS "for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv) [as added by the ACA], a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 through 2010, 0.5 percentage points". Therefore, the adjustment to the fee schedule can be an increase or a decrease.

Section 3401(l) of the ACA also adds new clause (iv) that applies in CY 2011 and each subsequent year. This clause requires the Secretary to reduce the adjustment in clause (i): (1) By the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act for 2011 and each subsequent year and (2) by 1.75 percentage points for each year of

2011 through 2015 (the "percentage adjustment"). However, section 3401(l) of the ACA states that the MFP adjustment will not apply in a year where the adjustment to the fee schedule determined under clause (i) is zero or a percentage decrease for a year. Further, the application of the MFP adjustment shall not result in an adjustment to the fee schedule under clause (i) of less than zero for a year.

Therefore, we proposed to apply the MFP adjustment as follows:

- If the CPI-U update factor is positive, it would be reduced by the MFP adjustment. However, if application of the MFP adjustment would result in a negative update, the update would be held to zero.
- If the CPI-U update factor is zero or negative, the MFP adjustment would not be applied.

Section 3401(l) of the ACA also states that the application of the percentage adjustment may result in an adjustment to the fee schedule under clause (i) being less than zero for a year and may result in payment rates for a year being less than such payment rates for the preceding year. Therefore, we are applying the percentage reduction of 1.75 percentage points to any adjustment to the fee schedule under the CLFS as directed by section 3401(l) of the ACA.

Table 64 provides illustrative examples of how we proposed these adjustments would be applied to fees under the CLFS.

TABLE 64—EXAMPLES OF THE APPLICATION OF THE MULTIFACTOR PRODUCTIVITY ADJUSTMENT TO THE CLINICAL LAB FEE SCHEDULE

A	B	C	D	E
CPI-U	MFP Adjustment	Productivity adjusted update	(-1.75%) Percentage point reduction	Resultant change to CLFS
		Greater of 0.0% or (Col. A) - (Col. B)		Col. C - Col. D
2.0%	1.3%	0.7%	-1.75%	-1.05%
0.0%	N/A	0.0%	-1.75%	-1.75%
-2.0%	N/A	0.0%	-1.75%	-1.75%

We did not receive any public comments on the proposed methodology for applying the MFP adjustment and the percentage adjustment to the CPI-U update factor for the CLFS. Therefore, we are finalizing the methodology for applying the MFP adjustment and the percentage adjustment to the CPI-U update factor for the CLFS as described in the proposed rule.

d. DMEPOS Fee Schedule

Sections 1834(a)(14), 1834(h)(4), and 1842(s)(1) of the Act mandate annual updates to the fee schedule amounts established in accordance with these respective sections for covered items of durable medical equipment defined in section 1834(a)(13) of the Act, prosthetic devices, orthotics, and prosthetics defined in section 1834(h)(4)(B) and (C) of the Act, and parenteral and enteral nutrients, equipment, and supplies described in section 1842(s)(2)(D) of the

Act. The annual updates for 2011 for these sections are based on the percentage increase in the CPI-U for the 12-month period ending with June 2010. The annual updates for years subsequent to 2011 will be based on the percentage increase in the CPI-U for the 12-month period ending with June of the previous year (that is, June 2011 for 2012, June 2012 for 2013, etc.). Since 1990 for durable medical equipment, prosthetic devices, orthotics, and prosthetics and since 2003 for

parenteral and enteral nutrients, equipment, and supplies, we have notified the public of these annual fee schedule updates through program instructions.

Section 3401(m) of the ACA amends section 1834(a)(14) of the Act to add a new subparagraph (L) which provides that, for CY 2011 and each subsequent year, the fee schedule update factor based on the CPI-U for the 12-month period ending with June of the previous year is to be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (as discussed previously). Section 3401(m) of the ACA further amends section 1834(a)(14) of the Act to state that the application of subparagraph (L) (that is, the reduction of the CPI-U percentage increase by the MFP adjustment) may result in that percentage increase being less than zero for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

Section 3401(n) of ACA amends section 1834(h)(4)(A) of the Act to add a new clause (xi) which provides that, for CY 2011 and each subsequent year, the fee schedule update factor based on the CPI-U for the 12-month period ending with June of the previous year is to be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (as discussed previously). Section 3401(n) of the ACA further amends section 1834(h)(4) of the Act to state that the application of subparagraph (A)(xi) (that is, the reduction of the CPI-U percentage increase by the MFP adjustment) may result in that percentage increase being less than zero for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

Section 3401(o) of ACA amends section 1842(s)(1) of the Act to add a new subparagraph (B) and clause (ii) which provides that, for CY 2011 and each subsequent year, the fee schedule update factor based on the CPI-U for the 12-month period ending with June of the previous year is to be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (as discussed above). Section 3401(o) of the ACA further amends section 1842(s)(1) of the Act to state that the application of subparagraph (B)(ii) (that is, the reduction of the CPI-U percentage increase by the MFP adjustment) may result in that percentage increase being less than zero for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

The MFP adjustments to the CPI-U percentage increases used in calculating the fee schedule adjustment factors for these DMEPOS items and services as mandated by sections 3401(m), (n), and (o) of ACA are simple mathematical calculations and are ministerial in nature. Therefore, we plan to implement these adjustments for 2011 and subsequent years as part of the annual program instructions related to the DMEPOS fees schedule updates.

Comment: Several commenters stated that there were flawed assumptions underlying the statutory requirements of section 3401 of the ACA. Since the MFP measures the contributions to productivity of all sectors involved in production, the commenters argued that the indiscriminate application of the MFP to DMEPOS items was fundamentally flawed.

Response: As discussed previously, sections 3401(m), (n), and (o) of the ACA require us to implement the MFP adjustments to the CPI-U percentage increases for DMEPOS items and services. Therefore, we are finalizing our proposal to apply the MFP adjustments to the CPI-U percentage increases for DMEPOS items and services for calendar year 2011 and subsequent years.

Q. Section 4103: Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan

1. Background and Statutory Authority

a. Medicare Coverage of Preventive Physical Examinations and Routine Checkups

Section 1862(a)(7) of the Act explicitly prohibits Medicare payment for routine physical checkups with certain exceptions. One exception is for the Initial Preventive Physical Exam (also referred to as the "Welcome to Medicare" exam) established for new beneficiaries effective for services furnished on or after January 1, 2005. Section 4103 of the ACA has provided another exception to section 1862(a)(7) of the Act. Congress expanded Medicare coverage under Part B to include an Annual Wellness Visit (AWV) Providing Personalized Prevention Plan Services (hereinafter referred to as the annual wellness visit) in sections 1861(s)(2)(FF) and 1861(hhh) of the Act. This expanded benefit is effective on January 1, 2011.

Preventive care has become an increasing focus of the Medicare program. For instance, section 101 of the MIPPA expanded Medicare's authority to establish coverage for additional preventive services that meet specified criteria. Among other things,

the AWV will encourage beneficiaries to obtain the preventive services already covered by Medicare, and that are appropriate for each individual beneficiary.

b. Requirements for Coverage of an Annual Wellness Visit

Section 4103 of the ACA provides for coverage of an AWV, which includes and/or takes into account a health risk assessment (HRA), and creates a personalized prevention plan for beneficiaries, subject to certain eligibility and other limitations. Section 4103 of the ACA also requires the identification of elements that must be provided to a beneficiary as part of the first visit for personalized prevention plan services and requires the establishment of a yearly schedule for appropriate provision of such elements thereafter.

The ACA specifies elements to be included in a personalized prevention plan, including establishment of, or update to, the individual's medical and family history, a list of the individual's current providers and suppliers and medications prescribed for the individual; measurement of height, weight, body-mass index (BMI) or waist circumference, and blood pressure; detection of any cognitive impairment; establishment or update of an appropriate screening schedule for the next 5 to 10 years; establishment or update of a list of risk factors and conditions (including any mental health conditions) for which interventions are recommended or underway; and furnishing of personalized health advice and referral, as appropriate, to health education or preventive counseling services or programs. The ACA also permits the Secretary to add other elements to the AWV determined to be appropriate.

2. Regulatory Revisions—Summary of Proposed Rule and Comments

The following is a summary of the provisions of the proposed rule and of the comments received. We received 75 public comments on the proposed rule regarding the AWV. Commenters included national and state professional associations, medical societies and national medical advisory groups, hospital associations and hospitals, physicians, registered dietitians, occupational therapists, senior advisory groups, health insurance associations, manufacturers, and others. While a number of commenters expressed concern that the proposal was either too prescriptive, not sufficiently targeted to development of an individual's personalized prevention plan, or was

not broad enough to include additional screening or prevention services; a large majority of commenters applauded CMS' efforts in developing the rule and generally supported its major elements. Many suggested clarification and revision of the rule in a number of different areas, including the proposed definitions of "detection of any cognitive impairment," and "health professional," and the components of the first and subsequent AWWs. One special concern of a number of commenters was related to the health risk assessment (HRA). Some provisions of section 4103 of the ACA require the HRA be included in the new AWW, which is effective January 1, 2011. Other provisions of section 4103 of the ACA give the Secretary a longer period of time to develop an HRA in consultation with relevant groups and entities.

a. Revisions to § 411.15, Particular Services Excluded From Coverage

To conform the regulations to the statutory requirements of the ACA, we proposed to revise § 411.15 by specifying an exception to the routine physical checkups exclusion from coverage in § 411.15(a)(1) and modifying § 411.15(k)(15). We proposed to add a provision to permit coverage of AWWs that meet the eligibility limitations and the conditions for coverage we are specifying in § 410.15 (Annual Wellness Visit Providing Personalized Prevention Plan Services).

Coverage of the AWW is furnished under Medicare Part B only. As provided in the statute, this new coverage allows payment for an AWW if provided on or after January 1, 2011 for an individual who is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period, and has not received either an IPPE or an AWW within the past 12 months.

b. Revisions to Part 410, Subpart B—Medical and Other Health Services

We proposed to add § 410.15, Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage, to codify the coverage of the annual wellness visit providing personalized prevention plan services.

We proposed to define several terms in § 410.15(a), including: (1) Detection of any cognitive impairment; (2) Review of the individual's functional ability and level of safety; (3) Health professional; (4) Establishment of, or update to the individual's medical and family history; (5) Eligible beneficiary; (6) First annual wellness visit providing personalized prevention plan services; and (7)

Subsequent annual wellness visit providing personalized prevention plan services.

Further, the ACA allows the addition of any other element determined appropriate by the Secretary for inclusion in an AWW. We reviewed the relevant medical literature, current clinical practice guidelines, and the recommendations of the United States Preventive Services Task Force (USPSTF). Pursuant to that review, we proposed to add depression screening and functional status screening as elements of the first AWW only. In its December 2009 Recommendation Statement, the USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment and follow-up (Grade: B recommendation). That is, the USPSTF recommends the service; there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

The USPSTF is currently updating its 1996 recommendation regarding screening for hearing impairment in older adults as well as its recommendation on falls in the elderly. Until those recommendations can be published, functional status screening (including assessment of hearing impairment, ability to successfully perform activities of daily living, fall risk, and home safety) appears supportable by evidence only for the first AWW.

We also proposed that the definition of the term "Establishment of, or an update to the individual's medical and family history" include more than a list of all of an individual's prescribed medications as provided in the statute, but also supplements such as vitamins and calcium that an individual may be exposed to or use. Supplements such as these are commonly used by many beneficiaries and the medical literature supports that their use be closely monitored by health professionals because they can interact with prescribed medications and may result in unintended medical problems in individual cases. The statute expressly permits the Secretary to add other elements such as this to the AWWs.

To facilitate future consideration of coverage of additional elements in the definitions of the first and subsequent AWWs in § 410.15(a), we proposed that the determination of other required elements for those purposes will be made through the national coverage determination (NCD) process. The NCD process, as described in section 1862(l) of the Act, is evidence based,

transparent, and furnishes the opportunity for public comment.

(1) Definitions

We proposed to add the following definitions to § 410.15(a):

- *Detection of any cognitive impairment*, for purposes of this section, means assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers, or others.

Comment: A number of commenters strongly supported the mandatory inclusion of "detection of any cognitive impairment" in the new AWW, but several suggested the proposed definition did not go far enough and needed to be clarified. One commenter suggested that the definition was "too vague and may be interpreted as optional by a provider unless a subjective memory complaint is raised by the individual or a concern is raised by family members, friends, caretakers, or others", and that a brief cognitive screening test was necessary "to accurately identify the presence of cognitive deficits, and to indicate whether additional testing is necessary * * *". Another commenter expressed concern that "physicians cannot accurately assess cognitive function * * * by relying on direct observation or by report of the patient or knowledgeable informant." The commenter cited several recent publications and their own experience in support of revising the definition to include use of a standardized screening test. A number of commenters supporting the importance of the "detection of cognitive impairment" element, however, agreed with the definition that is used in the proposed rule, which does not require a standardized screening tool.

Response: We agree with the commenters that the "detection of cognitive impairment" is an important element of the AWW. As Boustani and colleagues (*Ann Internal Medicine* 2003;138:927–937) noted: "Dementia causes a high burden of suffering for patients, their families, and society. For patients, it leads to increased dependency and complicates other comorbid conditions. For families, it leads to anxiety, depression, and increased time spent caring for a loved one. The annual societal cost of dementia is approximately \$100 billion (health care and related costs as well as lost wages for patients and family caregivers)."

Several commenters suggested revising the proposed definition by the

addition of a standardized screening tool. With the considerable variability in the range and causes of cognitive impairment, it is difficult to more specifically define this element without limiting it to specific diseases such as Alzheimer's since dementia in and of itself is broadly defined. The American Psychiatric Association stated: "the essential features of a dementia are acquired multiple cognitive deficits that usually include memory impairment and at least one of the following phenomena in the absence of a delirium that might explain the deficit: aphasia, apraxia, agnosia, or a disturbance in executive functioning (the ability to think abstractly and to plan, initiate, sequence, monitor, and stop complex behavior)" (<http://www.psychiatryonline.com/content.aspx?aid=152634#152634>).

However, an evidence-based, standardized screening tool is not currently available. The USPSTF noted: "most screening tests have been evaluated in studies with small sample sizes, and the populations of patients on whom screening instruments have been tested have varied greatly, making it difficult to determine the overall performance of screening tests for dementia" (<http://www.uspreventiveservicestaskforce.org/3rduspstf/dementia/dementtr.pdf>). They concluded "that the evidence is insufficient to recommend for or against routine screening for dementia in older adults (I grade)." Since there is no nationally recognized screening tool for the detection of cognitive impairments at the present time, we are adopting the language in § 410.15(a) as proposed.

We disagree with one of the commenter's assertions that, in general, a physician cannot accurately assess cognitive function by direct observation or report of the patient or by report of the patient knowledgeable informant. We believe that physicians can use their best clinical judgment in the detection and diagnosis of cognitive impairments, along with determining whether additional resources may need to be used in the course of screening and treatment of the patient. We will continue to actively monitor advancements in screening, collaborate with the USPSTF, and will consider revising this element if the evidence is sufficient and a standardized screening test becomes available.

• *Review of the individual's functional ability and level of safety*, for purposes of this section includes, at a minimum, assessment of the following topics:

++ Hearing impairment;

++ Ability to successfully perform activities of daily living;
++ Fall risk;
++ Home safety.

Comment: One commenter asked CMS to add "assessment of level of support" to the proposed definition of "review of the individual's functional ability and level of safety" to recognize that the availability of a caregiver is an important indication of a beneficiary's ability to function and of their level of safety.

Response: We agree that family caregivers play an important role in the lives of the individuals they care for and support. However, we believe that the term as defined in the proposed rule is flexible enough to include a discussion of the availability of a caregiver as part of the review of functional ability and level of safety, if determined appropriate by the health professional furnishing the AWW. Therefore, we are not adopting this public comment and are adopting the definition as proposed.

• *Health professional*, for purposes of this section means:

++ A physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); or

++ A practitioner as described in clause (i) of section 1842(b)(18)(C) of the Act, that is, a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act); or

++ A medical professional (including a health educator, registered dietitian, or nutritionist) or a team of medical professionals, who are working under the supervision of a physician as defined in this definition.

Comment: A number of commenters requested clarification of specific elements of the definition of the term "health professional" and offered specific suggestions for revisions that might be made in the definition in the final rule. One commenter suggested that section 4103 of the ACA provided that the AWW could be performed by a health professional or a team of health professionals such as a registered nurse that works under the supervision of a physician. When registered nurses or other medical professionals who are not Medicare-recognized providers or practitioners perform the AWW under the supervision of a physician, the commenter assumes that the visit "would be billed by the supervising physician who may or may not see the patient during the visit." The commenter believed that because the AWW has its own benefit category then Medicare payments would not fall under the "incident to" benefit (section

1861(s)(2)(B) of the Act and the "incident to" criteria would not need to be met.

Response: We agree with the commenter that the AWW has its own benefit category as provided in section 1861(s)(2)(FF) and section 1861(hhh) of the Act and, therefore, is not subject to the "incident to" rules. The commenter is also correct that our intent is that where the wellness visit is performed by a "team of medical professionals working under the supervision of a physician" it is the supervising physician who would bill Medicare Part B for the visit. In this final rule, we are clarifying that the visit would be furnished under the "direct supervision" (as defined in 42 CFR 410.32(b)(3)(ii)), of a physician (as defined in paragraph (i) of this definition). Direct supervision in the office setting means that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. In response to the public comment, we are amending the definition of the term "health professional" in the final rule to read in paragraph (iii) as follows:

"A medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner or a team of such medical professionals, working under the direct supervision (as defined in 42 CFR 410.32(b)(3)(ii)) of a physician as defined in paragraph (i) of this definition."

Comment: A commenter asserted that the definition of "health professional" should recognize other potential members of the team beyond those listed in the examples in the statute. The commenter recommends that CMS "specify who may or should be a part of the team and should define 'medical professional' as licensed health practitioners whose services are specifically covered and regulated by Medicare. Otherwise, in the commenter's view, paraprofessionals, non-licensed providers or others may be inappropriately used as part of the team. The commenter supported the requirement "that the team should be directed by a physician," but believes "CMS should provide some standards for the members of the team as a protection for consumers and to assure that funding for this visit will be spent on authentic, appropriate and regulated services." The commenter also suggested that occupational therapists be specifically included as a potential component of the team.

Another commenter asked CMS to clarify "how the required tasks in the visit will be performed and how care coordination will occur among the eligible medical professionals and/or team that provides the AWW."

Response: While we appreciate the commenters' concerns, we are not assigning particular tasks or restrictions for specific members of the team in this final rule. We believe it is better for the supervising physician to assign specific tasks to qualified team members (as long as they are licensed in the State and working within their state scope of practice). This approach gives the physicians and the team the flexibility needed to address the beneficiary's particular needs on a particular day. It also empowers the physician to determine whether specific medical professionals (such as occupational therapists) who will be working on his or her wellness team are needed on a particular day. The physician is able to determine the coordination of various team members during the AWW.

Comment: One commenter urged CMS to revise its proposed definition of "Health professional" to include the phrase "practicing in any particular patient care setting." The commenter believed that this clarification is needed to "encourage retail based practitioners to provide these services, thereby making this benefit more appealing for patients." The commenter suggested that "retail based health practitioners are uniquely positioned to ensure the optimal utilization of this new benefit."

Response: Although we are interested in encouraging the maximum use of the AWW and encourage all of the health professionals listed in section 1861(hhh)(3) of the Act that are qualified to furnish this service to participate in providing this part B service, we are not adopting the commenter's suggestion to include the phrase "practicing in any particular patient care setting." This particular phrase is not used in section 1861(hhh)(3) of the Act, which instead references specific health professionals that may furnish the AWW without regard to a particular physical location. Moreover, we note that the phrase "any particular patient care setting" is ambiguous, and may in fact unintentionally narrow the availability of the benefit or raise unnecessary questions regarding the setting. Therefore, we are not adopting the commenter's suggested revision of that definition to include language on specific patient care settings.

Comment: One commenter noted that certified nurse-midwives (CNMs) are not specifically mentioned in the ACA

as it relates to the AWW, though nurse practitioners and clinical nurse specialists are enumerated among practitioners eligible to participate. The commenter requested that CMS review the education, background and scope of practice services under the Medicare program and ensure that CNMs are clearly eligible to provide the Medicare AWW.

Response: Congress defined the term "health professional" as including certain practitioners "described in clause (i) of section 1842(b)(18)(C)" of the Act. Clause (i) specifically includes physician assistants (PAs), nurse practitioners (NPs) and clinical nurse specialists. CNMs, in contrast, are identified in clause (iii) of 1842(b)(18)(C) of the Act. Given the specificity of the cross-reference to only clause (i), we presume that Congress acted intentionally by not including a reference to clause (iii). Thus, we believe additional legislation would be needed to recognize CNMs as a "health professional" under this section. However, we note, that it is possible that a CNM could be chosen by a physician as a member of the team of professionals under the physician's supervision.

Comment: One commenter requested that CMS clarify the language of the proposed rule in the definition of "medical professional" in § 410.31(a). Section 4103 of the ACA uses the terms "registered dietitian" or "nutrition professional" in its definition of "medical professional" eligible to be involved in the AWW. The proposed rule used the term "nutritionist" instead of "nutrition professional." The commenter asks CMS to replace the term "nutritionist" with "nutrition professional" in § 410.15(a).

Response: We agree with the commenter and we are replacing the term "nutritionist" with the term "nutrition professional" in § 410.15(a) of the final rule, which is consistent with the language used in section 4103 of the ACA.

Comment: One commenter is concerned about the CMS proposal to require the term "physician" for purposes of the definition of "health professional" to be either a doctor of medicine or a doctor of osteopathy as defined in section 1861(r)(1) of the Act. The commenter suggests that we use the full definition of a "physician as defined in section 1861(r) of the Act.

Response: Section 4103 of the ACA does not specifically define what type of physician is eligible for performing or supervising the team of health professionals who will be performing or supervising the AWW. In developing the

proposed rule, we considered the various types of physicians that are identified in section 1861(r)(2), (r)(3), (r)(4), and (r)(5) of the Act. These include doctors of dental surgery, doctors of podiatric medicine, doctors of optometry, and chiropractors, whose scope of medical practice is generally limited by State law to a particular part (or parts) of the human anatomy. Given the State licensing restrictions, some individuals who are physicians for certain limited purposes under section 1861(r) of the Act could exceed their scope of practice if they attempted to furnish the AWW. Based on this information, we are leaving the definition of a physician unchanged in the final rule.

• *Establishment of, or an update to the individual's medical and family history,* for purposes of this section, means, at minimum, the collection and documentation of the following:

++ Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

++ Use or exposure to medications and supplements, including calcium and vitamins.

++ Medical events experienced by the beneficiary's parents and any siblings and children, including diseases that may be hereditary or place the individual at increased risk.

Comment: A number of commenters requested that additional items be included in the definition of the term "Establishment of, or an update to the individual's medical and family history," such as tobacco use, sexual history, history and results of pelvic exams, and falls history.

Response: Our proposed definition at § 410.15(a) was not intended to establish an exhaustive list of the elements of an individual's medical and family history. We included the phrase "at minimum" to reflect that the listed criteria represent a floor and not a ceiling on the items included in the medical and family history. We agree that the items of additional information identified by the commenters are relevant and could be included in the medical and family history that is maintained by the health professional for the Medicare beneficiary. However, we believe that the term as defined in the proposed rule is flexible enough to encompass the additional items requested by the commenters. Therefore, we are not adopting the commenters' specific language and are implementing the proposed definition in this final rule.

• *Eligible beneficiary,* for purposes of this section, means an individual who is no longer within 12 months after the

effective date of his or her first Medicare Part B coverage period, and has not received either an initial preventive physical examination or an AWW providing a personalized prevention plan within the past 12 months.

Comment: Several commenters suggested that CMS misinterpreted the eligibility criteria for the AWW and its relationship to the one-time initial preventive physical examination defined in section 1861(w)(1) of the Act, which is only covered during the first 12 months after a beneficiary's enrollment in Medicare Part B takes effect.

In suggesting that CMS' proposed definition was inappropriate, one commenter pointed to statutory language that states: "A beneficiary shall only be eligible to receive an initial preventive physical examination (as defined under subsection (ww)(1)) at any time during the 12-month period after the date that the beneficiary's coverage begins under Part B and shall be eligible to receive personalized prevention plan services under this subsection provided that the beneficiary has not received such services within the preceding 12 month period." The commenter argued that this language intends either an initial preventive physical examination or an AWW to be available during the 12-month period after an individual's Part B coverage begins provided the individual has not received either service within the preceding 12-months. To further bolster this argument, the commenter points to clause (ii) of paragraph (G) directing the Secretary to "establish procedures to make beneficiaries aware of the option to select an initial preventive physical examination or personalized prevention plan services during the period of 12-months after the date that a beneficiary's coverage begins under Part B, which shall include information regarding any relevant differences between such services."

Response: The statutory text cited by the commenter fails to reflect a later Congressional amendment. Specifically, Congress replaced the language of paragraph (G) by section 10402(b) of the ACA. That amendment replaced the text cited by the commenter so that the version of paragraph (G) that was enacted into law reads: "A beneficiary shall be eligible to receive only an initial preventive physical examination (as defined under subsection (ww)(1)) during the 12-month period after the date that the beneficiary's coverage begins under Part B and shall be eligible to receive personalized prevention plan services under this subsection each year thereafter provided that the beneficiary

has not received either an initial preventive physical examination or personalized prevention plan services within the preceding 12-month period."

This amendment clarifies that only an initial preventive physical examination is covered during the 12-month period after an individual's Part B coverage begins, and that coverage of the new AWWs begins during the individual's second year of Part B coverage. In other words, they were intended to be sequential, not concurrent, benefits. We believe the proposed definition of "eligible beneficiary" included in the proposed rule correctly implements this aspect of sections 4103 and 10402(b) of the ACA. Therefore, we are finalizing the proposed definition without accepting the commenters' suggestion.

(2) Requirements of the First Annual Wellness Visit Providing Personalized Prevention Plan Services

We proposed that the first AWW providing personalized prevention plan services for purposes of this benefit include the following:

- Establishment of an individual's medical and family history.
- Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.
- Measurement of an individual's height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the individual's medical and family history.
- Detection of any cognitive impairment that the individual may have.
- Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional as defined in this section may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in this section may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by

national professional medical organizations.

• Establishment of the following:
 ++ A written screening schedule, such as a checklist, for the next 5 to 10 years as appropriate, based on recommendations of the USPSTF and the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered by Medicare.

++ A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under § 410.16), and a list of treatment options and their associated risks and benefits.

• Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

• Any other element determined appropriate through the National Coverage Determination process.

Comment: A number of commenters were supportive of the proposal to use the national coverage determination process and rely on the USPSTF recommendations in developing the definitions of the first and subsequent AWW definitions, along with the addition of any other elements in the future, since the services need to be based on evidence. One commenter suggested that CMS publish a notice in the **Federal Register** about consideration of other preventive services via the NCD process. The commenter expressed concern that many groups and members of the public were more familiar with the regulatory notification process than the NCD process.

Response: We appreciate the commenter's concerns regarding receiving timely information about topics that CMS is considering for coverage of preventive services via the NCD process. As discussed in the preamble, the NCD process is an evidence-based, transparent process and furnishes the opportunity for public comment, and is described in section 1862(l) of the Act. The CMS Web site at http://www.cms.gov/mcd/index_list.asp?list_type=nca contains a

list of all national coverage analyses that are currently under consideration. Those interested in receiving information via e-mail regarding national coverage analyses under consideration can sign up to receive e-mail notifications via the CMS coverage listserv at <http://www.cms.gov/InfoExchange/>

[03_listserv.asp#TopOfPage](#). Given the relatively fast timeline described in section 1862(l) of the Act, we do not believe it is feasible to add a requirement for publication of a notice in the **Federal Register** whenever an NCD is opened. Therefore, we are not adopting the public comment. Please note that we do publish a listing in the **Federal Register** of all NCDs that are issued. This information is included in the quarterly notice issued pursuant to section 1871(c) of the Act.

Comment: Several commenters noted that we did not include the health risk assessment (HRA) in our proposal that section 4103 of the ACA ultimately requires to be part of the AWW. Several of these commenters strongly supported the CMS approach of not immediately implementing the HRA requirement on January 1, 2011. Some commenters noted that a separate ACA provision also concerns the establishment of an HRA, but used later deadlines. Specifically, section 1861(hhh)(4)(A) of the Act requires consultation to develop publically available guidelines for HRAs by March 23, 2011. One commenter noted that "the relative recent enactment of the Affordable Care Act provided CMS little time to establish standard processes related to a health risk assessment (HRA)." Another commenter stressed the need for a standardized HRA model or models that is/are recognized and accepted nationally. Another commenter urged us to act as expeditiously as possible in a consultative way by directly engaging the major medical organizations and stakeholders who represent physicians and other clinicians who see Medicare beneficiaries. One commenter recommended that the "HRA program should also be pilot-tested before widely imposed to determine such critical factors as the effectiveness of the guidelines and the administrative burden imposed on the physicians."

However, other commenters expressed the view that the HRA is such a fundamental element of the new AWW that it should be added to the final rule and required beginning January 1, 2011. One commenter indicated that the absence of an HRA "will delay the opportunity to improve beneficiaries' health and to control costs as a result. We believe that the HRA is the lynchpin

that makes the wellness visit more than another office visit and should be included as a required element beginning January 1, 2011." Several of these commenters suggested that CMS should rely on the National Committee for Quality Assurance (NCQA) certification process, the Utilization Review Accreditation Committee (URAC) accreditation process, or another certification process that already exists effective January 1, 2011, at least as an interim measure.

Response: We agree with commenters that the HRA is an important part of the AWW and we are working to fully implement this relevant provision of the ACA. However, because the statute has specified a time frame and procedures that require consultation with relevant groups and entities prior to publication of the required HRA guidelines, it is not possible to complete those procedures by January 1, 2011. Moreover, we do not believe it would be prudent to mandate an interim HRA without completing the consultation process that Congress has specifically required. The point of the consultation is to achieve a greater national consensus on the HRA to be used. As one of the large physician specialty groups has noted during the public comment period, a standardized HRA is needed to "ensure use of appropriate and robust HRA from a marketplace where considerable variation exists today." We agree with this commenter that what is needed is an HRA "that has been standardized by the Department of Health and Human Services." The development of an evidence-based, standardized model, nonetheless requires extensive work and input from a number of public agencies, professional societies and private organizations. It is important to carefully complete that process so that the evidence-based standard will have a sound scientific foundation and broad acceptance.

Consistent with the statutory deadlines, and one commenter's suggestion "that the Secretary of HHS expedite the development of a standardized HRA," CMS is collaborating with the Centers for Disease Control and Prevention (CDC) which is directed by section 4004(f) of the ACA to develop a personalized prevention plan tool and has an in-depth knowledge of HRAs. We understand that CDC is planning to convene an open scientific meeting in Atlanta at the beginning of 2011 to facilitate that development. This meeting should allow broad public input into the development of an evidence-based standardized HRA, as recommended by the American Medical

Association (AMA) which urged "CMS to continue to develop the HRA guidelines, in consultation with the AMA and other relevant stakeholders representing physicians," and the American College of Physicians (ACP) which recommended "that the agency engage directly with the most relevant stakeholders * * * to ensure that the HRA fulfills the vital role of promoting optimal preventive care and related interventions envisioned by the ACA." CMS has also commissioned a technology assessment from the Agency for Healthcare Research and Quality (AHRQ) to be completed by the end of 2010 that will help in the development of the HRA guidelines and model.

While commenters have suggested that we require the use of one or more currently available assessment tools until an evidence-based standardized model is available, we believe it would be premature and inefficient to make such a recommendation at this time without adequate scientific review and broader stakeholder input. As noted in the proposed rule, HRA guidelines and standards are being developed by the CDC and when a model HRA instrument is available and determined by the Secretary to be appropriate for the use of Medicare beneficiaries, we will revise these regulations to include the HRA as an element in the definition of the AWW.

Comment: Several comments expressed concern that there were too many required elements in the definition of the "First annual wellness visit" and that the definition should be modified so that some of the elements are discretionary based on an individual's medical history or the results of an HRA and one suggested that CMS should "clarify the role that the HRA care plan plays in addressing these elements as a prelude to the office visit." This commenter noted that the proposed CMS definition "assumes that the physician does not already know the patient's medical and family history or other providers and suppliers involved in the patient's care" which may not always be the case.

One commenter stated that the AWW "is supposed to deliver a service tailored to the specific needs of the patient based on some combination of the HRA results, medical history, and practitioner expertise. Some elements could be required for every patient because the level of appropriateness does not vary much from patient to patient based on age, gender, and other factors. However, there are some elements the need for which varies greatly from patient to patient and even over time." This commenter

recommended "that CMS add general language stating that certain elements can be addressed, at least to some degree, as part of the HRA."

Response: We agree that a physician's or other health professional's need to include certain elements of the AWV may vary with the professional's knowledge of the individual's medical and family history and, in particular, with the results of an HRA, if available. However, until HRA guidelines have been developed and a standardized HRA model or models has/have been recognized and accepted nationally by the Secretary for use by Medicare beneficiaries, we do not believe it is appropriate to include more flexibility or alternatives to the proposed elements of the first wellness visit. Therefore, we are leaving the proposed elements (i) through (viii) of the definition of the first AWV unchanged in this final rule.

(3) Requirements of Subsequent Annual Wellness Visits Providing Personalized Prevention Plan Services

We proposed that subsequent AWVs providing personalized prevention plan services for purposes of this benefit include the following:

- An update of the individual's medical and family history.
- An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual, as that list was developed for the first AWV providing personalized prevention plan services.
- Measurement of an individual's weight (or waist circumference), blood pressure, and other routine measurements as deemed appropriate, based on the individual's medical and family history.
- Detection of any cognitive impairment, as that term is defined in this section, that the individual may have.
- An update to both of the following:
 - ++ The written screening schedule for the individual as that schedule was developed at the first AWV providing personalized prevention plan services.
 - ++ The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are under way for the individual as that list was developed at the first AWV providing personalized prevention plan services.
- Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of this section.

- Any other element determined through the NCD process.

We proposed that body-mass index (BMI) should be calculated at the first AWV and may be recalculated at subsequent AWVs, if indicated. Given the general stability of adult height, we would not expect the BMI to meaningfully change in the absence of significant weight change. In the proposed rule, we did not require measurement of the individual's height in the subsequent annual visit.

We proposed to add two distinct elements to the definition of the first AWV only: Depression screening and functional status and level of safety assessment. Our review of the medical literature and the USPSTF recommendations indicates that the optimum frequency for those services is unknown. In the proposed rule, we stated we believe it would be premature and beyond the current evidence to require depression screening and functional status assessment included in the definition of subsequent visits, but they may be performed at these visits, if indicated.

Comment: A number of commenters expressed concern that the proposed definition of the term "Subsequent annual wellness visit * * *" did not include the depression screening and the functional ability and level of safety screening, elements (v) and (vi), respectively, that were included in the proposed definition of the term "First annual wellness visit." One commenter noted that "while the USPSTF states that the optimal interval for screening is unknown, it does recognize that recurrent screening may be needed for certain patients." At a minimum, the commenter suggested that "the regulations should require additional screening for depression after new chronic conditions are diagnosed and when reduction in functioning is noted." The commenter also indicated that yearly screening for functional ability and level of safety "is important to determine changes in functional impairments identified in previous screening as well as any new limitations. Such screening will assist in determining care plans, further assessments, and other services to allow a beneficiary to remain in the community as long as possible."

Response: We agree that depression screening in older adults is important. We have reviewed the USPSTF guidelines (<http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addepr.htm>) and have decided not to include it as a required element for subsequent AWVs largely since the USPSTF states that "the

optimum interval for screening for depression is unknown." In addition, the USPSTF only recommends depression screening "when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up." It is unclear if these supports are universally available in physician offices to allow adequate routine screening at the AWV. The USPSTF further notes: "recurrent screening may be most productive in patients with a history of depression, unexplained somatic symptoms, comorbid psychological conditions (for example, panic disorder or generalized anxiety), substance abuse, or chronic pain." If an individual is determined to be in this category from prior screening, such as at the IPPE or through an HRA, then it would appear appropriate on an individual basis to continue screening and to tailor the AWV based on risk.

Regarding functional ability and safety, we agree that for certain individuals, functional status and safety assessments (for example, fall prevention) may be important to consider on a more routine basis. For the general Medicare population, there are no A or B recommendations by the USPSTF in these areas and thus we have decided not to add functional status and safety assessments as universally required elements for the subsequent AWV. The AWV does allow for an individualized approach with a personalized prevention plan. For certain individuals where these areas are determined to be priorities, specific evaluations may be voluntary parts of subsequent visits. Since we closely monitor the USPSTF recommendations for updates or changes, if specific new or revised recommendations come out in the future, we may consider modifications at that time.

Comment: Several commenters requested that we add additional screening elements to the first and subsequent AWVs regarding: (1) Alcohol use status; (2) Tobacco use or other substance use status; (3) Sexual health and incontinence; (4) Physical activity level; (5) Risk of falls; (6) Nutrition status including under nutrition and/or malnutrition; (7) Vision and eye health; (8) an assessment for osteoarthritis; and (9) assessment of gait and balance.

Response: We appreciate the suggestions provided. The intent of the proposed definition for "establishment of, or an update to the individual's medical and family history" means at a minimum the collection and documentation of the information outlined in the proposed definition of this term. Additional items like those

suggested by the commenters can be identified and discussed as part of the establishment of, or an update to the individual's medical and family history. We do not believe that it is necessary to outline an exhaustive list of various items that may be included in the definition. We believe that physical activity level and risk of falls are adequately addressed in the definition of "review of the individual's functional ability and level of safety".

We recognize that the health professional (or supervising physician in the case of a team of medical professionals) furnishing the AWW is qualified and would be able to determine the specific additional information that needs to be discussed in order to establish a comprehensive medical and family history and provide the best care possible for the individual.

In the future, as the medical science continues to evolve, CMS may consider adding other elements to the first and subsequent AWWs through use of the national coverage determination process, if considered appropriate.

Comment: One commenter requested that the first and subsequent AWWs include a detailed current medications and supplements list as part of the individual's medical and family history.

Response: We agree that medications and supplements such as vitamins and calcium are an important part of an individual's medical and family history. We included in the proposed definition of the "Establishment of, or an update to the individual's medical and family history" provisions for the collection and documentation of use or exposure to medications and supplements, including calcium and vitamins. We believe the information included in the definition addresses the commenter's concerns and, therefore, we are implementing element (i) of the first AWW and element (i) of the subsequent AWW, as proposed, in this final rule.

Comment: One commenter suggested that measurement of BMI be viewed as a vital sign that should be included in both the first and subsequent AWWs.

Response: We explained in the preamble to the proposed rule that "body mass index (BMI) should be calculated at the first AWW and may be recalculated at subsequent visits if indicated. Given the general stability of adult height, we would not expect the BMI to meaningfully change in the absence of significant weight change, and therefore we are not requiring measurement of the individual's height during subsequent AWWs. Accordingly, in this final rule, we are not adding the BMI requirement to the subsequent AWW.

Comment: Several commenters suggested CMS should specify in the final rule that an individual's family history of various diseases, obesity, or risk factors for a disease such as diabetes should be included in the list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended for an individual as described in element (vii)(B) of the first AWW and element (v)(B) of the subsequent AWW.

Response: We agree that the risk factors and conditions identified by the commenters should be reflected in the list of risk factors referenced in element (vii)(B) of the first AWW and element (v)(B) of the subsequent AWW for possible referral if the individual's health professional determines that it is appropriate to do so, based on the information obtained during the first and/or subsequent AWW. Therefore, we believe no additional changes to the description of "individual's medical and family history" as part of the elements of the first and subsequent AWWs are in order.

Comment: We received a number of comments from physicians, health care providers, and others urging us to add voluntary advance care planning as an element to the definitions of both the "first annual wellness visit" and the "subsequent annual wellness visit." They base their recommendation upon a number of recent research studies, and the inclusion by statute of a similar element in the existing initial preventive physical examination (IPPE) benefit. One commenter noted that "the new wellness visit was wisely designed to build on the initial preventive physical exam, providing an ongoing, systematic focus on wellness and prevention by harmonizing Medicare services into a coordinated benefit." Another commenter stated that "the AWW provides an appropriate setting for providers to initiate voluntary conversations about future care wishes, as they counsel beneficiaries on other aspects of their health and achieving their personal health goals." The commenter added that the "care plans discussed in the 'Welcome to Medicare visit' should not be frozen in time, but revisited as an important component of patient wellness."

Response: We agree that voluntary advance care planning should be added as an element of the definitions of both the "first annual wellness visit" and the "subsequent annual wellness visit" based on the evidence described below, and the inclusion of a similar element in the IPPE benefit (also referred to as the Welcome to Medicare visit), since January 1, 2009. We believe that this

will help the physician to better align the personal prevention plan services with the patient's personal priorities and goals.

Recently, Detering and colleagues (British Medical Journal 2010; 340:c1345) reported that "advance care planning improves end of life care and patient and family satisfaction and reduces stress, anxiety, and depression in surviving relatives." Silveira and colleagues (New England Journal of Medicine 2010; 362:1211-8) reported that "data suggest that most elderly patients would welcome these discussions." Lastly, a study by Fischer and colleagues (Journal of the American Geriatric Society 2010; 58:400-401) found "no evidence that these (advance directive) discussions or completing an advance directive lead to harm."

Based on the available evidence and other relevant information, we are adding to the final regulation a definition of the term "voluntary advance care planning" to read as follows:

"Voluntary advance care planning" means, for purposes of this section, verbal or written information regarding the following areas:

(1) An individual's ability to prepare an advance directive in the case where an injury or illness causes the individual to be unable to make health care decisions.

(2) Whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

This definition is based on the definition of "end-of-life planning", which is included as an element of the IPPE as described in section 1861(w)(3) of the Act. Thus, the addition of "voluntary advance care planning" to the AWWs extends to those visits a similar element to the one already in the one-time IPPE.

We are also revising the definitions of the terms "First annual wellness visit" and "Subsequent annual wellness visit" by inserting a new element (ix) to the definition of the term "first annual wellness visit" and a new element (vii) to the definition of the term "subsequent annual wellness visit" in § 410.15 (a) of the final regulation text that would read as follows: "Voluntary advance care planning as that term is defined in this section upon agreement with the individual."

Comment: Commenters requested that we specifically require that certain referrals for various services be included as part of the personalized prevention plan including: (1) Community-based and other lifestyle management services; (2) kidney disease education services; (3) urogynecologist visits to discuss

incontinence issues; and (4) tobacco use cessation counseling and related services.

Response: In the proposed rule, the definition for the first AWW included provisions for the furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition. Under the definition of the subsequent AWW, we included provisions for furnishing of personalized health advice to the individual and a referral as appropriate, to health education or preventive counseling services.

We believe that the health professionals who are furnishing the AWWs whether they be first or subsequent visits are the most qualified to determine an appropriate list of referrals for education services and preventive counseling services for each individual. We believe that the proposed definitions for the first and subsequent AWWs address commenters' concerns regarding community-based and lifestyle management services, kidney disease education services, referrals to further discuss treatment for incontinence issues, and tobacco use cessation counseling services.

Comment: One commenter suggested that CMS require the identification of a family caregiver that provides care for and supports a beneficiary with chronic conditions. The commenter states that "it is vitally important for medical professionals to know whether the beneficiary has a family caregiver or has a family member/friend who will fill that role."

Response: We appreciate the role that family caregivers provide in the lives of individuals with chronic conditions. We expect that the identification of a family care giver will be addressed when the health professional furnishing the AWW discusses the patient's ability to successfully perform activities of daily living. However, we do not believe the identification of a caregiver should be required of beneficiaries who wish to take advantage of AWWs so we are not requiring such identification in the final rule.

Comment: Several commenters suggested that CMS use its authority under section 4105 of the ACA to expand Medicare coverage of certain preventive services that are already available under Part B such as screening for abdominal aortic aneurysms, HIV screening, colorectal cancer screening, breast cancer screening

(mammography), and counseling/intensive behavioral (nutrition) counseling in accordance with the USPSTF recommendations for these services. Other commenters suggested using this authority to expand Medicare Part B coverage for preventive immunizations to include vaccinations such as herpes zoster and tetanus shots, which are currently covered under Part D in accordance with the recommendations of the Advisory Committee on Immunizations Practices (ACIP) for adults age 65 and older.

Response: We appreciate the commenters' support for expanded coverage of preventive services under the Part B program. Section 4105 of the ACA grants the Secretary the authority to modify or eliminate coverage of certain preventive services that are already available to certain beneficiaries to the extent that such modification or elimination of coverage is consistent with the recommendations of the USPSTF. Many of the items requested (including coverage of ultrasound screening for abdominal aortic aneurysms, medical nutrition therapy, certain colorectal cancer screening tests, and mammography) are already recognized as "preventive services" in section 1861(w)(2) of the Act. Because those items are already covered by Medicare, we will need to further evaluate whether coverage for those items or services should be modified in light of the specific grades of the USPSTF as permitted under section 4105 of the ACA. Due to the complexities of considering whether to modify or eliminate coverage of certain preventive services under Medicare Part B, we decided not to address this subject in the proposed rule, which focuses instead on implementation of section 4103 and 4104 of the ACA.

We note that we may consider other expansions in Medicare coverage for "additional preventive services" in the future through section 1861(ddd)(1) of the Act. Under the "additional preventive service" statute, however, the recommendations of the Advisory Committee on Immunizations Practices (ACIP) alone do not provide a basis for expanded coverage. Additional information regarding Medicare coverage for additional preventive services can be found in the *Federal Register* (November 19, 2008, (73 FR 69869 through 69870 and 69933)) and § 410.64. We will continue to monitor the USPSTF recommendations for updates or changes, and when appropriate, consider possible coverage through the NCD process. We also note that individuals can request a NCD using the procedures set forth in our

Guidance Document: "Factors CMS Considers in Opening a National Coverage Determination," available at http://www.cms.gov/mcd/npcp_view_document.asp?id=6. We also note that the Secretary has exercised the authority granted by section 1861(ddd)(1) of the Act to add coverage under Part B of "additional preventive services" such as HIV screening for individuals at high risk consistent with the USPSTF recommendations. Since many of the items that the commenters requested are already covered as "preventive services" or "additional preventive services," we are not making any changes based on these comments at the present time. We will continue to monitor access to these preventive services and may exercise the authority granted by section 4105 of the ACA in the future.

Comment: A commenter requested CMS to "consider whether there are opportunities to leverage its 'coverage with evidence development' process to help build the evidence base for new preventive services." The commenter further suggested CMS "review those preventive services with a USPSTF grade of 'I' ('insufficient evidence to recommend for or against') and consider the development of a 'coverage with evidence development' initiative to help generate the data needed to fully assess certain preventive services" via partnerships with other federal agencies.

Response: We are interested in increasing the evidence base concerning new preventive services. We will need to further consider whether the CED process could be used for items or services that currently are rated with an "I." We note that under § 410.64 of these regulations, an "additional preventive service" must have a grade of A or B recommendation by the USPSTF. Because this suggestion will require further study, we are not making any changes to our final rule at this time.

Comment: Several commenters provided suggestions for continuing education and outreach regarding issues related to the new AWW. One commenter asked that we educate providers about evidence based recommendations for colorectal cancer screening and monitor adherence to guidelines via performance measures. Another commenter requested education and outreach materials regarding the AWW and materials that also explain the differences between the initial preventive physical examination and the new AWW. An additional commenter requested that we inform patients of the importance of preventive services including colorectal cancer

screening options (colonoscopy, sigmoidoscopy, and fecal occult blood tests).

Response: We agree that it is important to raise awareness concerning the expanded Medicare coverage provided under the ACA. We will issue appropriate manual instructions and other educational information to the Medicare providers and beneficiaries, including an MLN Matters article (Medicare Learning Network) and information in the 2011 Medicare and You Handbook regarding implementation of the new AWW benefit.

Comment: One commenter recommended that we eliminate the initial preventive physical examination since it is similar to the provisions of the new AWW.

Response: We appreciate the attention being drawn to the similarity between the initial preventive physical examination and the new AWW. While we did model some of the elements of the new AWW after elements in the initial preventive physical exam, we note that these statutory provisions are separate and distinct benefits and that Medicare beneficiaries will be eligible to receive both of these benefits in sequence if the appropriate regulatory requirements are met.

In summary, as a result of the comments received, we are making the following changes in this final rule:

- We are amending the definition of the term "health professionals" to read in paragraph (iii) as follows: "A medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner or a team of such medical professionals, working under the direct supervision (as defined in § 410.32(b)(3)(ii)) of a physician as defined in paragraph (i) of this definition."

- We are adding to the final regulation the definition of the term "voluntary advance care planning" to read as follows:

"Voluntary Advance care planning" means, for purposes of this section, verbal or written information regarding the following areas:

- (1) An individual's ability to prepare an advance directive in the case where an injury or illness causes the individual to be unable to make health care decisions.

- (2) Whether or not the physician is willing to follow the individual's wishes, as expressed in an advance directive.

- We are also revising the definitions of the terms "First AWW" and "Subsequent AWW" by inserting a new

element (ix) to the definition of the term "first AWW" and a new element (vii) to the definition of the term "subsequent AWW" in § 410.15(a) of the final regulation text that would read as follows: "Voluntary advance care planning as that term is defined in this section upon agreement with the individual."

3. Payment for the Annual Wellness Visit Providing Personalized Prevention Plan Services (PPPS)

Section 4103 of the ACA created a new benefit for an "annual wellness visit" (AWV) with personalized prevention plan services. The ACA amended section 1861(s)(2) of the Act by adding a new subparagraph (FF) to provide for coverage of the AWW beginning January 1, 2011. Section 4103 of the ACA also added new subsection (hhh) to section 1861 of the Act to define "personalized prevention plan services" and to specify who may furnish these services. Finally, section 4103 of the ACA amended section 1848(j)(3) of the Act and provided for payment of AWWs under the PFS, and specifically excluded the AWW from the hospital OPSS. Therefore, a single payment under the PFS would be made when an AWW is furnished by a physician, physician assistant, nurse practitioner, or clinical nurse specialist, or by a medical professional or team of medical professionals, as determined appropriate by the Secretary, under the supervision of a physician.

To allow for Medicare reporting and payment of the AWW, we proposed to create two new HCPCS G-codes for reporting the first wellness visit and creation of a personalized prevention plan and the subsequent visits available to the beneficiary every 12 months. Specifically, we proposed to establish the following two new HCPCS codes for CY 2011: GXXXXA (AWV; includes a personalized prevention plan of service (PPPS), first visit) and GXXXXB (AWV; includes a personalized prevention plan of service (PPPS), subsequent visit). A beneficiary's first AWW to any practitioner would be reported to Medicare under HCPCS code GXXXXA, even if the beneficiary had previously received an initial preventive physical examination (IPPE) that was covered by Medicare. Beneficiaries, in their first 12 months of Part B coverage, would continue to be eligible only for an IPPE. After the first 12 months of Part B coverage, on or after January 1, 2011, beneficiaries would be eligible for an AWW described by HCPCS code GXXXXA or GXXXXB, provided that the beneficiary has not received an IPPE or AWW within the preceding 12-month period.

Comment: Several commenters noted that the IPPE and the first AWW are very similar services with significant overlap. These commenters urged CMS not to develop a separate coding structure for the first AWW as it would be a burden for practitioners to review and determine the specific preventive service the beneficiary is eligible for on a given date. In addition, the commenters noted that a delay in information being available through the Common Working File (CWF) may cause practitioners to inaccurately determine a beneficiary's eligibility for a particular service, be it the IPPE, the first AWW, or a subsequent AWW. One commenter requested that CMS clarify that a beneficiary may choose either an IPPE or a first AWW during the beneficiary's first 12 months of Part B coverage.

Response: The set of services described by the IPPE is very specific and while the services contained in the IPPE may be similar to the services included in the AWW, these are two separate benefits under Medicare. Just as there are component services specified for the IPPE, there are component services specified for the AWW. Moreover, according to section 1861(hhh)(4)(G) of the Act (as added by section 4103(b) of the ACA), a beneficiary is eligible only for the IPPE during the 12-month period after the date the beneficiary's coverage begins under Part B and is only eligible for the AWW each year thereafter. Therefore, in order to be able to identify the particular benefit and services furnished to a beneficiary and ensure coverage of the services, we believe that we must distinguish between the IPPE and the AWW through the use of distinct HCPCS codes. We understand that there may be instances where practitioners may experience a delay in the information available through the CWF, but we expect the situations where this would affect the services furnished (and subsequently billed) by a practitioner would be uncommon. The CWF will reflect the beneficiary's eligibility for the IPPE or first or subsequent AWW based on all claims submitted to date to the Medicare contractors. Only under the limited circumstances where a practitioner previously furnished an IPPE or AWW to the beneficiary but had not yet submitted the claim to Medicare would a practitioner inaccurately determine a beneficiary's eligibility for the IPPE or first or subsequent AWW.

Comment: Several commenters urged CMS to recognize the CPT codes in the Preventive Medicine Services series, ranging from 99381 (Initial comprehensive preventive medicine

evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; infant (age younger than 1 year) through 99397 (Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; 65 years and older), for reporting and payment of the AWW, rather than creating the two new HCPCS G-codes as proposed. The commenters noted that the practitioner could report the appropriate CPT code based on the beneficiary's age and new or established patient status, allowing specific reporting of the AWW with a CPT code that would result in appropriate payment for the service provided to the beneficiary. In addition, the commenters urged CMS to use the existing CPT Editorial Panel and the AMA RUCs process to modify these existing codes so they would be applicable for AWW services.

Response: Prior to the establishment of the IPPE benefit, Preventive Medicine Services CPT codes in the range from 99381 through 99397 were excluded from Medicare coverage because preventive medicine evaluation and management services were noncovered by Medicare. When the IPPE benefit was implemented, we created HCPCS code G0402 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment) as we have specifically defined through the regulatory process the elements that are required for this service to be billed and paid by Medicare. We refer readers to the Medicare Claims Processing Manual, Pub. 100-04, chapter 18, section 80 for additional information regarding the components of the IPPE. When implementing the IPPE, we recognized that CPT codes describing preventive services were available, but we did not believe it was appropriate to use these existing CPT codes for the IPPE, given the general nature of the services they describe in contrast to the specific nature of the IPPE service.

Similarly, in section VI.Q.2. of this final rule with comment period, we have adopted the final specific components of the AWW for CY 2011, consistent with the statutory requirements for the service. While we acknowledge that the elements of the

preventive medicine evaluation and management (E/M) services reported by the CPT codes could significantly overlap with the components of the AWW, we believe that it is important to utilize specific HCPCS codes to identify the AWW as there are coverage periodicity requirements that apply to the AWW, as well as specific requirements regarding the elements of the AWW. While we understand the commenters' request to use the established set of CPT codes for the AWW, we do not believe that the existing CPT code descriptors should be subject to adjustment and limitation based on this new benefit as these CPT codes are currently used by many practitioners to report noncovered preventive medicine E/M services furnished to Medicare beneficiaries. In addition, coverage for the AWW begins on January 1, 2011, and we believe that our authority to create and maintain Level II HCPCS codes allows us a mechanism to implement these codes quickly and effectively. While we would not necessarily be opposed to the use of CPT codes to report the AWW in the future if CPT codes existed that met our specific purposes, time does not allow for the establishment of new CPT codes or the revision of existing codes for the AWWs that are covered as of January 1, 2011.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to adopt two new HCPCS G-codes for reporting the AWW in CY 2011. While we proposed these codes as GXXXXA and GXXXXB for the first and subsequent AWWs, respectively, the final codes and their descriptors are G0438 (Annual wellness visit; includes a personalized prevention plan of service (PPPS), first visit) and G0439 (Annual wellness visit; includes a personalized prevention plan of service (PPPS), subsequent visit). We note that practitioners furnishing a preventive medicine E/M service that does not meet the requirements for the IPPE or the AWW would continue to report one of the preventive medicine E/M services CPT codes in the range of 99381 through 99397 as appropriate to the patient's circumstances, and these codes continue to be noncovered by Medicare.

A beneficiary would be eligible for one first AWW covered by Medicare that must include all of the required elements that we have adopted in our final policy for CY 2011, as discussed in section VI.Q.2. of this final rule with comment period. All subsequent AWWs would include the required elements for those visits as also described in section VI.Q.2. of this final rule with comment

period. All AWWs other than the beneficiary's first AWW would be reported as subsequent visits, even if a different practitioner furnished the subsequent AWW. We expect there to be continuity and communication among the practitioners caring for beneficiaries over time with respect to AWWs, and this would include the case where a different practitioner furnishing a subsequent AWW would update the information in the patient's medical record based on the patient's interval history since the previous AWW.

As we stated in the CY 2011 PFS proposed rule (75 FR 40128), the first AWW described by HCPCS code GXXXXA (G0438) is similar to the IPPE that is currently reported with HCPCS code G0402 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment). We believe that the physician work and nonfacility PE of the IPPE and the first AWW are very similar, given that both represent an initial beneficiary visit focused on prevention. In the CY 2010 PFS final rule with comment period discussion of payment for the IPPE (74 FR 61767), we noted that in the context of physician work and intensity, HCPCS code G0402 was most equivalent to CPT code 99204 (Level 4 new patient office or other outpatient visit). Therefore, for CY 2011, we proposed to crosswalk the same physician work RVUs of 2.43 from CPT code 99204 to HCPCS codes G0402 and GXXXXA (G0438). Similarly, we believe the direct PE inputs for all of these services are similar and, therefore, we proposed to assign the same direct PE inputs to HCPCS codes G0402 and GXXXXA (G0438) as are included for CPT code 99204. We noted that currently, the direct PE inputs for HCPCS code G0402 also include preventive assessment forms, and we proposed to add this supply to the PE for HCPCS code GXXXXA (G0438) as well because we believe it would be used in the first AWW. The proposed CY 2011 PE and malpractice RVUs for HCPCS code GXXXXA (G0438) were displayed in Addendum B to the proposed rule (75 FR 40640). We also noted that we proposed no facility PE RVUs for HCPCS code GXXXXA (G0438) because only a single payment would be made under the PFS when this service is furnished. There is no separate facility payment for GXXXXA (G0438) when a practitioner furnishes this service in the facility setting.

Moreover, in the CY 2011 PFS proposed rule (75 FR 40128), we also indicated that we believe that a subsequent AWW described by HCPCS code GXXXXB (G0439) is most similar,

from the perspectives of physician work and PE, to CPT code 99214 (Level 4 established patient office or other outpatient visit). The subsequent AWW is a patient visit for PPS that includes certain required elements, such as updating information regarding the patient's history, risk factors, and regular medical care providers and suppliers since the prior AWW, and obtaining routine measurements. We believe the physician work and direct PE of a subsequent AWW are similar, in terms of E/M visit level, to the first AWW, which we proposed to value like a level 4 new patient office or other outpatient visit, as we had previously valued the IPPE. However, the subsequent AWW would typically be for an established patient and, as described earlier in this section, we proposed that only certain AWW elements must be furnished in the first AWW. As a result, in the CY 2011 PFS proposed rule (75 FR 40129), we stated that we believe it would be most appropriate to value the subsequent AWW based upon an E/M visit for an established patient. Therefore, for CY 2011 we proposed to crosswalk the same physician work RVUs of 1.50 from CPT code 99214 to HCPCS code GXXXB (G0439). Furthermore, we believe the direct PE inputs for these two services are also similar and, therefore, we proposed to assign the same direct PE inputs to HCPCS code GXXXB (G0439) as were assigned to CPT code 99214. We note that we also proposed to add the same preventive assessment forms to the PE for HCPCS code GXXXB (G0439) as we proposed to add for HCPCS code GXXXA (G0438) because we believe this supply would be used in both the first and subsequent AWWs. The proposed CY 2011 PE and malpractice RVUs for HCPCS code GXXXB were displayed in Addendum B to the CY 2011 PFS proposed rule (75 FR 40640). Similar to our treatment of HCPCS code GXXXA (G0438) for the first AWW, we proposed no facility PE RVUs for HCPCS code GXXXB (G0439) as only a single payment would be made under the PFS when this service is furnished. There is no separate facility payment for GXXXB (G0439) when a practitioner furnishes this service in the facility setting.

Comment: A number of commenters supported the proposed payment for the first and subsequent AWWs based on a crosswalk to level 4 new and established patient office and other outpatient visits. Several commenters recommended that CMS vary the payment for the AWW based on the visit's complexity, arguing that beneficiaries with multiple health risk

factors would require additional practitioner time and intensity for the AWW. One commenter recommended that CMS value the first and subsequent AWWs based on the values applicable to level 5 new and established patient office and other outpatient visits, arguing that the typical Medicare beneficiary would have multiple health risk factors that would need to be addressed in the AWW through a complex plan specific to that beneficiary's situation. Other commenters argued that CMS should recognize the preventive medicine E/M services CPT codes from 99381 through 99387, whose values vary based on age and new or established patient status, to ensure appropriate payment for the first and subsequent AWWs. Furthermore, one commenter also pointed out that the existing preventive medicine E/M services CPT codes are currently being revalued by the AMA RUC as part of the Fourth 5-Year Review of Work to ensure that the values for the services are commensurate with the level of practitioner work involved in furnishing the medical service.

A few commenters noted that they currently bill preventive medicine services E/M CPT codes 99381 through 99397 which are noncovered in Medicare, and indicated as such with status "N" (Noncovered service), in conjunction with Medicare-covered E/M visits. The commenters requested that CMS clarify whether practitioners would continue to be able to bill additional preventive services in the CPT code range of 99381 through 99397 in conjunction with the AWW.

Response: As discussed earlier in this section, we are adopting the final HCPCS codes G0438 and G0439 for reporting the first and subsequent AWWs, rather than recognizing the CPT codes for preventive medicine E/M services as covered only for purposes of the AWWs. With respect to the values for those preventive medicine E/M services CPT codes that some commenters believe would be appropriate for payment of the first and subsequent AWWs, we have not adopted the values for Medicare because the codes are noncovered by Medicare. Nevertheless, we publish the AMA RUC-recommended work values and the PE RVUs that result from application of our standard PE methodology to the AMA RUC-recommended PE inputs in Addendum B for the CPT codes. We compared the values we proposed for HCPCS codes G0438 and G0439 with the preventive medicine E/M services CPT codes because of the commenters' reasoning that these AMA RUC-recommended values would result in

appropriate payment for AWWs. The values we proposed for HCPCS codes G0438 based on the work value and direct PE inputs for a level 4 new patient office or other outpatient visit are actually slightly higher (2.43 work RVUs; 2.14 fully implemented nonfacility PE RVUs) than the new patient, 65 years and older CPT preventive medicine E/M services code (2.06 work RVUs; 1.87 nonfacility PE RVUs). In contrast, the values we proposed for HCPCS code G0439 based on the work value and direct PE inputs for a level 4 established patient office or other outpatient visit are slightly lower (1.50 work RVUs; 1.59 nonfacility PE RVUs) than the establish patient, 65 years and old CPT preventive services code (1.71 work RVUs; 1.62 nonfacility RVUs). We note that if the AMA RUC provides revised recommendations to us for these preventive medicine E/M services CPT codes for a future year, we may conduct this analysis again based on that new information.

As discussed above, we note that additional preventive medicine services E/M CPT codes 99381 through 99397, noncovered by Medicare and indicated with status "N," may be furnished in conjunction with Medicare-covered E/M visits, including the AWW. However, we believe that it would be difficult to distinguish an AWW from another preventive medicine E/M service furnished in the same encounter that would be reported under a preventive medicine services E/M CPT code as there is substantial overlap in the components of CPT codes 99381 through 99397 and HCPCS codes G0438 and G0439 reported for the AWW.

Based on the final elements of the first and subsequent AWWs as adopted in section VI.Q.2. of this final rule, we do not believe that the first and subsequent AWWs would usually require the 60 or 40 minutes of physician face-to-face time that is typically associated with the level 5 new or established patient office or other patient visit, respectively. We continue to believe, as we proposed, that the typical physician time would be 45 or 25 minutes of face-to-face time, like that of the level 4 new or established patient office or other outpatient visit, respectively. We also believe the direct PE inputs for the AWW may be appropriately crosswalked to the direct PE inputs for the level 4 new or established patient office or other outpatient visit, with the addition of preventive assessment forms to both HCPCS codes G0438 and G0439, as we also proposed.

Comment: One commenter suggested that the upcoming definition of a health risk assessment (HRA) may add more

work to the AWW. The commenter recommended that once the HRA has been established, CMS should incorporate the RVUs from CPT code 99420 (Administration and interpretation of health risk assessment instrument (eg, health hazard appraisal) into the RVUs associated with the AWW to ensure that the costs of the HRA are recognized as part of the AWW service.

Response: As discussed previously in this section, the HRA guidelines and the model HRA tool are not yet available. As is our standard process, when more information becomes available on the nature of a particular service or the elements of the services change, we reevaluate the valuation of the services. Therefore, when the HRA is incorporated into the AWW, we will reevaluate the values for HCPCS codes G0438 and G0439.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to crosswalk the physician work RVUs of 2.43 from CPT code 99204 (level 4 new patient office or other outpatient visit) to HCPCS codes G0402 (IPPE) and G0438 (first AWW) and the physician work RVUs of 1.50 from CPT code 99214 (level 4 established patient office or outpatient visit) to HCPCS code G0439 (subsequent AWW). Similarly, we believe the direct PE inputs for all of these services are similar and, therefore, we are assigning the same direct PE inputs to HCPCS codes G0402 and G0438 as are included for CPT code 99204 and the same direct PE inputs to HCPCS code G0439 as are assigned to CPT code 99214. Preventive assessment forms have been added as supplies to both HCPCS codes G0438 and G0439. The final direct PE inputs for these codes are included in the final CY 2011 direct PE database available under downloads for the CY 2011 PFS final rule with comment period on the CMS web site at: <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>. The final work, PE, and malpractice RVUs for HCPCS codes G0438 and G0439 are displayed in Addendum B to this final rule with comment period. There is no separate facility payment for HCPCS code G0438 or G0439 when a practitioner furnishes either service in the facility setting.

In the CY 2011 PFS proposed rule (75 FR 40129), we noted that while we believe there could be overlap in the direct PE, malpractice expense, and physician work in both history taking and examination of the patient in the context of the initial or subsequent AWW and another E/M service, we did not propose to limit the level of a medically necessary E/M visit when

furnished and billed with an AWW. As we stated in the CY 2005 PFS final rule with comment period with respect to the IPPE (69 FR 66289 through 66290), we do not want to prohibit the reporting of an appropriate level of service when it is necessary to evaluate and treat the beneficiary for acute and chronic conditions. However, at the same time, we believe the practitioner is better able to discuss health promotion, disease prevention, and the educational opportunities available with beneficiaries when their health status has been stabilized and the beneficiary is physically receptive. Therefore, depending on the clinical circumstances, a CPT code for a medically necessary E/M visit may be reported and appended with CPT modifier-25 (Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service) to designate the E/M visit as a separately identifiable service from the initial or subsequent AWW. However, in the CY 2011 PFS proposed rule (75 FR 40129) we explained that we believe this scenario would be uncommon, and that we expect that no components of an encounter attributable to the AWW would be used in determining the level of a separate E/M visit that would also be reported.

Comment: A few commenters disagreed with CMS' assertion that reporting a significant, separately identifiable E/M visit for the same encounter as an AWW would be unusual. The commenters believe that reporting an E/M visit with an AWW would be typical, as the age and health conditions of the typical Medicare beneficiary would likely result in problem-oriented E/M services being furnished in association with the AWW in order to fully address the medical problems that were identified in the encounter. The commenters explained that providing this care during the same encounter as the AWW would be both clinically appropriate and convenient for the beneficiary.

Response: While we continue to believe that a practitioner is better able to discuss health promotion, disease prevention, and health education opportunities with beneficiaries when their health status has been stabilized and the beneficiary is physically receptive to prevention, the goal of the AWW, we acknowledge that the AWW encounter may provide an annually recurring opportunity for a beneficiary to receive medical care for his or her health problems. However, we continue to believe that a beneficiary who has an acute medical problem or condition

would not receive optimal benefit from the AWW, which focuses on health promotion in the longer term. We encourage practitioners to be thoughtful regarding the best timing of the AWW to maximize its impact on beneficiary health since the AWW is covered by Medicare no more frequently than once every 12 months. Therefore, as we proposed, depending on the clinical circumstances, a CPT code for a medically necessary E/M visit may be reported and appended with CPT modifier - 25 (Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service) to designate the E/M visit as a separately identifiable service from the initial or subsequent AWW.

With respect to beneficiary cost-sharing, section 4103(c)(1) of the ACA amended section 1833(a)(1) of the Act and added subparagraph (X), referring to the PPS to state that the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848 of the Act, thereby eliminating coinsurance for the AWW. Finally, section 4103(c)(4) of the ACA amended section 1833(b) of the Act to specify that the Part B deductible will not apply to the AWW.

Comment: Many commenters expressed support for CMS' proposal to waive the beneficiary deductible and coinsurance for the AWW. The commenters noted that this waiver would likely encourage more beneficiaries to receive an AWW.

Response: We appreciate the commenters' support for our proposal to eliminate the beneficiary cost-sharing for the AWW as the statute requires. We refer readers to section VI.R. of this final rule with comment period for further discussion of the waiver of the deductible and coinsurance for preventive services beginning in CY 2011.

In summary, for CY 2011 we are adopting the following new HCPCS G-codes for reporting the AWW: G0438 (Annual wellness visit; includes a personalized prevention plan of service (PPPS), first visit); and G0439 (Annual wellness visit; includes a personalized prevention plan of service (PPPS), subsequent visit). These codes are valued for payment under the PFS using a crosswalk methodology for the work RVUs and direct PE inputs from the level 4 new and established patient office or other outpatient visit CPT codes. The final work, PE, and malpractice RVUs for HCPCS codes G0438 and G0439 are displayed in

Addendum B to this final rule with comment period. The deductible and coinsurance for the AWW is waived when coverage begins in CY 2011. Finally, the CPT code for a medically necessary E/M visit may be reported and appended with CPT modifier -25 (Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service) to designate the E/M visit as a separately identifiable service from the initial or subsequent AWW when both are provided in the same encounter.

R. Section 4104: Removal of Barriers to Preventive Services in Medicare

1. Definition of "Preventive Services"

Section 4104 of the ACA revised section 1861(ddd) of the Act and added paragraph (3), which defined the term "preventive services" as follows:

- The specific services currently listed in section 1861(ww)(2) of the Act with the explicit exclusion of electrocardiograms (as specified in section 1861(ww)(2)(M) of the Act);
- The initial preventive physical examination (IPPE) established by section 611 of the MMA and defined in section 1861(ww)(1) of the Act; and
- The annual wellness visit including personalized preventive plan services, as specified by section 1861(hhh) of the Act as added by section 4103 of the ACA. We refer readers to section VI.Q. of this final rule with comment period for the CY 2011 provisions related to the coverage of and payment for the annual wellness visit. The regulations regarding coverage of the IPPE are specified in § 410.16 and remain unchanged by the ACA.

The specific preventive services included in the definition of "preventive services" in section 1861(ddd)(3)(A) of the Act as cross-referenced to section 1861(ww)(2) of the Act, excluding electrocardiograms, include the following:

- Pneumococcal, influenza, and hepatitis B vaccine and administration.
- Screening mammography.
- Screening pap smear and screening pelvic exam.
- Prostate cancer screening tests.
- Colorectal cancer screening tests.
- Outpatient diabetes self-management training (DSMT).
- Bone mass measurement.
- Screening for glaucoma.
- Medical nutrition therapy (MNT) services.
- Cardiovascular screening blood tests.
- Diabetes screening tests.
- Ultrasound screening for abdominal aortic aneurysm (AAA).

- Additional preventive services identified for coverage through the national coverage determination (NCD) process.

In the CY 2011 PFS proposed rule (75 FR 41029), we indicated that at that time the only additional preventive service identified for coverage through the NCD process was HIV testing. A proposed NCD for smoking cessation services for asymptomatic patients was released in May 2010 on the CMS Web site at: http://www.cms.gov/mcd/index_list.asp?list_type=nca. We stated that we would address the applicability of section 1861(ddd)(3)(A) of the Act (as added by section 4104 of the ACA) to these services if an NCD establishing them as additional preventive services was finalized. As of August 25, 2010, CMS finalized an NCD for "Counseling to Prevent Tobacco Use" and established smoking cessation services for asymptomatic patients, thus qualifying them as "additional preventive services" as defined at section 1861(ddd)(3)(A) of the Act, as cross-referenced to section 1861(ww)(2) of the Act.

We proposed to add the definition of "preventive services" in § 410.2 to implement the provisions of section 1861(ddd)(3) of the Act (as added by section 4104 of the ACA).

Comment: Many commenters supported CMS' definition of "preventive services," observing that the definition was fully aligned with section 1861(ddd)(3) of the Act (as added by section 4104 of the ACA).

Response: We appreciate the support of the commenters and are adopting this definition of "preventive services" in this final rule with comment period.

Comment: Several commenters expressed confusion about Medicare's definition of "preventive services" and its relationship to those services with a United States Preventive Services Task Force (USPSTF) recommendation grade of A [An "A" rating means the USPSTF recommends the service. There is high certainty that the net benefit is substantial.] or B [A "B" rating means the USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.].

Response: It appears that some of the commenters' confusion may be due to the use of two similar terms in the Medicare Act. In section 1861(ddd) of the Act, Congress defined two terms of art. The term, "preventive services," is described in section 1861(ddd)(3) of the Act and in this final rule with comment period in § 410.2. Congress also defined the term "additional preventive services" and that term was previously

defined in § 410.64 of our regulations. Under section 1861(ddd)(1) of the Act, in order for the Secretary to add an "additional preventive service," the Secretary is required to use the national coverage determination process. Moreover, in addition to other standards, the item or service must be recommended with a grade of A or B by the USPSTF.

In section 1861(ddd)(3) of the Act (as added by section 4104 of the ACA), Congress expanded Medicare coverage under Part B to encourage the use of "preventive services." Among other things, Congress removed some of the Part B cost-sharing obligations to encourage patients to obtain certain of these services. We note that "additional preventive services" are one of the categories of specific services that are covered under section 1861(ww)(2) of the Act and, therefore, also fall within the term "preventive services" based on the cross-reference in section 1861(ddd)(3)(A) of the Act. Other specific services that are listed in section 1861(ww)(2) of the Act and that are included in the definition of "preventive services" are not required to have a grade A or B recommendation from the USPSTF. As we stated in the CY 2011 PFS proposed rule (75 FR 40130), "[n]ot all preventive services described in subparagraph (A) of section 1861(ddd)(3) of the Act are recommended by the USPSTF with a grade of A or B, and, therefore, some of the preventive services do not meet the criteria in sections 1833(a)(1) and (b)(1) of the Act for the waiver of the deductibles and coinsurance." We hope that this technical explanation helps to eliminate any confusion concerning the two separate terms of art.

Comment: Several commenters observed that some services, such as intensive behavioral (nutrition) counseling, have been given a grade A or B recommendation by the USPSTF but are not listed as "additional preventive services" in the CY 2011 PFS proposed rule. Another commenter requested that CMS identify all USPSTF-recommended services as "additional preventive services" and, therefore, recognize them as having a benefit category under Medicare, even if their coinsurance and deductible are not waived because their USPSTF recommendation is not a grade A or B.

Response: Under section 1861(ddd)(1) of the Act and our regulations in § 410.64, an item or service must meet other standards in addition to having received a grade of A or B recommendation by the USPSTF in order for the Secretary to determine that an item is an "additional preventive

service." As we previously noted, "additional preventive services" must also be established by using the NCD process. While some of the services recommended by the commenters for addition to Medicare's list of "additional preventive services" have a grade A or B recommendation by the USPSTF, this recommendation alone is not sufficient for those services to be included as "additional preventive services" that are covered by Medicare Part B. For instance, some of the USPSTF recommendations may be directed to a particular patient population (for example, pediatric services) that may not include Medicare beneficiaries.

However, we acknowledge the potential value to Medicare beneficiaries of those preventive services recommended by the USPSTF for populations covered by Medicare based on the medical evidence that led to the grade A or B recommendation. While certain preventive services with such a recommendation may not yet be covered by Medicare, these services have the potential to improve the health of beneficiaries. Therefore, we plan to proactively pursue Medicare coverage of "additional preventive services" with a grade A or B USPSTF recommendation through our current processes on our own initiative in light of our commitment to the health and wellness of Medicare beneficiaries.

Comment: A few commenters suggested the inclusion of additional services in the definition of "preventive services," including items or services that have not been reviewed by the USPSTF or where there is no NCD. In addition, several commenters urged CMS to recognize recommendations from organizations other than the USPSTF when considering services for inclusion as "additional preventive services."

Response: Because the term "preventive services," is specifically defined by statute in section 1861(ddd)(3) of the Act, we do not have unlimited authority to simply add items or services to this definition. As we have noted, however, the Secretary may add items or services as "additional preventive services" if the item or service meets the existing criteria in § 410.64. Among other things, the statute specifically requires that a new "additional preventive service" must have a grade A or B recommendation by the USPSTF.

We do not have the authority under section 1861(ddd)(1)(B) of the Act to add "additional preventive services" based on the recommendations of other groups or organizations. We recognize that in other sections of the ACA,

Congress specifically recognized the expertise of other organizations with respect to coverage of preventive health services. For instance, in section 1001 of the ACA, Congress amended section 2713 of the Public Health Service Act so that certain group health plans and health insurance issuers must provide coverage of preventive health services that were recommended by several other organizations. The Medicare statute, however, does not permit recommendations from other advisory bodies to substitute for recommendations from the USPSTF regarding Medicare coverage of "additional preventive services."

Comment: A number of commenters supported CMS' inclusion of certain vaccines in the definition of "preventive services." Other commenters were concerned that the USPSTF does not currently review or provide recommendations regarding vaccine or vaccine administration and instead urged CMS to consider recommendations from the CDC's Advisory Committee on Immunization Practices (ACIP). Several commenters requested that vaccines such as diphtheria, pertussis, herpes zoster, tetanus, hepatitis A vaccine, meningococcal vaccine, measles-mumps-rubella, and varicella be considered "additional preventive services" as they are recommended by the ACIP. The commenters requested that CMS provide coverage for all vaccines recommended by the ACIP under Part B, noting that currently some vaccines are covered under Part B while others are covered under Part D.

Response: Medicare has covered certain vaccines and their administration under Part B, including influenza, pneumococcal, and hepatitis B, as a result of a specific statute, section 1861(s)(10) of the Act. Those services are specifically cross-referenced in section 1861(ww)(2)(A) of the Act, and are included in the definition of "preventive services" by section 1861(ddd)(3)(A) of the Act. While we acknowledge that the ACIP currently makes recommendations concerning immunizations, section 1861(ddd)(1) of the Act does not permit us to use recommendations from the ACIP as the basis for coverage of vaccines as "additional preventive services." As the commenters observed, vaccines that are not covered by Medicare Part B may be covered by Part D.

Comment: Several commenters requested that CMS not wait for an NCD for smoking cessation services but, instead, proactively identify smoking cessation services as preventive services effective for CY 2011.

Response: The Medicare statute requires the Secretary to use the national NCD process when considering adding services as an "additional preventive service." Consistent with the public process and timeframes required by section 1862(l) of the Act, our NCD expanding coverage for counseling to prevent tobacco use for asymptomatic patients was effective on August 25, 2010. Thus, the "additional preventive services" covered by Medicare Part B currently include services described by HCPCS codes G0436 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes) and G0437 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes).

Comment: Several commenters requested coverage of routine HIV testing for all individuals, including persons at low risk for HIV infection, regardless of risk, based on more recent data, or based upon the C rating of the USPSTF.

Response: We are not able to accept the public comment to extend coverage for HIV screening for all individuals under the Medicare program because the USPSTF grade A or B recommendation was limited to specific populations and the USPSTF specifically made a grade C recommendation about HIV screening for "adolescents and adults who are not at increased risk for HIV infection." Our statute and regulations only permit coverage of "additional preventive services" which have been recommended with a grade of A or B by the USPSTF and do not permit coverage as "additional preventive services" of services with grade C recommendations.

As a result of the NCD, Medicare covers screening of at risk individuals for HIV described by three HCPCS codes, specifically G0432 (Infectious agent antigen detection by enzyme immunoassay (EIA) technique, qualitative or semi-qualitative, multiple-step method, HIV-1 or HIV-2, screening); G0433 (Infectious agent antigen detection by enzyme-linked immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening); and G0435 (Infectious agent antigen detection by rapid antibody test or oral mucosa transudate, HIV-1 or HIV-2, screening)). These HCPCS codes are all listed in Table 65 of the following section because their beneficiary cost-sharing will be waived in CY 2011.

Comment: Several commenters encouraged CMS to develop transparency in its interactions with the USPSTF and CMS coverage

determinations. The commenters urged CMS to support increased opportunities for stakeholders to participate in the USPSTF process.

Response: As required by section 1862(l) of the Act, the NCD process includes an opportunity for public comment on a proposed decision. With respect to any proposed NCD for an "additional preventive service," we include a summary of the USPSTF recommendations in our proposed decision memorandum. The Secretary is required to respond to the public comments when issuing a final determination. We believe that this process is open and transparent and that the public comments have improved the quality of our final decisions.

While some commenters have requested greater opportunities for public participation prior to the USPSTF recommendations, the process that the USPSTF utilizes in making its expert recommendations is beyond the scope of this rulemaking. The USPSTF, first convened by the U.S. Public Health Service in 1984, and since 1998 sponsored by the AHRQ, is an independent panel of private-sector experts in prevention and primary care that makes recommendations that are independent of the U.S. government. The USPSTF conducts impartial assessments of the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications. The mission of the USPSTF is to evaluate the benefits of individual services based on age, gender, and risk factors for disease; make recommendations about which preventive services should be incorporated routinely into primary medical care and for which populations; and identify a research agenda for clinical preventive care. The USPSTF has partners from the fields of primary care, public health, health promotion, policy, and quality improvement. Liaisons from these groups and from Federal health agencies, including CMS, contribute their expertise in the peer review of draft USPSTF documents and help disseminate the work of the USPSTF to their members.

After consideration of the public comments we received, we are finalizing our proposed definition of preventive services. Specifically, preventive services include the IPPE; the AWW; pneumococcal, influenza, and hepatitis B vaccine and administration; screening mammography; screening pap smear and screening pelvic exam; prostate cancer screening tests; colorectal cancer screening tests; outpatient diabetes self-management

training (DSMT); bone mass measurement; screening for glaucoma; medical nutrition therapy (MNT) services; cardiovascular screening blood tests; diabetes screening tests; ultrasound screening for abdominal aortic aneurysm (AAA); and additional preventive services identified for coverage through the NCD process. To date, two items or services have been added as "additional preventive services" by NCDs. These services are HIV screening for at risk individuals and smoking and tobacco cessation counseling for asymptomatic individuals.

We are adopting the proposed definition of "preventive services" in § 410.2 to implement the provisions of section 1861(ddd)(3) of the Act (as added by section 4104 of the ACA), with modification of § 410.2(3) to read "Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS) (as specified by section 1861(hhh)(1) of the Act)" to utilize wording that is consistent with final § 410.15, Annual Wellness Visits Providing Personalized Prevention Plan Services: Conditions for and Limitations on Coverage.

Furthermore, in this final rule with comment period, we are making a technical revision to § 410.64 (Additional Preventive Services) to conform with section 1861(ddd)(1) of the Act, as amended by section 4104 of the ACA. We are revising § 410.64(a) by removing the words "not otherwise described in this subpart" and adding the words "not described in subparagraphs (1) or (3) of § 410.2 of this subpart" in their place. This change reflects section 1861(ddd)(1) of the Act (as amended by section 4104(a)(2) of the ACA).

2. Deductible and Coinsurance for Preventive Services

Section 4104(b)(4) of the ACA amended section 1833(a)(1) of the Act by requiring 100 percent Medicare payment for the IPPE and for those Medicare-covered preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. In other words, this provision waived any coinsurance that would otherwise be applicable under section 1833(a)(1) of the Act for the IPPE and for those items and services listed in section 1861(ww)(2) of the Act (excluding electrocardiograms) to which the USPSTF has given a grade of A or B recommendation. In addition, section 4103(c)(1) of the ACA amended section

1833(a)(1) of the Act to waive the coinsurance for the AWW. The coinsurance represents the beneficiary's share of the payment to the provider or supplier for furnished services. Coinsurance generally refers to a percentage (for example, 20 percent) of the Medicare payment rate for which the beneficiary is liable and is applicable under the PFS, while copayment generally refers to an established amount that the beneficiary must pay that is not necessarily related to a particular percentage of the Medicare payment, and is applicable under the OPSS. We refer readers to the CY 2011 OPSS/ASC final rule with comment period for provisions related to payment for preventive services, including waiver of the deductible and copayment, under the OPSS.

Section 4104(c) of the ACA amended section 1833(b)(1) of the Act to waive the Part B deductible for preventive services described in subparagraph (A) of section 1861(ddd)(3) of the Act that have a grade of A or B recommendation from the USPSTF for any indication or population and are appropriate for the individual. In addition, section 1833(b)(1) of the Act (as amended by section 4103(c)(4) of the ACA) waived the Part B deductible for the AWW including personalized prevention plan services. These provisions are effective for services furnished on or after January 1, 2011. Section 101(b)(2) of the MIPPA previously amended section 1833(b) of the Act to waive the deductible for the IPPE effective January 1, 2009.

Not all preventive services described in subparagraph (A) of section 1861(ddd)(3) of the Act are recommended by the USPSTF with a grade of A or B and, therefore, some of the preventive services do not meet the criteria in sections 1833(a)(1) and (b)(1) of the Act for the waiver of the deductible and coinsurance. However, with certain exceptions noted below, the changes made by section 4104 of the ACA do not affect most of the preexisting provisions in sections 1833(a) and 1833(b) of the Act (codified in regulations in § 410.160(b) and § 410.152) that waive the deductible and coinsurance for specific services. For example, section 1833(a)(1)(D) of the Act already waives the coinsurance and section 1833(b)(3) of the Act already waives the deductible for clinical laboratory tests (including tests furnished for screening purposes). Section 4104 of the ACA does not change these provisions and, therefore, the waiver of both the deductible and coinsurance remain in place for all clinical laboratory tests, regardless of

whether the particular clinical laboratory test meets the USPSTF grading criteria specified in sections 1833(a)(1) and 1833(b)(1) of the Act (as amended by section 4104 of the ACA) for waiver of the deductible and coinsurance as a preventive service. Similarly, both the deductible and coinsurance were already waived, prior to the ACA, for influenza and pneumococcal vaccines and their administration, and the deductible (but not the coinsurance) was already waived for screening mammography, screening pelvic exams, colorectal cancer screening procedures, ultrasound screening for abdominal aortic aneurysms, and the IPPE.

As discussed in the CY 2011 PFS proposed rule (75 FR 40130), the following preventive services listed in section 1833(ddd)(3)(A) of the Act (as added by section 4104 of the ACA) are not recommended by the USPSTF with a grade of A or B for any indication or population: digital rectal examination furnished as a prostate cancer screening service; glaucoma screening; DSMT services; and barium enema furnished as a colorectal cancer screening service.

Specifically, HCPCS code G0102 (Prostate cancer screening; digital rectal exam), which does not have a grade of A or B from the USPSTF for any indication or population, will continue to be subject to the deductible and coinsurance as there is no statutory provision to the contrary. However, the deductible and coinsurance for HCPCS code G0103 (Prostate cancer screening; prostate specific antigen test (PSA)) will continue to be waived in accordance with sections 1833(a)(1)(D) and 1833(b)(3) of the Act (applying to clinical laboratory tests), even though this service also does not have a grade of A or B from the USPSTF.

Glaucoma screening services, described by HCPCS codes G0117 (Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist) and G0118 (Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist), will continue to be subject to the deductible and coinsurance because these services are not recommended with a grade of A or B by the USPSTF for any indication or population and there is no other statutory provision to exempt them. Similarly, DSMT services are currently not rated by the USPSTF, and there is no other statutory provision to exempt them from applicability of the deductible and coinsurance. Therefore the deductible and coinsurance requirements will continue to apply.

Barium enemas furnished as colorectal cancer screening tests, described by HCPCS codes G0106 (Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema) and G0120 (Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema), do not have a grade of A or B from the USPSTF for any indication or population. However, the deductible does not apply to barium enemas furnished as colorectal cancer screening tests, because colorectal cancer screening tests are explicitly excluded from the deductible in section 1833(b)(8) of the Act. However, there is no specific exclusion of barium enemas from the coinsurance requirement in section 1833(b)(1) of the Act and, therefore, this requirement, as applicable, continues to apply to barium enemas. We note that the USPSTF has given a grade A recommendation to screening colonoscopy, screening flexible sigmoidoscopy, and fecal occult blood screening tests, and that, as a result, both the deductible and coinsurance are waived for these colorectal cancer screening tests under section 4104 of the ACA.

In developing recommendations regarding preventive services for the CY 2011 PFS proposed rule, we recognized that the USPSTF may make recommendations that are specific to a clinical indication or population, at times including characteristics such as gender and age in its recommendations. In accordance with section 4014 of the ACA, we proposed to waive the deductible and coinsurance for a Medicare-covered preventive service, with no limits on the indication or population, as long as that service is recommended by the USPSTF with a grade of A or B for at least one indication and/or population. However, we noted that all existing Medicare coverage policies for such services, including any limitations based on indication or population would continue to apply. In some cases, national coverage policies may currently limit Medicare coverage based on the indication or population, consistent with the USPSTF recommendations with a grade of A or B for the indication or population. In other cases where Medicare does not explicitly noncover preventive services for a specific population or indication, we stated that we would expect that, particularly in those cases where the USPSTF recommendation grade is a D (that is, the USPSTF recommends against the service because there is moderate or high certainty that the service has no net

benefit or that the harms outweigh the benefits), practitioners would only order those preventive services that are clinically appropriate for the beneficiary. We noted that if we had concerns in the future about the appropriateness of preventive services for an indication or population in light of the USPSTF's recommendations, we may consider using our authority under section 1834(n)(1) of the Act (as added by section 4105 of the ACA) to modify Medicare coverage of any preventive service to be consistent with the recommendations of the USPSTF.

We note also that the USPSTF ceased to make recommendations with regard to vaccines and vaccine administration after CY 1996, so as not to conflict with the recommendations of the CDC's ACIP. However, the USPSTF's most recent vaccine recommendations gave a grade of B to influenza and pneumococcal vaccines and their administration and a grade of A to hepatitis B vaccine and its administration. While sections 1833(a)(1) and 1833(b)(1) of the Act (as amended by section 4104 of the ACA) require that a preventive service receive a grade A or B recommendation from the USPSTF for the coinsurance and deductible to be waived, the statute does not specify that the recommended grade must be furnished by the USPSTF within any given timeframe. The USPSTF grades from 1996 for these vaccination services are the most current USPSTF grades and have never been withdrawn. Therefore, we believe that these preventive services meet the requirements of the statute for the waiver of the deductible and coinsurance. We also noted that the CDC's ACIP currently recommends influenza, pneumococcal, and hepatitis B vaccines.

We proposed to update § 410.160(b), which lists the services for which expenses incurred are not subject to the Part B annual deductible and do not count toward meeting that deductible. Specifically, we proposed to revise § 410.160(b)(2) to include influenza and hepatitis B vaccines and their administration, in addition to pneumococcal vaccine and its administration. In addition, in § 410.160(b), we also proposed to add exceptions for bone mass measurement, MNT services, and the AWV.

In § 410.152, we proposed to revise paragraph (l) to establish the amount of payment under the applicable payment system for providers and suppliers of the services listed in paragraph (1). Table 38 of the CY 2011 PFS proposed rule (75 FR 40131 through 40135) identified the HCPCS codes that we

proposed to identify as "preventive services," in addition to the IPPE and the AWW, as well as the most recent USPSTF grade, if any, that was the basis for our policy with regard to waiver of the deductible and coinsurance. Table 38 also identified the Medicare payment system under which the HCPCS code would be paid when furnished outside of the facility setting.

Comment: Many commenters supported CMS' proposal to waive the deductible and coinsurance for those Medicare-covered preventive services with a grade A or B USPSTF recommendation for any indication or population, as well as for the IPPE and the AWW. The commenters acknowledged that CMS did not propose to modify current Medicare policy that may cover a preventive service only under specific circumstances. The commenters supported CMS' proposal to rely on practitioners' clinical judgment to order preventive services that are clinically appropriate for specific beneficiaries. Many commenters noted that CMS' "quick implementation" of this provision underscores the agency's commitment to removing barriers to preventive health care.

A few commenters expressed concern regarding how CMS may incorporate USPSTF recommendations into the Medicare benefit structure in the future and cautioned CMS not to adopt policies that would result in Medicare not covering important preventive services for an older population. For example, the USPSTF recommendations for mammography in women do not apply to individuals age 75 or older, and the commenters were concerned that future changes to CMS policies could result in Medicare not covering important preventive services for an older population.

Response: We appreciate the commenters' support for our proposal to waive the beneficiary deductible and coinsurance for most preventive services beginning in CY 2011. We continue to believe that it is appropriate to waive the beneficiary deductible and coinsurance for preventive services with a grade A or B recommendation by the USPSTF for any indication or population, if Medicare covers the particular service under Part B. However, we reiterate that if we develop concerns in the future about the appropriateness of preventive services for an indication or population in light of the USPSTF's recommendations, we may consider using our authority under section 1834(n)(1) of the Act (as added by section 4105 of the ACA) to modify Medicare coverage of any preventive

service to be consistent with the recommendations of the USPSTF.

Comment: Several commenters expressed concern over the USPSTF rating of I for glaucoma screening [An "I" rating means that the USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined]. Others were concerned about the rating of D for prostate cancer screening [A "D" rating means that the USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits]. Other commenters noted the lack of a specific USPSTF rating for DSMT services. The commenters argued that because these services were covered by Medicare as preventive services, the beneficiary cost-sharing should be waived to ensure access to these services.

Response: Glaucoma screening, digital prostate screening, and DSMT services are covered by Medicare under Part B and are specific categories of "preventive services" included in section 1861(ddd)(3)(A) of the Act (as added by section 4014 of the ACA). However, as these services do not have a USPSTF grade A or B recommendation, the deductible and coinsurance cannot be waived. Thus, the coinsurance and deductible will continue to apply to these services when they are furnished to a Medicare beneficiary.

Comment: Some commenters were concerned that ultrasound screening for abdominal aortic aneurysm (AAA), while a preventive service covered by Medicare and with a grade B recommendation from the USPSTF, would continue to require a physician referral in order for the preventive service to be furnished and for the waiver of cost-sharing to apply. Furthermore, the commenters objected to the current requirement that coverage of ultrasound screening for AAA relies upon a referral as a result of the IPPE because the IPPE is only available to beneficiaries during their first 12 months of Part B enrollment.

Response: Ultrasound screening for AAA is a preventive service covered by Medicare, with certain restrictions set forth in § 410.19 of our regulations. Because this service has a grade B recommendation from the USPSTF, the deductible and coinsurance will be waived beginning in CY 2011 for covered services. While we appreciate the commenters' concerns regarding the existing requirements for ultrasound

screening for AAA, the current requirement for a referral as a result of the IPPE is required by section 1861(s)(2)(AA) of the Act and continues to apply.

Comment: In the context of many commenters' recommendations to add new preventive services for coverage under Part B as "additional preventive services," most commenters also recommended that the beneficiary cost-sharing for these services be waived. The services addressed by the commenters included services with current grade A or B USPSTF recommendations, those with other grade USPSTF recommendations, those that have never been reviewed by the USPSTF, those with recommendations from other advisory organizations but the USPSTF, and other vaccines for which the USPSTF no longer makes recommendations.

Response: As discussed earlier in this section, the statute permits us to add "additional preventive services" to Medicare coverage only if those services have a grade A or B recommendation from the USPSTF. Other grade USPSTF recommendations or recommendations from other advisory groups, including the ACIP, cannot substitute for the grade A or B USPSTF recommendation. In the event that we add "additional preventive services" in the future, as we have HIV screening for at risk individuals and smoking and tobacco cessation counseling for asymptomatic individuals in CY 2010, the Medicare deductible and coinsurance will be waived for those services.

Comment: One commenter expressed concern that CMS was limiting the waiver of beneficiary cost-sharing to only those vaccines covered under Medicare Part B. The commenter contended that the ACIP recommends vaccines that are covered under Medicare Part D, and not Part B, and therefore not subject to the waiver.

Response: We recognize that many preventive vaccines such as herpes zoster and hepatitis A are covered for beneficiaries under Medicare Part D and the commenter is correct that Medicare Part D is not included in section 1861(ddd) of the Act (as amended by section 4104 of the ACA). Section 1861(ddd)(1)(C) of the Act limits "additional preventive services" to those appropriate for individuals entitled to benefits under Medicare Part A or enrolled under Medicare Part B only. In addition, the statute only permits expansions if the item or services based on a grade of A or B recommendation by the USPSTF.

Comment: Several commenters appreciated the clarity of Table 38 in the

CY 2011PFS proposed rule (75 FR 40131 through 40135), and requested that a table such as this be made available on the CMS Web site that reflects CMS' final policies regarding preventive services and beneficiary cost-sharing on a HCPCS code-specific basis. Other commenters requested additional provider and beneficiary educational materials to clarify preventive services benefits under Medicare, to identify which preventive services would continue to be subject to beneficiary cost-sharing, and to specify which preventive services would meet the requirements for the waiver of deductible and coinsurance where Medicare would make 100 percent payment.

Response: We are in the process of developing educational materials that will reflect and communicate to beneficiaries and providers the CY 2011 changes to beneficiary cost-sharing for preventive services under Medicare. We agree with the commenters that it is critical to effectively educate beneficiaries and providers about the preventive services covered by Medicare and specifically those services that will be paid at 100 percent by Medicare beginning in CY 2011 to help expand access to these important services. MLN Matters articles, quick reference guides, and the Medicare and You Handbook will all be developed and/or updated to reflect the provisions of the ACA and are examples of some of the provider and beneficiary educational materials that will be available. We appreciate the recommendations of the commenters regarding the format for specific information that we could make available on the CMS web site, and we will keep these suggestions in mind as we further refine our educational strategy.

After consideration of the public comments we received, we are finalizing our proposal to waive the deductible and coinsurance for most preventive services, and for the IPPE and the AWV, beginning in CY 2011.

Table 65 displays the HCPCS codes that we are finalizing as "preventive services" under section 1861(ddd)(3)(A) of the Act (as added by section 4014 of the ACA) and identifies the HCPCS codes for the IPPE and the AWV. Table 65 also indicates the most recent USPSTF grade, if any, that is the basis for our policy with regard to waiver of the deductible and coinsurance, as applicable, and the Medicare payment system under which the HCPCS code would be paid when furnished outside of the facility setting.

Since the publication of the CY 2011 PFS proposed rule, final Level II HCPCS

codes have been assigned for the AWV, as well as the "additional preventive services" for HIV screening for at risk individuals and smoking and tobacco cessation counseling for asymptomatic individuals. Therefore, these services and their associated Level II HCPCS codes are all displayed in Table 65. In addition, beginning in CY 2011, Medicare will no longer recognize CPT code 90658 (Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use) but, instead will use 5 new HCPCS Q codes to report influenza vaccines that would otherwise have been reported under CPT code 90658. Therefore, these HCPCS Q-codes are included in Table 65, and they will be recognized as of January 1, 2011. CPT code 86689 (HTLV or HIV antibody, confirmatory test (e.g., Western Blot)) describes a diagnostic test, not specifically an HIV screening test that would be reported for a screening service that is covered by Medicare, and, therefore, this CPT is not included in Table 65.

We are adopting proposed § 410.152 to specify the amounts of payment, with modification of (13) to read "Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS)" and proposed § 410.160 to specify exclusion from the Part B annual deductible, with modification of (12) to read "Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS)." These modifications utilize wording that is consistent with final § 410.15, Annual Wellness Visits Providing Personalized Prevention Plan Services: Conditions for and Limitations on Coverage.

Section 10501(i)(2) of the ACA amended the definition of Federally Qualified Health Center (FQHC) services as defined in section 1861(aa)(3)(A) of the Act by replacing the specific references to services provided under section 1861(qq) and (vv) of the Act (diabetes outpatient self-management training services and medical nutrition therapy services, respectively) with preventive services as defined in section 1861(ddd)(3) of the Act, as established by section 4014(a)(3) of the ACA. These changes are effective for services provided on or after January 1, 2011. Accordingly, we are proposing to conform the regulations to the new statutory requirement by adding a new section § 405.2449 which would add the new preventive services definition to the definition of FQHC services effective

for services provided on or after January 1, 2011.

Section 1861(ddd)(3) of the Act defines "preventive services" as consisting of the following three components:

- Screening and preventive services described in section 1861(ww)(2) of the Act (other than electrocardiograms described in subparagraph (M) of that subsection).
- An initial preventive physical examination, as defined in section 1861(ww) of the Act.
- Personalized prevention plan services as defined in section 1861(hhh)(1) of the Act.

We proposed to add each of these three components into the new Medicare FQHC preventive services definition in a new § 405.2449.

Section 4104(b) of the ACA, as amended by section 10406 of the ACA, waives coinsurance for preventive services by adding section 1833(a)(1)(Y) to the Act to require waiver of coinsurance for preventive services that are recommended with a grade of A or B by the USPSTF for any indication or population. This provision is specifically designed to remove barriers to affording and obtaining such preventive services under Medicare.

In addition, section 10501(i)(3)(B)(ii) of the ACA added section 1833(a)(1)(Z) to the Act to require a 20 percent coinsurance on all FQHC services after implementation of the FQHC prospective payment system. We believe we can give both section 1833(a)(1)(Y) and (Z) of the Act, and the definition of FQHC services (revised to include the broader scope of preventive services) their best effect by providing Medicare payment at 100 percent for preventive services as defined at section 1861(ddd)(3) of the Act, effective January 1, 2011.

Section 1833(b)(4) of the Act stipulates that the Medicare Part B deductible shall not apply to FQHC services. The ACA makes no change to this provision; therefore Medicare will continue to waive the Part B deductible for all FQHC services, including preventive services added by the ACA.

We received a number of public comments on the addition of preventive services to the Medicare FQHC benefit. These comments included questions regarding how these benefits are paid and clarification on the waiver of coinsurance on these benefits in the Medicare FQHC setting. The comments are addressed individually below.

Comment: One commenter indicated that prior to enactment of the ACA, many health centers provided added preventive services as part of the

primary and preventive care offered at the center. Yet when provided to Medicare beneficiaries, they received no additional reimbursement. The commenter noted that since the inception of the Medicare FQHC benefit in 1992, Medicare added thirteen new services to its coverage, yet those services have not been included as FQHC services, except for diabetes self management training and medical nutrition therapy which were added by the Deficit Reduction Act.

Response: We recognize that prior to enactment of the ACA, many FQHCs may have provided some or all of the same preventive services since added to the Medicare FQHC benefit package by the ACA. We also agree that many new preventive services have been added to Medicare since 1992, and except for diabetes self management training and medical nutrition therapy, which were added by the Deficit Reduction Act of 2005, these services had not been specifically added to the Medicare FQHC benefit package under the law. We believe the addition of these preventive services to the Medicare FQHC benefit through provisions in the ACA, along with the waiver of beneficiary cost sharing for these services in the Medicare FQHC setting, eliminates both prior statutory restrictions from Medicare coverage in the FQHC setting as well as potential financial barriers beneficiaries might otherwise face in obtaining these services.

Comment: One commenter requested further clarification in both this preamble and the final regulation text at § 405.2449 on the application of the waiver of coinsurance in the FQHC setting and CMS' statement that it will allow 100 percent reimbursement for these preventive services. The commenter stated that health centers are reimbursed 100 percent of their costs for the provision of influenza, pneumococcal, and Hepatitis B vaccinations, in accordance with Section 1861(s)(10)(A) of the Act. The commenter further noted that this reimbursement is done separately and outside the Medicare FQHC upper payment limit. The commenter asserted that the payment limit negatively impacts an overwhelming majority of health centers, and therefore encouraged CMS to use a similar method to determine the reimbursement for these new FQHC preventive services. The commenter further asserted that using a similar method to determine reimbursement would allow for health centers to provide more comprehensive preventive care to their patients, alleviate the financial restrictions faced

by health centers in providing these critical services, and would be in the best interests of CMS, health centers, and their patients. Finally, the commenter noted that because the list of new preventive services includes the provision of influenza, pneumococcal and hepatitis B vaccinations, CMS must ensure that health centers do not lose their current reimbursement structure for these services.

Response: No coinsurance will be imposed upon ACA-added preventive services in Medicare FQHCs. Accordingly, final settlement with FQHCs will reflect the policy that no coinsurance amounts will be subtracted from the reasonable cost of ACA-added preventive benefits. Final settlement is determined on the basis of the Medicare cost report, the CMS-222-92. We made no proposal to exempt ACA-added preventive services from tests of reasonableness such as the Medicare FQHC upper payment limits. Further, we do not agree that CMS should use the same methodology presently employed to pay FQHCs for influenza and pneumococcal vaccinations (see discussion of Hepatitis B vaccinations below) to pay for new Medicare FQHC preventive services added by the ACA. We believe the average cost per-visit payment methodology, which is the general payment methodology employed by Medicare to pay for Medicare FQHC services, was implicit in the proposal as we proposed no changes to Medicare FQHC payment regulations to implement this new preventive services addition. In addition, we believe the general payment methodology for Medicare FQHCs, which is based on an all-inclusive-cost-per-visit, is better suited and most appropriate for payment of new preventive services such as the annual wellness visit. It is our belief that the Medicare FQHC per-visit upper payment limits (\$126.10 urban and \$109.14 rural in CY 2011) remain reasonable and adequate not only for existing Medicare FQHC services but also for new preventive services as well. Accordingly, we cannot accept the comment to exclude new preventive services from the Medicare FQHC upper payment limits. The Medicare FQHC upper payment limits and the general per-visit payment methodology employed to pay for Medicare FQHC services will apply to new Medicare FQHC preventive services.

While we clarify the waiver of coinsurance and application of Medicare FQHC payment methodology and upper payment limits to new preventive services in this preamble, we cannot accept the comment to provide

further clarification within the final regulation text at § 405.2449. Section 405.2449 is placed within Medicare FQHC regulations which pertain to the description of Medicare FQHC services and not payment. We made no proposal to change payment and accordingly make no changes to Medicare FQHC payment regulations.

Finally, we note that we did not propose, nor are we making any changes to, how influenza, pneumococcal and hepatitis B vaccinations are paid in Medicare FQHCs. Accordingly, health centers will not lose their current reimbursement structure for these services. We agree that health centers are reimbursed 100 percent of their costs for the provision of influenza and pneumococcal vaccinations. We further agree that payment for influenza and pneumococcal vaccinations in Medicare FQHCs is done separately and outside the Medicare FQHC upper payment limit. However, we note for clarification purposes that prior to the effective date of the ACA provisions adding new preventive services to the Medicare FQHC benefit, the waiver of Part B coinsurance did not extend to Hepatitis B vaccinations. Hepatitis B vaccinations were covered in Medicare FQHCs in accordance with Section 1861(aa)(3)(A) of the Act which through reference to section 1861(aa)(1)(A) of the Act included all section 1861(s)(10) of the Act services including section 1861(s)(10)(B) of the Act, Hepatitis B vaccinations. The waiver of the 20 percent Medicare Part B coinsurance in Section 1833(a)(3)(A) of the Act extended only to Section 1861(s)(10)(A) of the Act services and not to section 1861(s)(10)(B) of the Act Hepatitis B vaccinations. To summarize this clarification, prior to the effective date of the ACA provisions adding new preventive services to the Medicare FQHC benefit, the waiver of Medicare Part B coinsurance did not extend to Section 1861(s)(10)(B) of the Act Hepatitis B vaccinations, hence these services were subject to Medicare Part B coinsurance and paid at 80 percent (not 100 percent) of reasonable costs in accordance with the provisions in section 1833(a)(3) of the Act. Effective with implementation of ACA provisions on January 1, 2011, Part B coinsurance on Hepatitis B vaccinations is waived as they are now included in the definition of "preventive services" in section 1861(ddd)(3)(A) of the Act as cross-referenced to section 1861(ww)(2) of the Act.

Consistent with our response to public comment above, and in conformance with the preventive services definition in section

1861(ddd)(3) of the Act, we are finalizing this new Medicare FQHC preventive services provision without modification. We will conform the

regulations to the new statutory requirements by adding a new section § 405.2449, adding the new preventive services definition to the definition of

FQHC services effective for services provided on or after January 1, 2011.

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TABLE 65: CY 2011 Deductible and Coinsurance for Preventive Services Under Section 1861(ddd)(3)(A) of the Act (Includes the IPPE and the Annual Wellness Visit)

Preventive Service	CPT/HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
Initial Preventive Physical Examination, IPPE	G0402	Initial preventive physical examination; face to face visits, services limited to new beneficiary during the first 12 months of Medicare enrollment	*Not Rated	PFS	Coinsurance applies & deductible is waived	WAIVED
	G0403	Electrocardiogram, routine ECG with 12 leads; performed as a screening for the initial preventive physical examination with interpretation and report		PFS	Not Waived	Not Waived
	G0404	Electrocardiogram, routine ECG with 12 leads; tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination		PFS	Not Waived	Not Waived
	G0405	Electrocardiogram, routine ECG with 12 leads; interpretation and report only, performed as a screening for the initial preventive physical examination		PFS	Not Waived	Not Waived
Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)	G0389	Ultrasound, B-scan and /or real time with image documentation; for abdominal aortic aneurysm (AAA) ultrasound screening	B	PFS	Coinsurance applies & deductible is waived	WAIVED

Preventive Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
Cardiovascular Disease Screening	80061	Lipid panel	A	CLFS	WAIVED	WAIVED
	82465	Cholesterol, serum or whole blood, total		CLFS	WAIVED	WAIVED
	83718	Lipoprotein, direct measurement; high density cholesterol (hdl cholesterol)		CLFS	WAIVED	WAIVED
	84478	Triglycerides		CLFS	WAIVED	WAIVED
Diabetes Screening Tests	82947	Glucose; quantitative, blood (except reagent strip)	B	CLFS	WAIVED	WAIVED
	82950	Glucose; post glucose dose (includes glucose)		CLFS	WAIVED	WAIVED
	82951	Glucose; tolerance test (gtt), three specimens (includes glucose)		CLFS	WAIVED	WAIVED
Diabetes Self- Management Training Services (DSMT)	G0108	Diabetes outpatient self- management training services, individual, per 30 minutes	*Not Rated	PFS	Not Waived	Not Waived
	G0109	Diabetes outpatient self- management training services, group session (2 or more), per 30 minutes		PFS	Not Waived	Not Waived
Medical Nutrition Therapy (MNT) Services	97802	Medical nutrition therapy; initial assessment and intervention, individual, face- to-face with the patient, each 15 minutes	B	PFS	Not Waived	WAIVED
	97803	Medical nutrition therapy; re- assessment and intervention, individual, face-to-face with the patient, each 15 minutes		PFS	Not Waived	WAIVED
	97804	Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes		PFS	Not Waived	WAIVED

Preventive Service	CPT/HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
	G0270	Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face to face with the patient, each 15 minutes	B	PFS	Not Waived	WAIVED
	G0271	Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition, or treatment regimen (including additional hours needed for renal disease), group (2 or more individuals), each 30 minutes				
Screening Pap Test	G0123	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, screening by cytotechnologist under physician supervision	A	CLFS	WAIVED	WAIVED
	G0124	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician				
				PFS	Coinsurance applies & deductible is waived	WAIVED

Preventive Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
	G0141	Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician	A	PFS	Coinsurance applies & deductible is waived	WAIVED
	G0143	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual screening and rescreening by cytotechnologist under physician supervision	A	CLFS	WAIVED	WAIVED
	G0144	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system, under physician supervision	A	CLFS	WAIVED	WAIVED
	G0145	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system and manual rescreening under physician supervision	A	CLFS	WAIVED	WAIVED
	G0147	Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision	A	CLFS	WAIVED	WAIVED
	G0148	Screening cytopathology smears, cervical or vaginal, performed by automated system with manual rescreening	A	CLFS	WAIVED	WAIVED

Preventive Service	CPT/HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
	P3000	Screening papanicolaou smear, cervical or vaginal, up to three smears, by technician under physician supervision		CLFS	WAIVED	WAIVED
	P3001	Screening papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician		PFS	Coinsurance applies & deductible is waived	WAIVED
	Q0091	Screening papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory		PFS	Coinsurance applies & deductible is waived	WAIVED
	G0101	Cervical or vaginal cancer screening; pelvic and clinical breast examination		PFS	Coinsurance applies & deductible is waived	WAIVED
Screening Mammography	77052	Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; screening mammography (list separately in addition to code for primary procedure)	B	PFS	Coinsurance applies & deductible is waived	WAIVED
	77057	Screening mammography, bilateral (2-view film study of each breast)		PFS	Coinsurance applies & deductible is waived	WAIVED
	G0202	Screening mammography, producing direct digital image, bilateral, all views			Coinsurance applies & deductible is waived	WAIVED

Preventive Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
Bone Mass Measurement	G0130	Single energy x-ray absorptiometry (sexa) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	B	PFS	Not Waived	WAIVED
	77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		PFS	Not Waived	WAIVED
	77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		PFS	Not Waived	WAIVED
	77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		PFS	Not Waived	WAIVED
	77081	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		PFS	Not Waived	WAIVED
	77083	Radiographic absorptiometry (eg, photodensitometry, radiogrammetry), 1 or more sites		PFS	Not Waived	WAIVED
	76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method		B	PFS	Not Waived
Colorectal Cancer	G0104	Colorectal cancer screening; flexible sigmoidoscopy	A	PFS	Coinsurance applies & deductible is waived	WAIVED

Preventive Service	CPT/HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible	
Screening	G0105	Colorectal cancer screening; colonoscopy on individual at high risk		PFS	Coinsurance applies & deductible is waived	WAIVED	
	G0106	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema	*Not Rated	PFS	Coinsurance applies & deductible is waived	Coinsurance applies & deductible is waived	
	G0120	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema.		PFS	Coinsurance applies & deductible is waived	Coins. Applies & ded. is waived	
	G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk	A	PFS	Coinsurance applies & deductible is waived	WAIVED	
	82270	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive		CLFS	WAIVED	WAIVED	
	G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous		CLFS	Coinsurance applies & deductible is waived	WAIVED	
	G0102	Prostate cancer screening; digital rectal examination		PFS	Not Waived	Not Waived	
	Prostate Cancer Screening	G0103	Prostate cancer screening; prostate specific antigen test (PSA)	D	CLFS	WAIVED	WAIVED
		G0117	Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist		PFS	Not Waived	Not Waived
	Glaucoma Screening	G0118	Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist	I	PFS	Not Waived	Not Waived
90655		Influenza virus vaccine, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular use	Drug Pricing File		WAIVED	WAIVED	

Preventive Service	CPT/HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
	90656	Influenza virus vaccine, split virus, preservative free, when administered to individuals 3 years and older, for intramuscular use		Drug Pricing File	WAIVED	WAIVED
	90657	Influenza virus vaccine, split virus, when administered to children 6-35 months of age, for intramuscular use		Drug Pricing File	WAIVED	WAIVED
	90660	Influenza virus vaccine, live, for intranasal use		Drug Pricing File	WAIVED	WAIVED
	90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use		Drug Pricing File	WAIVED	WAIVED
	Q2035	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (afluria)		Drug Pricing File	WAIVED	WAIVED
	Q2036	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (flulaval)		Drug Pricing File	WAIVED	WAIVED
	Q2037	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (fluvirin)		Drug Pricing File	WAIVED	WAIVED
	Q2038	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (fluzone)		Drug Pricing File	WAIVED	WAIVED

Preventive Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
	Q2039	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (not otherwise specified)		Drug Pricing File	WAIVED	WAIVED
	G0008	Administration of influenza virus vaccine		PFS	WAIVED	WAIVED
	G9141	Influenza A (H1N1) immunization administration (includes the physician counseling the patient/family)		PFS	WAIVED	WAIVED
	G9142	Influenza A (H1N1) vaccine, any route of administration		Drug Pricing File (if not supplied at no cost)	WAIVED	WAIVED
Pneumococcal Vaccine	90669	Pneumococcal conjugate vaccine, polyvalent, when administered to children younger than 5 years, for intramuscular use	B	Drug Pricing File	WAIVED	WAIVED
	90670	Pneumococcal conjugate vaccine, 13 valent, for intramuscular use.		Drug Pricing File	WAIVED	WAIVED
	90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, when administered to individuals 2 years or older, for subcutaneous or intramuscular use		Drug Pricing File	WAIVED	WAIVED
Hepatitis B Vaccine	G0009	Administration of pneumococcal vaccine	A	PFS	WAIVED	WAIVED
	90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use		Drug Pricing File	Not Waived	WAIVED

Preventive Service	CPT/HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
	90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use		Drug Pricing File	Not Waived	WAIVED
	90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use		Drug Pricing File	Not Waived	WAIVED
	90746	Hepatitis B vaccine, adult dosage, for intramuscular use		Drug Pricing File	Not Waived	WAIVED
	90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use		Drug Pricing File	Not Waived	WAIVED
HIV Screening	G0010	Administration of hepatitis B vaccine	A	PFS	Not Waived	WAIVED
	G0432	Infectious agent antigen detection by enzyme immunoassay (EIA) technique, qualitative or semi-qualitative, multiple-step method, HIV-1 or HIV-2, screening	A	CLFS	WAIVED	WAIVED
	G0433	Infectious agent antigen detection by enzyme-linked immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening		CLFS	WAIVED	WAIVED
	G0435	Infectious agent antigen detection by rapid antibody test of oral mucosa transudate, HIV-1 or HIV-2, screening		CLFS	WAIVED	WAIVED

Preventive Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	Payment Method	CY 2010 Coinsurance/Deductible	CY 2011 Coinsurance/Deductible
Smoking and Tobacco Cessation	G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes	A	PFS	N/A	WAIVED
	G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes		PFS	N/A	WAIVED
Annual Wellness Visit	G0438	Annual wellness visit, including PPPS, first visit	*Not Rated	PFS	N/A	WAIVED
	G0439	Annual wellness visit, including PPPS, subsequent visit		PFS	N/A	WAIVED

¹ U.S. Preventive Services Task Force Recommendations:

A -- The USPSTF recommends the service. There is high certainty that the net benefit is substantial.

B -- The USPSTF recommends the service. There is high certainty that the net benefit is moderate of there is moderate certainty that the net benefit is moderate to substantial.

C -- The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.

I -- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

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3. Extension of Waiver of Deductible to Services Furnished in Connection With or in Relation to a Colorectal Cancer Screening Test That Becomes Diagnostic or Therapeutic

Section 4104(c) of the ACA amended section 1833(b) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic. Specifically, section 1833(b)(1) of the Act (as amended by section 4104(c)(2) of the ACA) waived the deductible with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test. We proposed that all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be considered to be furnished in connection with, as a result of, and in the same clinical encounter as the screening test. In the event of a legislative change to this policy (for example, a statutory change that would waive the coinsurance for these related services in addition to the deductible), we would reassess the appropriateness of this proposed definition of services that are furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test that becomes diagnostic. We also noted that the beneficiary's annual deductible would likely be met when any surgical procedure (related or not) is furnished on the same day as the scheduled screening test.

We proposed to implement this provision by creating a HCPCS modifier that providers and practitioners would append to the diagnostic procedure code that is reported instead of the screening colonoscopy or screening flexible sigmoidoscopy HCPCS code or as a result of the barium enema when the screening test becomes a diagnostic service. The claims processing system would respond to the modifier by waiving the deductible for all surgical services on the same date as the diagnostic test. We proposed that coinsurance would continue to apply to the diagnostic test and to other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

Comment: Many commenters expressed support for CMS' proposal to waive the deductible in cases where a screening colonoscopy for colorectal cancer becomes diagnostic. The

commenters believe that the proposal to waive the Medicare deductible for any surgical service performed on the same day and in the same clinical encounter as a screening colonoscopy if the service is appended with a modifier is a sound approach to implementing the policy.

However, a few commenters requested that CMS also waive the coinsurance for a procedure that was a planned colorectal cancer screening test, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, or as a result of, and in the same clinical encounter as a screening test. The commenters were concerned that beneficiaries may refrain from undergoing a covered colorectal cancer screening test if coinsurance could apply to a resulting diagnostic test and other services furnished in the same encounter as the planned colorectal cancer screening test. As an alternative, several commenters recommend that CMS not apply a coinsurance requirement to the part of the procedure that is screening in nature.

Response: We appreciate the commenters' support for our proposal, including the proposed administrative requirements for practitioners and providers to identify the circumstances under which the waiver of the deductible would apply. As stated above, section 1833(b)(1) of the Act (as amended by section 4104(c)(2) of the ACA) waived the Part B deductible for colorectal cancer screening tests that become diagnostic. The statute does not currently permit waiver of coinsurance for these circumstances as the 20 percent coinsurance applies to all service furnished under the PFS unless there is a specific statutory exception. We believe that a statutory change would be necessary in order to waive the coinsurance for these related services, in addition to the waiver of the deductible.

In response to those commenters who suggested, as an alternative, that we identify the screening portion of the diagnostic test in order to waive the coinsurance for only that portion, we are unable to identify a portion of a diagnostic test that is "screening" because a HCPCS code for a diagnostic test would be reported and, therefore, we would consider the whole test to be diagnostic in nature.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to waive the deductible for colorectal cancer screening tests that become diagnostic. Providers and practitioners

would append new HCPCS modifier -PT (Colorectal cancer screening test, converted to diagnostic test or other procedure) to the diagnostic procedure code that is reported instead of the screening colonoscopy or screening flexible sigmoidoscopy HCPCS code or as a result of the barium enema when the screening test becomes a diagnostic service. The claims processing system would respond to the modifier by waiving the deductible for all surgical services on the same date as the diagnostic test. Coinsurance would continue to apply to the diagnostic test and to other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

S. Section 5501: Expanding Access to Primary Care Services and General Surgery Services

1. Section 5501(a): Incentive Payment Program for Primary Care Services

a. Background

Section 5501(a) of the ACA revised section 1833 of the Act by adding a new paragraph (x), "Incentive Payments for Primary Care Services." Section 1833(x) of the Act states that in the case of primary care services, furnished on or after January 1, 2011 and before January 1, 2016 by a primary care practitioner, there shall also be paid on a monthly or quarterly basis an amount equal to 10 percent of the payment amount for such services under Part B.

Section 1833(x)(2)(A) of the Act (as added by section 5501(a) of the ACA) defines a primary care practitioner as: (1) A physician, as described in section 1861(r)(1) of the Act, who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or (2) a nurse practitioner, clinical nurse specialist, or physician assistant as defined in section 1861(aa)(5) of the Act, and in all cases, for whom primary care services accounted for at least 60 percent of the allowed charges under Part B for the practitioner in a prior period as determined appropriate by the Secretary.

Section 1833(x)(2)(B) of the Act (as added by section 5501(a)(2)(B) of the ACA) defines primary care services as those services identified by the following HCPCS codes as of January 1, 2009 (and as subsequently modified by the Secretary, as applicable):

- 99201 through 99215 for new and established patient office or other outpatient E/M visits;
- 99304 through 99340 for initial, subsequent, discharge, and other nursing facility E/M services; new and

established patient domiciliary, rest home (eg, boarding home), or custodial care E/M services; and domiciliary, rest

home (eg, assisted living facility), or home care plan oversight services; and
 • 99341 through 99350 for new and established patient home E/M visits.

These codes are displayed in Table 66. All of these codes remain active in CY 2011 and there are no other codes used to describe these services.

TABLE 66—PRIMARY CARE SERVICES ELIGIBLE FOR PRIMARY CARE INCENTIVE PAYMENTS IN CY 2011

CPT Code	Description
99201	Level 1 new patient office or other outpatient visit.
99202	Level 2 new patient office or other outpatient visit.
99203	Level 3 new patient office or other outpatient visit.
99204	Level 4 new patient office or other outpatient visit.
99205	Level 5 new patient office or other outpatient visit.
99211	Level 1 established patient office or other outpatient visit.
99212	Level 2 established patient office or other outpatient visit.
99213	Level 3 established patient office or other outpatient visit.
99214	Level 4 established patient office or other outpatient visit.
99215	Level 5 established patient office or other outpatient visit.
99304	Level 1 initial nursing facility care.
99305	Level 2 initial nursing facility care.
99306	Level 3 initial nursing facility care.
99307	Level 1 subsequent nursing facility care.
99308	Level 2 subsequent nursing facility care.
99309	Level 3 subsequent nursing facility care.
99310	Level 4 subsequent nursing facility care.
99315	Nursing facility discharge day management; 30 minutes.
99316	Nursing facility discharge day management; more than 30 minutes.
99318	Other nursing facility services; evaluation and management of a patient involving an annual nursing facility assessment.
99324	Level 1 new patient domiciliary, rest home, or custodial care visit.
99325	Level 2 new patient domiciliary, rest home, or custodial care visit.
99326	Level 3 new patient domiciliary, rest home, or custodial care visit.
99327	Level 4 new patient domiciliary, rest home, or custodial care visit.
99328	Level 5 new patient domiciliary, rest home, or custodial care visit.
99334	Level 1 established patient domiciliary, rest home, or custodial care visit.
99335	Level 2 established patient domiciliary, rest home, or custodial care visit.
99336	Level 3 established patient domiciliary, rest home, or custodial care visit.
99337	Level 4 established patient domiciliary, rest home, or custodial care visit.
99339	Individual physician supervision of a patient in home, domiciliary or rest home recurring complex and multidisciplinary care modalities; 30 minutes.
99340	Individual physician supervision of a patient in home, domiciliary or rest home recurring complex and multidisciplinary care modalities; 30 minutes or more.
99341	Level 1 new patient home visit.
99342	Level 2 new patient home visit.
99343	Level 3 new patient home visit.
99344	Level 4 new patient home visit.
99345	Level 5 new patient home visit.
99347	Level 1 established patient home visit.
99348	Level 2 established patient home visit.
99349	Level 3 established patient home visit.
99350	Level 4 established patient home visit.

b. Primary Care Incentive Payment Program (PCIP)

(1) Primary Specialty Designation

For primary care services furnished on or after January 1, 2011 and before January 1, 2016, we proposed to provide a 10 percent incentive payment to primary care practitioners, identified as the following: (1) In the case of physicians, enrolled in Medicare with a primary specialty designation of 08-family practice, 11-internal medicine,

37-pediatrics, or 38-geriatrics; or (2) in the case of nonphysician practitioners (NPPs), enrolled in Medicare with a primary care specialty designation of 50-nurse practitioner, 89-certified clinical nurse specialist, or 97-physician assistant; and (3) for whom the primary care services displayed in Table 66 accounted for at least 60 percent of the allowed charges under Part B for such practitioner during the time period that is specified by the Secretary, and proposed in this section. Hereinafter, we

refer to practitioners with these primary Medicare specialty designations as potential primary care practitioners and the potential primary care practitioner's ratio of primary care allowed charges to allowed charges under Part B (multiplied by 100) as the primary care percentage.

Comment: Many commenters expressed support for the PCIP and general appreciation for the increased payment for primary care services. Some commenters approved of the

proposed inclusion of nonphysician practitioners (NPPs) in the program, but asked for clarification on the practice settings where these practitioners may furnish PCIP-eligible services. However, several commenters disagreed with the proposed specialty limitations for the PCIP. The commenters recommended that several additional specialties be eligible for the PCIP including, but not limited to, neurology, chiropractics, infectious disease, endocrinology, and certified nurse-midwives. The commenters contended that many practitioners in these other specialties provide primary care services and have the requisite education and training, similar to the potential primary care practitioners in the designated specialties to which payment under the PCIP was proposed.

Response: We appreciate the commenters' support of the PCIP. We recognize that a variety of specialties may provide primary care services as defined broadly under the statute by the E/M codes displayed in Table 66 and, in some cases, these specialist practitioners may truly function as "primary care practitioners" in the common use of the term (providing first contact, coordinated, continuous care for certain patients under their care). However, section 1833(x) of the Act (as added by section 5501(a) of the ACA) specifies in the definition of primary care practitioner the physician specialties that are considered as primary care for purposes of the PCIP. Under section 1833(x)(2)(A)(i)(I) of the Act, only physicians with a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine are considered potential primary care physicians. The provision does not authorize us to add other Medicare specialty designations to the definition of a primary care practitioner for purposes of the PCIP. Therefore, as proposed, we will identify physicians that have a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine (along with nurse practitioners, clinical nurse specialists, and physician assistants) for further evaluation as potential primary care practitioners for purposes of the PCIP.

We note that the PCIP does not place limitations on the setting of the primary care services for which a primary care practitioner may be paid an incentive payment. However, as a practical matter, the statutorily defined primary care services to which the PCIP applies may limit the setting of the services on which a PCIP payment is based. For example, there are no inpatient hospital

care E/M services on the list of primary care services for purposes of the PCIP. The PCIP payment is an amount equal to 10 percent of the payment for primary care services furnished by the primary care practitioner.

Comment: Several commenters commended CMS for proposing that the PCIP payment would be in addition to payments under other incentive programs under Medicare, arguing that this policy is particularly important to encourage the delivery of primary care services to underserved Medicare populations. However, some commenters recommended that CMS increase the amount of PCIP payments because the commenters believe that 10 percent is an insufficient financial incentive to encourage primary care practice over specialty practice as a career path for medical and other health professional students.

Response: We appreciate the commenters' suggestions that primary care should continue to be a Medicare priority and acknowledge that payment incentives are one of many factors that may influence health professional student career choice. While we recognize the importance of encouraging primary care practice and ensuring the accessibility of primary care services, section 1833(x) of the Act (as added by section 5501(a) of the ACA) explicitly states the incentive payment amount, and does not grant authority to the Secretary to adjust the payment amount. According to this provision, primary care practitioners (those who meet the specialty designation and primary care percentage criteria) qualify for an incentive payment equaling 10 percent of the payment amount under Part B for the primary care services they furnish. Therefore, we are maintaining the PCIP incentive payment amount at 10 percent, as we proposed. The statute also specifies that the PCIP payment is to be determined without regard to any payment for the primary care service under section 1833(m) of the statute (currently, the HPSA physician bonus payment program). Therefore, we are also adopting as final our proposal to make any PCIP payment in addition to, but determined without regard to, any HPSA physician bonus payment.

(2) Primary Care Percentage Calculation

In the CY 2011 PFS proposed rule (74 FR 10137), we proposed to use the most current full year of claims data to identify primary care practitioners eligible for the PCIP for a CY based on the practitioner's primary specialty (as identified on claims) and the practitioner's primary care percentage calculated based on the primary care

services displayed in Table 66. We commonly use the most recent full year of claims data for purposes of establishing annual payment amounts under a number of Medicare's fee-for-service programs. A potential primary care practitioner would be eligible for the PCIP in a CY if the practitioner's primary care percentage, calculated as the practitioner's allowed charges for primary care services (identified in Table 66) (the numerator) divided by his or total allowed charges under Part B (the denominator) and multiplied by 100, meets or exceeds the 60 percent threshold. We note that the practitioner's specialty is applied to the claim by the claims processing system and reflects the practitioner's primary specialty designation for purposes of Medicare enrollment on the date the claim is processed, which would usually be close to the date on which the service was actually furnished to the beneficiary. We would identify primary care practitioners eligible for the PCIP for a year by the individual physician/practitioner national provider identifier (NPI) number using the most current full year of claims data available.

Comment: Many commenters described problems potential primary care practitioners would likely encounter in meeting the 60 percent eligibility threshold requirement for the PCIP. The commenters pointed to a few reasons why a potential primary care practitioner's primary care percentage may not meet the 60 percent threshold. Most commenters believe that the denominator in the primary care percentage calculation, or "allowed charges under Part B" as CMS proposed, was too broad, and would limit the number of potential primary care practitioners who would qualify for the PCIP. For example, the commenters speculated that under the proposed threshold calculation, more than one-third of family practitioners and more than 60 percent of general internists would not qualify for the PCIP. Generally, the commenters requested that CMS interpret the phrase "allowed charges under this part" in section 1833(x) of the Act (as added by section 5501(a)(2)(A)(ii) of the ACA) more narrowly to decrease the denominator in the primary care percentage calculation and thereby increase the number of potential primary care practitioners who would qualify for the PCIP.

Several commenters, including MedPAC, recommended that CMS use only the total allowed charges under the PFS, rather than all charges under Part B, as the denominator in the potential primary care practitioner's primary care percentage calculation. The commenters

argued that a potential primary care practitioner's billings under his or her NPI for Part B services not paid under the PFS (including laboratory services, drugs, and durable medical equipment (DME)) would depend upon the organizational structure of the potential primary care practitioner's practice and, therefore, would be unrelated to whether the practitioner was serving as a "true primary care practitioner" for Medicare beneficiaries under his or her care. The commenters asserted that under other sections of the Act, "allowed charges under this part" has been interpreted by CMS to mean "allowed charges under the PFS." The commenters did not believe that potential primary care practitioners serving as "true primary care practitioners" should be penalized with respect to PCIP eligibility because they furnish non-PFS Part B services to their patients.

In addition, other commenters argued that "true primary care practitioners" caring for their patients across all settings in accordance with a traditional primary care model commonly furnish other types of services to their patients that are paid under the PFS but that are not defined as primary care services under the PCIP, such as inpatient hospital care and emergency department visits. The commenters were concerned that providing hospital care to their patients consistent with the goal of improved continuity of care would disadvantage "true primary care practitioners" with respect to the primary care percentage calculation and, ultimately, eligibility for the PCIP. Several commenters emphasized that potential primary care practitioners in rural areas would be more likely to provide a wider variety of services to their patients due to the lack of other more specialized providers in their area, which could make them less likely to qualify for the PCIP. Many commenters contended that the amount of these specific non-primary care PFS allowed charges would be sufficiently large to prevent "true primary care practitioners" from meeting the 60 percent primary care percentage threshold. MedPAC and several other commenters recommended that CMS remove hospital E/M visits from the denominator of the primary care percentage calculation, explaining that this approach would neither penalize nor reward potential primary care practitioners who provide hospital care to their patients with respect to eligibility for the PCIP.

Response: We understand commenters' concerns regarding the criteria for the PCIP eligibility determination, and in particular the

total amount of allowed charges used in the denominator for calculation of the potential primary care practitioner's primary care percentage. We also believe that it is important that the eligibility determination be based on a fair representation of potential primary care practitioners' services so that "true primary care practitioners" may meet or exceed the qualifying primary care percentage threshold for the PCIP, regardless of how they may have chosen to organize their medical practice.

We agree with some commenters who suggested that section 1833(x)(2)(A)(ii) of the Act (as added by section 5501(a) of the ACA) allows some flexibility in implementing the PCIP primary care percentage calculation, based on the phrase in the 60 percent threshold specification that states, "at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary."

We considered several refinements to determine a potential primary care practitioner's allowed charges consistent with the goal of eliminating potential biases that could affect "true primary care practitioners" who practice under certain conditions and structural constraints. We reviewed recent Medicare claims data by specialty designation to determine which Part B services accounted for the highest allowed charges for primary care practitioners, focusing on those services that are not defined as primary care services and, therefore, contribute to increasing the magnitude of the denominator in the primary care percentage. We found that many potential primary care practitioners had significant allowed charges for hospital inpatient care and emergency department visits, which are not considered primary care services for purposes of the PCIP, consistent with the observations of some commenters. Due to the high allowed charges for these hospital visits compared to other primary care services, "true primary care practitioners" providing hospital inpatient and emergency department care for their patients would be less likely to qualify for the PCIP. We also found that rural practitioners, specifically family physicians, may be disproportionately unlikely to qualify for the PCIP because they typically provide a wider variety of services, including hospital inpatient care and emergency department visits, than their urban counterparts. This difference in the profile of potential primary care practitioners' services was even greater for family physicians in frontier states.

Our review of non-PFS Part B services furnished by potential primary care practitioners, including laboratory services, drugs, and DME, showed that allowed charges for these services were typically only a small percentage of the total amount of a potential primary care practitioner's allowed charges under Part B. However, while less influential than the inclusion of hospital visits in the denominator of the primary care percentage for purposes of determining whether a potential primary care practitioner meets the PCIP eligibility threshold, we believe that the inclusion of the non-PFS services in the denominator could also lead to bias against "true primary care practitioners" who provide a full spectrum of care to their patients.

Therefore, in an effort to eliminate potential bias against potential primary care practitioners who are "true primary care practitioners" with certain primary care practice patterns, we are modifying our proposal and will remove certain services from the total allowed charges that is the denominator of the primary care percentage calculation. In the CY 2011 PFS proposed rule (74 FR 40136), we proposed to use all allowed charges under Part B as the denominator in the calculation to determine whether a potential primary care practitioner meets the 60 percent eligibility threshold requirement. Following our analysis of Medicare claims data, we will remove all non-PFS allowed charges and allowed charges for evaluation and management (E/M) services furnished to hospital inpatients and outpatients by potential primary care practitioners from the total allowed charges under Part B. The specific E/M services that we are removing from the denominator for purposes of the primary care percentage calculation are displayed in Table 67. We note that we are not removing hospital inpatient consultation E/M services from the denominator, either face-to-face or via telehealth, because we believe these E/M services do not reflect the types of services that would be furnished by "true primary care practitioners" serving a primary care function for their patients as reflected in their primary care practice patterns.

In other words, PFS charges excluding allowed charges for hospital E/M services will be the denominator in the final primary care percentage calculation for PCIP eligibility determination: $[\text{primary care services} / (\text{PFS charges} - \text{hospital E/M charges})] \text{ multiplied by } 100$. The potential primary care practitioner primary care percentage calculation is subject to traditional rounding rules with respect

to the 60 percent eligibility threshold, meaning 59.5 percent and above will be rounded to 60 percent.

These refinements remove the largest categories of non-primary care allowed charges furnished by "true primary care practitioners" from the primary care percentage calculation used for determination of PCIP eligibility, typically decreasing the magnitude of the denominator and resulting in a higher proportion of primary care to non-primary care services for a given potential primary care practitioner. Limiting the allowed charges to the PFS also removes drugs, laboratory services, and DME from the denominator calculation. While these non-PFS allowed charges are not a large percentage of most potential primary

care practitioners' allowed charges under Part B, we acknowledge the commenters' assertions that many potential primary care practitioners who are "true primary care practitioners" furnish these services to their patients under certain primary care practice models. Therefore, we also believe it is appropriate to remove the non-PFS allowed charges from the denominator of the primary care percentage calculation. In effect, removing allowed charges for hospital E/M and non-PFS services from the total allowed charges in the denominator of the primary care percentage calculation allows significantly more potential primary care practitioners to qualify for the PCIP, while still limiting the payment

incentive to "true primary care practitioners" who predominantly serve a primary care function for their patients. With use of this revised denominator in the primary care percentage calculation, we estimate that over 80 percent of physicians who currently are enrolled in Medicare with a primary specialty designation of family medicine and almost 60 percent of physicians with a designation of internal medicine would qualify for the PCIP based on CY 2009 claims data. This revised calculation removes bias with respect to eligibility of "true primary care practitioners" for the PCIP based on the specific primary care practice characteristics and model they utilize in caring for their patients.

TABLE 67—EXCLUDED HOSPITAL EVALUATION AND MANAGEMENT SERVICES FROM THE DENOMINATOR FOR THE PCIP PRIMARY CARE PERCENTAGE CALCULATION

CPT Code	Description
99217	Observation care discharge day management.
99218	Level 1 initial observation care, per day.
99219	Level 2 initial observation care, per day.
99220	Level 3 initial observation care, per day.
99221	Level 1 initial hospital care, per day.
99222	Level 2 initial hospital care, per day.
99223	Level 3 initial hospital care, per day.
99231	Level 1 subsequent hospital care, per day.
99232	Level 2 subsequent hospital care, per day.
99233	Level 3 subsequent hospital care.
99234	Level 1 observation or inpatient hospital care.
99235	Level 2 observation or inpatient hospital care.
99236	Level 3 observation or inpatient hospital care.
99238	Hospital discharge day management; 30 minutes or less.
99239	Hospital discharge day management; more than 30 minutes.
99281	Level 1 emergency department visit.
99282	Level 2 emergency department visit.
99283	Level 3 emergency department visit.
99284	Level 4 emergency department visit.
99285	Level 5 emergency department visit.

Comment: A number of commenters recommended that CMS add additional services commonly furnished by "true primary care practitioners" to the list of primary care services for purposes of calculation of the primary care percentage and payment of the incentive payments themselves, which are made at 10 percent of the Medicare payment for primary care services. Among the numerous services recommended as additions by the commenters are hospital E/M visits, preventive services such as immunizations, certain diagnostic tests, and services related to home health. The commenters argued that, by increasing the numerator of the primary care percentage calculation used for determining PCIP eligibility, more potential primary care

practitioners would qualify for the PCIP. Moreover, several commenters argued that, when furnished by "true primary care practitioners," these additional services are, in fact, primary care services and therefore should be subject to the incentive payment. The commenters suggested the phrase, "and as subsequently modified by the Secretary" in section 1833(x)(2)(B) of the Act (as added by section 5501(a) of the ACA) following the HCPCS codes defined as primary care services, could be read to provide CMS authority to add services to the list of primary care services. However, some commenters expressed concern that adding services, such as hospital E/M visits, to the list primary care services would qualify many hospitalists for the PCIP with the

result that the PCIP would be applied inappropriately to practitioners predominantly furnishing hospital services. If CMS were to contemplate adding hospital E/M services to the list of primary care services, the commenters argued that CMS should exclude clinicians with hospitalists' claim patterns, even when those practitioners have a potential primary care specialty designation.

Response: While we appreciate commenters' interest in increasing the number of practitioners qualifying for the PCIP, we do not believe that section 1833(x)(2)(B) of the Act (as added by section 5501(a) of the ACA) authorizes us to add services to the list of primary care services specified in the Act. Section 1833(x)(2)(B) of the Act (as

added by section 5501(a) of the ACA) clearly specifies the HCPCS codes that are considered primary care services for purposes of the PCIP, stating "The term 'primary care services' means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary) * * *." This phrase appears in other sections of the Act, and we have consistently interpreted it to refer to the same services that may be reported under different HCPCS codes when those codes change over time. We do not believe the phrase "and as subsequently modified by the Secretary" authorizes us to add codes (additional services) to the definition of primary care services.

Comment: Several commenters expressed concern regarding the reduced likelihood that "true primary care practitioners" in rural areas would qualify for the PCIP because primary care practitioners in remote areas commonly furnish a greater variety of services than those on the list of specific primary care services. The commenters recommended that rural practitioners be qualified for the PCIP based on another primary care percentage threshold that better suits the practice patterns of rural practitioners, including accounting for hospital E/M visits without penalizing the practitioners. Some commenters asserted that the PCIP would only benefit those practitioners furnishing services in health professional shortage areas (HPSAs) based on their belief that the PCIP was limited to primary care practitioners furnishing primary care services in HPSAs or that primary care practitioners would benefit at the cost of other specialty practitioners because of considerations of budget neutrality under the PFS.

Response: We appreciate the concerns of the commenters regarding rural practitioners and their special practice patterns. As discussed earlier in this section, we have modified our primary care percentage calculation for purposes of comparison with the 60 percent PCIP eligibility threshold so that all potential primary care practitioners, including potential primary care practitioners in rural areas, will not miss the PCIP eligibility threshold as a result of furnishing hospital visits to their patients. With regard to applying special criteria for the primary care percentage calculation for rural practitioners, we note that section 1833(x) of the Act does not include any provision that would make the location of the primary care services or the primary care practitioner a factor for PCIP eligibility; the same eligibility determination is applicable to all potential primary care practitioners.

In contrast to the HPSA physician bonus payment program and the HPSA Surgical Incentive Program (HSIP), the PCIP does not consider geographic location in determining practitioner eligibility or the primary care services for which the incentive payments will be made. Although practitioners in rural areas will benefit from the PCIP in the same way as practitioners in other regions, as we note above, PCIP payments will be made in addition to the regular Part B payments for primary care services furnished by eligible primary care practitioners and, if applicable, the HPSA physician bonus payment will also be made. Finally, we note that primary care incentive payments are not subject to the budget neutrality adjustment under the PFS, so PCIP payments will not affect payment for other services for which payment is made under the PFS.

After consideration of the public comments we received, we are finalizing our policy for calculation of the primary care percentage, with certain modifications from the proposed policy. The numerator of the primary care percentage for each NPI is the sum of the allowed charges for the primary care services listed in Table 66, as we proposed. However, the denominator is the allowed charges under the PFS minus the allowed charges for the hospital E/M services listed in Table 67, which is a change from our proposal. We will calculate the primary care percentage for each NPI of a potential primary care practitioner and, if the calculation rounds to 60 percent or greater, the potential primary care practitioner with that NPI will qualify to receive PCIP payments for the applicable year.

(3) Period of Claims Data for Primary Care Percentage Calculation

As we discussed in the CY 2011 PFS proposed rule (74 FR 40137), we proposed to use CY 2009 PFS claims data, processed through June 30, 2010, for determining PCIP practitioner eligibility for CY 2011. This would ensure analysis of about 99 percent of CY 2009 claims to determine practitioner eligibility for PCIP payment beginning January 2011. We note that the MMA changed the requirements for critical access hospital (CAH) billing for practitioners' professional services and, therefore, modifications were made to the Medicare claims processing system to require CAHs to identify the practitioner furnishing a service on the CAH claim for that professional service. However, because the rendering practitioner has only been identified on CAH claims since July 1, 2009, for the

first year of the PCIP we are proposing to identify eligible practitioners using only 6 months of CAH data for those CAHs paid under the optional method. Thereafter, we would update the list of practitioners eligible for the PCIP annually based on the most recent available full year of PFS and CAH claims data.

To the extent practitioners were paid under the PFS during the historical claims data year for some primary services, and CAHs were paid under the optional method for those same practitioners' other professional services, we would aggregate the historical claims data from all settings by the practitioner's NPI in order to determine whether the practitioner is eligible for PCIP payments. We proposed that for all potentially eligible primary care practitioners (both practitioners paid under the PFS and practitioners for whose professional services CAHs are paid under the optional method), the period of claims data used for the annual determination of the practitioner's primary care percentage would lag the PCIP payment year by 2 years (for example, CY 2010 claims data would be used for the CY 2012 PCIP). This 2-year lag is consistent with other areas of the Medicare program where we rely on information from claims data to inform payment in a future year, such as the use of CY 2009 PFS utilization data in the establishment of certain aspects of CY 2011 PFS payment rates.

Under the proposed PCIP eligibility determination method, it would be necessary to revise the list of PCIP-eligible primary care practitioners based on updated claims data regarding primary specialty designation and primary care percentage each year. The revised list of primary care practitioners developed prior to the beginning of the next CY would establish a practitioner's eligibility for PCIP payments for the full next CY. That is, once eligible for the PCIP for a given CY, the practitioner would receive PCIP payments for primary care services furnished throughout that full CY. We would then reassess the practitioner's PCIP eligibility for the next year's payments. As a result, under our proposal, a practitioner newly enrolling in Medicare during a CY would not be eligible for the PCIP until Medicare claims data reflecting the practitioner's primary care specialty and primary care percentage that equals or exceeds the 60 percent threshold were available to establish the practitioner's eligibility for the next PCIP year. Similarly, an enrolled practitioner's change in primary specialty designation (either to

or from a primary care specialty) would not affect that practitioner's eligibility for the PCIP until the practitioner's claims reflecting the change were available for analysis in preparation for the next applicable CY PCIP. In the CY 2011 PFS proposed rule (74 FR 40138), we indicated that, given the statutory requirement for PCIP eligibility that a potential primary care practitioner's primary care services account for at least 60 percent of the allowed charges under Part B for the practitioner in a prior period as determined by the Secretary, we saw no clear alternative methodologies that would allow PCIP payments to be made to those practitioners newly enrolling in Medicare without the 2-year lag in eligibility determination that was described previously. However, given our general interest in supporting primary care practitioners and entry into primary care practice by new physicians and nonphysician practitioners in order to ensure that Medicare beneficiaries have access to these important services, we asked for public comments on alternative approaches for establishing PCIP eligibility for newly enrolled practitioners that would be consistent with the statutory requirement.

Comment: Several commenters opposed the proposed 2-year lag in the data used for PCIP eligibility determination (for example, CY 2009 claims data for CY 2011 PCIP payment). The commenters contended that the 2-year lag would not accurately represent changes in practice or changes in specialty designation, and requested that CMS exercise flexibility in determining the prior period in order to more closely align the eligibility and payment periods. Some commenters recommended that CMS decrease the timeframe of claims data used for eligibility determination to less than a year in order to use claims data from the year immediately prior to the incentive payment year. Other commenters suggested that CMS repeat the eligibility determination for potential primary care practitioners more frequently than annually, allowing multiple opportunities for potential primary care practitioners to meet the primary care percentage threshold because the commenters believe that practitioners may experience seasonal variations in their practice patterns.

The commenters were especially concerned about the eligibility determination for practitioners who newly enroll in Medicare because there would be no Medicare claims data for these practitioners from the 2 years prior to the PCIP payment year. The

commenters were concerned that all newly enrolled potential primary care practitioners would, therefore, be ineligible for the PCIP for up to 2 years during their initial period of practice. The commenters contended that the 2-year interval would discourage, or at a minimum not encourage, primary care practice as a career choice. A few commenters also raised concerns about the corresponding 2-year lag time in PCIP eligibility for practitioners who change their Medicare-enrolled specialty to one that would make them potential primary care practitioners.

The commenters recommended a variety of approaches for CMS to consider in addressing PCIP eligibility for newly enrolled potential primary care practitioners. The commenters' recommendations included using claims data for a 6-month prior period in order to limit the lag time; making a lump sum PCIP payment after the conclusion of the PCIP payment year once eligibility could be confirmed; placing PCIP payments into escrow accounts to be paid after the potential primary care practitioner's first year of practice if the primary care percentage threshold was met; or presuming the eligibility of all practitioners with the designated enrolled specialties until claims data demonstrated that they did not qualify for the PCIP.

Response: We appreciate the commenters' interest in closely aligning the period of claims data used to determine PCIP eligibility with the time period where the primary care services subject to the incentive payment would be furnished in order to identify those primary care practitioners with the most current primary care practice patterns for the PCIP. For practitioners who were enrolled in Medicare 2 years prior to the PCIP payment year, as we proposed, we believe it is important to consider a full year of claims data rather than a shorter period, in order to account for seasonal variations in care patterns and more accurately represent the totality of PFS services provided by the potential primary care practitioner. Medical practices often experience fluctuations in the services that they provide over a year. A longer data period helps to smooth the variation and, therefore, better represents the totality of the potential primary care practitioner's practice. Due to the time necessary to receive and process claims data, using the claims data from the full year prior to the PCIP payment year for calculating the primary care percentage would delay incentive payments until after the third quarter of the PCIP payment year for all eligible primary care practitioners, a delay which we believe

is not desirable because the statute indicates that we should make quarterly or monthly PCIP payments. Therefore, we believe that the 2-year lag method, as described in the CY 2011 PFS proposed rule (74 FR 40137), is the most appropriate approach to determining eligibility for most potential primary care practitioners because it allows for a review of a full year of claims data without delaying incentive payments for most eligible primary care practitioners.

However, we recognize the special circumstances of newly enrolled potential primary care practitioners, in that they do not have the claims history from 2 years prior to the PCIP payment year to determine their eligibility. We believe it is important to give potential primary care practitioners newly enrolling in Medicare in the year immediately preceding the PCIP payment year the opportunity to qualify for the PCIP with minimal delay. Therefore, for these practitioners, we will determine PCIP eligibility based on a different prior period than for those practitioners who are already enrolled in Medicare and who have Medicare claims data from 2 years prior to the PCIP payment year available for analysis. Section 1833(x) of the Act (as added by Section 5501(a) of the ACA) gives the Secretary the authority to establish the period of allowed charges used to assess the potential primary care practitioner's primary care percentage with regard to the minimum 60 percent threshold required for PCIP eligibility. For newly enrolled potential primary care practitioners only, we will use the available claims data from the year immediately preceding the PCIP payment year (for example, CY 2010 claims data for CY 2011 PCIP payment) to determine PCIP eligibility. We will use all claims data available for the newly enrolled potential primary care practitioner from that prior year to determine PCIP eligibility, with no minimum time period that the potential primary care practitioner must have been enrolled in Medicare in that prior year. Therefore, a newly enrolled potential primary care practitioner would need to wait no more than one year and potentially significantly less than one year following enrollment and first billing in order for the primary care services furnished by that eligible primary care practitioner to be subject to the PCIP in the year following the practitioner's initial enrollment.

Due to the processing lag for claims data from the previous CY, PCIP payments for newly enrolled primary care practitioners will be delayed until after the end of the third quarter of the PCIP payment year, although the PCIP

payments will ultimately be made for all primary care services the eligible practitioners furnished throughout the full PCIP payment year. Following that first PCIP eligibility determination in the year immediately following the potential primary care practitioner's enrollment in Medicare, PCIP eligibility will be determined as specified previously for a practitioner who was enrolled in Medicare 2 years prior to the PCIP payment year.

For example, if a practitioner newly enrolled in Medicare any time during CY 2010 with a primary specialty designation of family medicine and furnished services that were billed to Medicare, in CY 2011 we will evaluate the family physician's CY 2010 claims data to determine whether the physician meets the 60 percent primary care percentage eligibility threshold for CY 2011 payment under the PCIP. We would not be able to make this assessment until the CY 2010 claims data are substantially complete and, therefore, would anticipate making a determination regarding the physician's eligibility some time after the midpoint of CY 2011. If the family physician is eligible for the PCIP, we would make a lump sum payment for those primary care services furnished earlier in CY 2011 prior to the determination of eligibility and then we would begin making quarterly PCIP payments following the third quarter of CY 2011. For the same physician for the CY 2012 PCIP payment year, we would again refer to CY 2010 claims data to assess whether the physician is eligible for the PCIP and, if applicable (eligibility could potentially change with more complete CY 2010 data than were available for the CY 2011 determination), make quarterly PCIP payments to that physician in CY 2012.

The use of a different prior period in the case of newly enrolled potential primary care practitioners will allow us more quickly to assess whether the practitioner qualifies for the PCIP and make any applicable PCIP payment, while allowing PCIP payments for established primary care practitioners to be made timely for each quarter of the PCIP payment year based on the use of a different prior period to determine the eligibility of previously enrolled potential primary care practitioners. The use of the more recent prior period for PCIP eligibility determination will not apply to practitioners who are already enrolled in Medicare 2 years prior to the PCIP payment year, but switch their specialty designation to a potential primary care specialty in the year immediately preceding the PCIP payment year. As we explained in the

CY 2011 PFS proposed rule (74 FR 40138) and discuss further below, we do not want to encourage practitioners to change their specialty designation merely for the purpose of garnering PCIP payments. Moreover, if we were to make an accommodation for practitioners enrolled in Medicare who change their specialty to a potential primary care practitioner specialty after the data year used for PCIP eligibility determination, we would also need to devise a process to remove practitioners from PCIP eligibility if they changed to a non-primary care specialty during that same period. We believe the incentives and the practice challenges experienced by newly enrolling practitioners are not the same as those for established practitioners and, on balance, we continue to believe it is appropriate to establish PCIP eligibility based upon claims data for a full CY. This policy will also ensure greater predictability of payment, which is an important objective of the PCIP and Medicare payment policy in general.

We do not agree with commenters who recommended that we make PCIP payments to newly enrolled potential primary care practitioners based on a self-certification process or presumptions about eligibility. Making incentive payments prior to review of a practitioner's eligibility based on claims data would inevitably result in inappropriate PCIP payments to potential primary care practitioners. Any such payments would constitute overpayments subject to recoupment, which would place a burden on our claims processing systems and on the practitioners themselves.

After consideration of the public comments we received, we are finalizing our CY 2011 proposal to use Medicare claims data for the year 2 years prior to the PCIP payment year to determine PCIP eligibility for those potential primary care practitioners who were enrolled in Medicare in that year. However, we are modifying the proposed policy to use claims data from the year immediately preceding the PCIP payment year in order to determine PCIP eligibility for potential primary care practitioners who newly enroll in Medicare in the year immediately preceding the PCIP payment year. The PCIP payments to newly enrolled potential primary care practitioners, if applicable, will be made as a lump sum for those primary care services furnished earlier in the PCIP payment year by the eligible primary care practitioner as soon as an eligibility determination can be made in the PCIP payment year. Quarterly PCIP payments for these eligible primary care

practitioners will begin following the third quarter of the PCIP payment year.

In the CY 2011 PFS proposed rule (74 FR 40138), we stated that we plan to monitor changes in the primary specialty designations of enrolled practitioners over time and would expect not to see significant changes in the specialties of currently enrolled practitioners as a result of the PCIP payments. We would expect that physicians changing their primary specialty to one of the primary care specialties of family medicine, internal medicine, geriatric medicine, or pediatric medicine and who would be newly eligible for the PCIP are furnishing primary care services to the patients in their practices. Consistent with our past policies, we would expect that physicians changing their primary specialty designation under Medicare would make such changes only so that their primary specialty designation is fully consistent with the specific or unique type of medicine they practice. If we find that physicians are changing their specialty designations (for example, cardiologists who designate their primary specialty as internal medicine, although they practice cardiology) in order to take advantage of the PCIP payments, we would consider making future revisions to eliminate such an outcome.

Comment: Several commenters agreed that CMS should review the specialty designations of physicians and nonphysician practitioners to ensure there is no gaming of the system in order for practitioners to qualify for the PCIP.

Response: We appreciate the commenters' support and plan to follow closely the changes in the Medicare primary specialty designations of physicians and nonphysician practitioners. As we stated previously, if we find that practitioners are changing their specialty designations in order to become eligible for PCIP payments rather than to reflect their actual practice, we may consider making future revisions to address this problem.

(4) PCIP Payment

We proposed in the CY 2011 PFS proposed rule (74 FR 40138) that PCIP payments would be calculated by the Medicare contractors and made quarterly on behalf of the eligible primary care practitioner for the primary care services furnished by the practitioner in that quarter, consistent with the established Medicare HPSA physician bonus program (Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, Section 90.4.4) and the proposed HSIP described in section

III.S.2. of this final rule with comment period. The primary care practitioners' professional services may be paid under the PFS based on a claim for professional services or, where the practitioner has reassigned his or her benefits to a CAH paid under the optional method, to the CAH based on an institutional claim.

Comment: Several commenters supported CMS' proposal to make incentive payments quarterly. These commenters agreed that quarterly payments would mitigate the administrative burden and better account for the practice patterns of the various types of primary care practitioners submitting claims for primary care services.

Response: We appreciate the commenters' support of the quarterly PCIP payments. We agree that the quarterly payments would work well with the billing cycles of many practitioners and would be consistent with Medicare payment policies for other incentive programs.

As discussed in CY 2011 PFS proposed rule (74 FR 40138), eligible primary care practitioners would be identified on a claim based on the NPI of the rendering practitioner. If the claim is submitted by a practitioner's group practice or a CAH, the rendering practitioner's NPI must be included on the line-item for the primary care service (identified in Table 66) in order for a determination to be made regarding whether or not the service is eligible for payment of the PCIP. We note that, in order to be eligible for the PCIP, physician assistants, clinical nurse specialists, and nurse practitioners must be billing for their services under their own NPI and not furnishing services incident to physicians' services. Regardless of the specialty area in which they may be practicing, these specific NPPs would be eligible for the PCIP based on their enrolled potential primary care practitioner specialty if their historical primary care percentage equals or exceeds the 60 percent threshold.

In the CY 2011 PFS proposed rule (75 FR 41038), we indicated that section 1833(x)(4) of the Act (as added by section 5501(a) of the ACA) specifies that "there shall be no administrative or judicial review under section 1869, or section 1878, or otherwise, respecting the identification of primary care practitioners." We believe that the inclusion of this language is intended to provide a means for the practical implementation of this provision. We explained that we must develop a process and identify primary care practitioners before we can make

payments under the PCIP to the eligible primary care practitioners. The statute gives CMS the authority to make final determinations of eligible primary care practitioners that are not subject to appeal through the various channels normally available to practitioners, in order for the timely payments under the PCIP to occur. In contrast, if the eligibility determinations that we must make under this provision were subject to appeal, the timely implementation of this program could be jeopardized and payments under the PCIP could be significantly delayed. However, we stated that we did not believe that the "no administrative or judicial review" clause precludes CMS from correcting errors resulting from clerical or mathematical mistakes. Therefore, we indicated that practitioners would have the opportunity to notify CMS of clerical or mathematical errors that may have occurred during the process of identifying eligible primary care practitioners for PCIP payment and that may have resulted in a mistaken eligibility determination for the PCIP.

Comment: Several commenters supported the review of the PCIP eligibility determinations for clerical or mathematical mistakes. The commenters agreed that a review of the data calculations may be necessary when errors are suspected. Some commenters further asked for clarification and transparency regarding the formula and data that are used for eligibility determinations. Finally, several commenters requested that CMS provide notification to individual qualifying primary care practitioners even if the PCIP payment is made to the group practice under a reassignment arrangement.

Response: We appreciate the support of the commenters for a review when suspected clerical or mathematical mistakes are identified. As described earlier in this section, the formula used to determine the primary care percentage for a potential primary care practitioner is the practitioner's allowed charges from the applicable data year (the prior period) for primary care services (listed in Table 66) divided by the total allowed charges under the PFS, excluding hospital E/M visits (listed in Table 67), and multiplied by 100. The specialty designation and allowed charges used to identify a potential primary care practitioner and calculate the primary care percentage are based on the claims data that are submitted by the practitioner during the applicable prior year for eligibility determination for the PCIP payment year, which depends on whether the potential primary care practitioner was newly

enrolled in Medicare in the year immediately prior to the PCIP payment year or previously enrolled in Medicare. Those data will be reviewed when we are assessing a suspected mistake.

We note that Medicare contractors will post a list of individual primary care practitioners eligible for the PCIP for a year, along with their NPIs, on their web sites. We do not anticipate providing individual notices to PCIP-eligible primary care practitioners for each year. Rather, primary care practitioners, including those who have reassigned their benefits, can confirm their eligibility for the PCIP for a year without direct individual notification.

In the CY 2011 PFS proposed rule (75 FR 41038), we further noted that section 1833(x)(3) of the Act (as added by section 5501(a) of the ACA) authorizes payment under the PCIP as an additional payment amount for specified primary care services without regard to any additional payment for the service under section 1833(m) of the Act. Therefore, an eligible primary care physician furnishing a primary care service in a HPSA may receive both a HPSA physician bonus payment under the established program and a PCIP payment under the new program beginning in CY 2011, but the PCIP payment is made without regard to the HPSA physician bonus payment amount. In addition, payments for outpatient CAH services under section 1834(g)(2)(B) of the Act (as amended by section 5501(a) of the ACA) would not be affected by the PCIP payment amounts made to the CAH on behalf of the primary care practitioner.

(5) Summary of Final PCIP Policies

In summary, after consideration of the public comments we received, we are finalizing our CY 2011 proposals for the PCIP, with modification. Practitioners with a designated primary Medicare-enrolled specialty of family medicine, internal medicine, geriatric medicine, pediatric medicine, nurse practitioner, clinical nurse specialist, or physician assistant and whose primary care percentage, calculated as primary care allowed charges divided by PFS allowed charges excluding hospital E/M visits, and then multiplied by 100, exceeds 60 percent will be eligible for the PCIP. The primary care percentage will be calculated based on claims data from 2 years prior to the PCIP payment year for practitioners enrolled in Medicare in that year, and from the year immediately prior to the PCIP payment year for practitioners newly enrolling in that year. Beginning immediately following the first quarter of CY 2011, incentive payments for primary care

services furnished by eligible practitioners will be paid quarterly after the conclusion of the calendar quarter, in addition to payments by Medicare for the primary care services and other incentive program payments. The list of eligible primary care practitioners will be updated annually based upon our analysis of claims data from the subsequent reference period.

Accordingly, we are finalizing our regulation at new § 414.80 to specify the requirements of the PCIP. While we are finalizing our proposed definition of primary care services in § 414.80(a), we are revising our proposed definition of eligible primary care practitioners in § 414.80(a)(i)(B) and (ii)(B) to specify that at least 60 percent of the physician's or practitioner's allowed charges under the PFS (excluding hospital evaluation and management visits) during a reference period specified by the Secretary are for primary care services. We are finalizing § 414.80(b) as proposed to provide eligible primary care practitioners a 10 percent incentive payment for primary care services, in addition to the amount that would otherwise be paid for their professional services under Part B. Quarterly PCIP payments will be made to eligible practitioners or to CAHs paid under the optional method that are billing on behalf of practitioners for their professional services for identified primary care services.

2. Section 5501(b): Incentive Payment Program for Major Surgical Procedures Furnished in Health Professional Shortage Areas

a. Background

Section 1833(m) of the Act provides for an additional 10 percent incentive payment when physicians' services are furnished to a covered individual in an area designated as a geographic Health Professional Shortage Area (HPSA) as identified by the Secretary prior to the beginning of such year. Section 5501(b) of the ACA revises section 1833 of the Act by adding new subparagraph (y), "Incentive Payments for Major Surgical Procedures Furnished in Health Professional Shortage Areas."

In the case of major surgical procedures furnished by a general surgeon on or after January 1, 2011 and before January 1, 2016, in an area designated under section 332(a)(1)(A) of the Act as a geographic HPSA, they would be paid on a monthly or quarterly basis an amount equal to 10 percent of the payment amount for eligible services under Part B. Section 1833(y)(2)(A) of the Act (as added by section 5501(b) of the ACA) defines a general surgeon as

a physician who is described in section 1861(r)(1) of the Act and who has designated a CMS specialty code of 02-general surgery as his or her primary specialty code in the physician's enrollment in Medicare under section 1866(j) of the Act.

Section 1833(y)(2)(B) of the Act (as added by section 5501(b) of the ACA) defines major surgical procedures as surgical procedures for which a 10-day or 90-day global period is used for payment under the PFS under section 1848(b) of the Act. In Addendum B to the CY 2010 PFS final rule with comment period (74 FR 62017 through 62143), as corrected in the correction notice (74 FR 65455 through 65457), we identified 489 10-day global procedure codes and 3,796 90-day global procedure codes for a total of 4,285 surgical procedure codes that would have met the surgical procedure criteria for the incentive payment if it were applicable in CY 2010.

b. HPSA Surgical Incentive Payment Program (HSIP)

For services furnished on or after January 1, 2011 and before January 1, 2016, in the CY 2011 PFS proposed rule (75 FR 40139) we proposed to provide a 10 percent incentive payment to general surgeons, identified by their enrollment in Medicare with a primary specialty code of 02-general surgery, in addition to the amount they would otherwise be paid for their professional services under Part B, when they furnish a major surgical procedure in a location defined by the Secretary as of December 31 of the prior year as a geographic HPSA. As with the PCIP described above, we stated in the CY 2011 PFS proposed rule (75 FR 40139) that we did not believe surgeons would change their Medicare specialty designation in order to take advantage of the HSIP payments. However, we described our plan to monitor the specialty designations of enrolled physicians, and if we were to find that surgeons were changing their primary specialty designation to general surgery in order to take advantage of the HSIP payments, we would consider making future revisions to eliminate such an outcome.

Consistent with the established Medicare HPSA physician bonus program, we proposed that HSIP payments be calculated by Medicare contractors based on the criteria for payment discussed earlier in this section, and payments would be made quarterly on behalf of the qualifying general surgeon for the qualifying major surgical procedures. The surgeons' professional services would be paid

under the PFS based on a claim for professional services or, when a physician has reassigned his or her benefits to a CAH paid under the optional method, to the CAH based on an institutional claim.

Qualifying general surgeons would be identified on a claim for a major surgical procedure based on the primary specialty of the rendering physician, identified by his or her NPI, of 02-general surgery. If the claim is submitted by a physician's group practice or a CAH, the rendering physician's NPI must be included on the line-item for the major surgical procedure in order for a determination to be made regarding whether or not the procedure is eligible for payment under the HSIP.

For HSIP payment to be applicable, the major surgical procedure must be furnished in an area designated by the Secretary as of December 31 of the prior year as a geographic HPSA. We stated that we would provide HSIP payments for major surgical procedures furnished by general surgeons in the same HPSAs as we currently recognize for purposes of payment of all physicians under the established Medicare HPSA physician bonus program under section 1833(m) of the Act.

Each year, we publish a list of zip codes eligible for automatic payment of the HPSA physician bonus payment at: http://www.cms.gov/hpsapsaphysicianbonuses/01_overview.asp. We proposed to use the same list of zip codes for automatic payment of the incentive payment for qualifying surgical procedures furnished by general surgeons. We also proposed to create a new HCPCS code modifier to identify circumstances when general surgeons furnish qualifying surgical procedures in areas that are designated as HPSAs as of December 31 of the prior year, but that are not on the list of zip codes eligible for automatic payment. The new modifier would be appended to the major surgical procedure on claims submitted for payment, similar to the current process for payment of the Medicare HPSA physician bonus when the geographic HPSA is not a HPSA identified for automatic payment.

Consistent with the statutory requirement, we would define major surgical procedures as those for which a 10-day or 90-day global period is used for payment under the PFS. For CY 2011, approximately 4,300 10-day and 90-day global surgical procedure codes were identified in Addendum B to the CY 2011 PFS rule (75 FR 40262 through 40641) under the far right column labeled "Global" and designated with "010" or "090," respectively.

We further noted that section 1833(y)(3) of the Act (as added by section 5501(b)(1) of the ACA) authorizes payment under the HSIP as an additional payment amount for specified surgical services without regard to any additional payment for the service under section 1833(m) of the Act. Therefore, a general surgeon may receive both a HPSA physician bonus payment under the established Medicare HPSA physician bonus program and a HSIP payment under the new program beginning in CY 2011, but the HSIP payment would be made without regard to the HPSA physician bonus payment amount. In addition, payments for outpatient CAH services under section 1834(g)(2)(B) of the Act (as amended by section 5501(b) of the ACA) would not be affected by the HSIP payment amounts made to the CAH on behalf of the general surgeon.

Accordingly, for CY 2011, we proposed to revise § 414.2 and add the definitions of "HPSA" and "major surgical procedure." We also proposed to revise § 414.67 to move the existing provisions to paragraph (a) to be grouped as the "Health Professional Shortage Area (HPSA) physician bonus program" and adding a new paragraph (b) for the "HPSA surgical incentive payment program" provisions. Section 414.67(b) would state that general surgeons who furnish identified 10-day and 90-day global period surgical procedures in an area designated by the Secretary as of December 31 of the prior year as a geographic HPSA that is recognized by Medicare for the HPSA physician bonus program as specified under renumbered § 414.67(a)(1) would receive a 10 percent incentive payment in addition to the amount that would otherwise be paid for their professional services under Part B. Physicians furnishing services in areas that are designated as geographic HPSAs prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA surgical incentive payments are made would report a specified HCPCS code modifier to receive the HSIP payment. Quarterly incentive payments would be made to physicians or to CAHs paid under the optional method when billing on behalf of physicians for their professional services.

Comment: A number of commenters supported CMS' proposal to implement the HSIP. A few commenters recommended expanding the geographic eligibility criteria for the HSIP to increase the number of qualifying procedures furnished by general surgeons for which the incentive payment would be made. These

commenters suggested that CMS introduce three modifications to the proposed criteria in order to provide the incentive payment for major surgical procedures furnished by general surgeons to Medicare beneficiaries who have limited access to general surgical care. Specifically, the commenters recommended that CMS additionally provide the incentive payment for: (1) Qualifying surgical procedures performed by a general surgeon in a hospital adjacent to a recognized HPSA; (2) qualifying surgical procedures performed by a general surgeon who resides in a recognized HPSA; and (3) qualifying surgical procedures performed by a general surgeon who has an office in a recognized HPSA. The commenters argued that the proposed policy would narrowly limit the availability of the general surgery incentive payments by linking payments only to surgical procedures furnished in established HPSAs. The commenters concluded that the proposed policy would result in relatively fewer general surgeons receiving the incentive payments and would not capture surgical procedures furnished in all of the nation's geographic areas in which there is a shortage of general surgeons.

Response: We appreciate the commenters' support for our proposal. Regarding commenters' requests for expansion of the locations for surgery when we would provide the incentive payment for major surgical procedures furnished by general surgeons, we do not believe that we have the authority to expand the care settings beyond the statutorily prescribed location, that is, "major surgical procedures * * * by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area." Section 1833(y) of the Act (as added by section 5501(b) of the ACA) relies solely on section 332(a)(1)(A) of the Public Health Service Act to identify qualifying HPSAs and expressly notes that the HPSA must be identified by the Secretary prior to the beginning of the HSIP payment year.

Comment: One commenter requested that CMS extend HSIP payment to physician assistants who are trained as first assistants at surgery. The commenter encouraged CMS to provide the 10 percent incentive payment to physician assistants, trained in surgical specialties, who ensure both that beneficiaries in rural areas have access to appropriate surgical care and that general surgeons furnishing surgical procedures in these locations are appropriately supported by physician assistants trained in surgical specialties.

Response: Section 1833(y)(2) of the Act (as added by section 5501(b) of the ACA) specifically limits HSIP eligibility to those physicians (a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action according to the definition in section 1861(r)(1)) of the Act who have designated 02-general surgery as their primary specialty code in Medicare's physician enrollment. On the other hand, physician assistants are not doctors of medicine or osteopathy and these practitioners are identified in Medicare enrollment with the specialty code 97-physician assistant. Therefore, we do not believe we have the statutory authority to extend HSIP payment to physician assistants who provide surgical support for major surgeries furnished by general surgeons in recognized HPSAs.

After consideration of the public comments we received, we are finalizing our CY 2011 HSIP proposal, with modification regarding the proposal to create a new HCPCS code modifier to identify circumstances when general surgeons furnish services in areas that are designated as HPSAs as of December 31 of the prior year, but that are not on the list of zip codes eligible for automatic payment. Under our final policy, under these circumstances practitioners would report the existing modifier-AQ (Physician providing a service in a HPSA) that is used for the established Medicare HPSA physician bonus program because we would make incentive payments under the HSIP for surgical procedures furnished by general surgeons in the same HPSAs that are recognized for the Medicare HPSA physician bonus program.

In summary, the HSIP provides a 10 percent incentive payment quarterly to qualifying physicians enrolled as general surgeons in Medicare (or to the CAHs to which they have reassigned their benefits) for qualifying 10-day and 90-day global surgical procedures furnished on or after January 1, 2011 and before January 1, 2016 by those general surgeons in recognized geographic HPSAs. CMS will make automatic payments when the zip code for the location of service is found in the applicable file for the payment year on the CMS web site for the HPSA physician bonus program at: http://www.cms.gov/hpsapsaphysicianbonuses/01_overview.asp. Existing HCPCS modifier-AQ should be appended to the major surgical procedure on claims submitted for payment to identify circumstances when general surgeons

furnish services in areas that are designated as HPSAs as of December 31 of the prior year, but that are not on the list of zip codes eligible for automatic payment.

We are also finalizing our proposed revisions to the Code of Federal Regulations related to the HSIP, with minor modification. We are revising § 414.2 as we proposed to add the definitions of "HPSA" and "major surgical procedure." We also are revising § 414.67 as we proposed to move the existing provisions to paragraph (a) to be grouped as the "Health Professional Shortage Area (HPSA) physician bonus program" and adding new paragraph (b) for the "HPSA surgical incentive payment program" provisions. We are finalizing our proposal for § 414.67(b) to state that general surgeons who furnish identified 10-day and 90-day global period surgical procedures in an area designated by the Secretary as of December 31 of the prior year as a geographic HPSA that is recognized by Medicare for the HPSA physician bonus program as specified under renumbered § 414.67(a)(1) would receive a 10 percent incentive payment in addition to the amount that would otherwise be paid for their professional services under Part B. We are modifying the proposal to specify in § 414.67(b)(3) that physicians furnishing services in areas that are designated as geographic HPSAs prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA surgical incentive payments are made would report HCPCS modifier-AQ to receive the HSIP payment and to change the term "bonus" to "incentive" when referring to the HSIP. Quarterly incentive payments will be made to physicians or to CAHs paid under the optional method when billing on behalf of physicians for their professional services.

3. Sections 5501(a) and (b) of the ACA and Payment for Critical Access Hospital Professional Services Under the Optional Method

Section 1834(g) of the Act established the payment rules for outpatient services furnished by a CAH. In 1999, section 403(d) of the Balanced Budget Refinement Act of 1999 (Pub. L. 106-113) (BBRA) amended section 1834(g) of the Act to provide for two methods of payment for outpatient services furnished by a CAH. Specifically, section 1834(g)(1) of the Act, as amended by the BBRA, specifies that the amount of payment for outpatient services furnished by a CAH is equal to the reasonable costs of the CAH in

furnishing such services. (The physician or other practitioner furnishing the professional service receives payment under the PFS.) In the alternative, the CAH may make an election, under section 1834(g)(2) of the Act, to receive amounts that are equal to "the reasonable costs" of the CAH for facility services plus, with respect to the professional services, the amount otherwise paid for professional services under Medicare, less the applicable Medicare deductible and coinsurance amount. The election made under section 1834(g)(2) of the Act is sometimes referred to as "method II" or "the optional method." Throughout this section we refer to this election as "the optional method."

In 2000, section 202 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554) (BIPA) amended section 1834(g)(2)(B) of the Act to increase the payment for professional services under the optional method to 115 percent of the amount otherwise paid for professional services under Medicare. In addition, in 2003 section 405(a)(1) of the MMA amended section 1834(g)(1) of the Act by inserting the phrase "equal to 101 percent of" before the phrase "the reasonable costs." However, section 405 of the MMA did not make a corresponding change to section 1834(g)(2)(A) of the Act regarding the amount of payment for facility services under the optional method. In 2010, section 3128 of the ACA amended section 1834(g)(2)(A) of the Act by inserting the phrase "101 percent of" before "the reasonable costs."

Section 5501(a) of the ACA amends section 1833 of the Act by adding a new paragraph (x), "Incentive Payments for Primary Care Services," that authorizes additional Part B payments to primary care practitioners for primary care services. Section 5501(b) of the ACA further amends section 1833 of the Act by adding new paragraph (y), "Incentive Payments for Major Surgical Procedures Furnished in Health Professional Shortage Areas," that authorizes additional Part B payments for major surgical procedures furnished by general surgeons in HPSAs. Sections 5501(a)(3) and 5501(b)(3) of the ACA make conforming amendments to section 1834(g)(2)(B) of the Act, which refers to payment to the CAH for professional services under the optional method, by adding at the end of section 1834(g)(2)(B) of the Act the following phrase, "Subsections (x) and (y) of 1833 of the Act shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence." As such,

section 1834(g)(2)(B) of the Act (as amended by sections 5501(a)(2) and 5501(b)(2) of the ACA) requires that under the optional method, the 115 percent adjustment payment to the CAH for professional services is calculated without considering the incentive payments for primary care services furnished by primary care practitioners and major surgical procedures furnished by general surgeons in HPSAs as these terms are defined under sections 1833(x) and (y) of the Act.

The regulations implementing section 1834(g)(2)(B) of the Act, payment to the CAH for professional services under the optional method, are in § 413.70(b)(3)(ii)(B). In order to implement the amendments to section 1834(g)(2)(B) of the Act as specified by sections 5501(a)(2) and 5501(b)(2) of the ACA, we are proposing to amend the regulations in § 413.70(b)(3)(ii)(B) to state that, effective for primary care services furnished by primary care practitioners and major surgical procedures furnished by general surgeons in HPSAs on or after January 1, 2011 and before January 1, 2016, the additional incentive payment amounts as specified in § 414.67 and § 414.80 are not included in the determination of the payment for professional services made to the CAH under the optional method. Accordingly, we are proposing that payment for professional services to the CAH at 115 percent of the PFS amount under the optional method would not take into account the additional Part B incentive payments for primary care services furnished by primary care practitioners and major surgical procedures furnished by general surgeons in HPSAs as provided in § 414.67 and § 414.80.

Comment: Several commenters supported CMS' proposal to make HSIP and PCIP payments to CAHs paid under the optional method for qualifying services furnished by eligible practitioners who have reassigned their billing rights to the CAHs. No commenters addressed CMS' proposal to calculate the 115 percent adjustment payment to the CAH for professional services without considering the incentive payments for primary care services furnished by primary care practitioners and major surgical procedures furnished by general surgeons in HPSAs.

Response: We appreciate the commenters' support for our proposal to include qualifying professional services billed by CAHs paid under the optional method furnished by eligible practitioners in the PCIP and HSIP.

After considering the public comments we received, we are finalizing our CY 2011 proposal to

include CAHs paid under the optional method in the PCIP and HSIP. Payment to a CAH paid under the optional method, will be made quarterly, for eligible professional services furnished by qualifying physicians and nonphysician practitioners who have reassigned their billing rights to the CAH. Furthermore, we are finalizing our CY 2011 proposal to specify that payment for professional services to the CAH at 115 percent of the PFS amount under the optional method would not take into account the additional Part B incentive payments for primary services furnished by primary care practitioners and major surgical procedures furnished by general surgeons in HPSAs. We are amending § 413.70(b)(3)(ii)(B) as we proposed to reflect this final policy.

T. Section 6003: Disclosure Requirements for In-Office Ancillary Services Exception to the Prohibition on Physician Self-Referral for Certain Imaging Services

1. Background

Section 1877 of the Act (also known as the physician self-referral law): (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 or compensation), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare (or billing another individual, entity, or third party payer) for those DHS rendered as a result of a prohibited referral. The statute establishes a number of exceptions and grants the Secretary the authority to create regulatory exceptions that pose no risk of program or patient abuse.

Section 1877(b)(2) of the Act, entitled "In-office Ancillary Services" sets forth the exception that permits a physician in a solo or group practice to order and provide designated health services (DHS), other than most durable medical equipment and parenteral and enteral nutrients, in the office of the physician or group practice, provided that certain criteria are met. The requirements of the in-office ancillary services exception are described at § 411.355(b).

Section 6003 of the ACA amended section 1877(b)(2) of the Act by creating a new disclosure requirement for the in-office ancillary services exception to the prohibition on physician self-referral. Specifically, section 6003 of the ACA provided that, with respect to referrals for magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), and any

other DHS specified under section 1877(h)(6)(D) of the Act that the Secretary determines appropriate, the referring physician inform a patient in writing at the time of the referral that the patient may obtain the service from a person other than the referring physician or someone in the physician's group practice and provide the patient with a list of suppliers who furnish the service in the area in which the patient resides.

In the CY 2011 PFS proposed rule, we proposed regulations related to section 6003 of the ACA. We are finalizing that proposal with modification. We received approximately 45 comments related to this section. Most commenters offered support for the proposed rule and some stated that it was consistent with the intent of the legislation, which was to provide choice for patients; as well as a degree of protection against conflicts of interest. Others stated that disclosure might be a first step towards ending abuses in self-referral, but questioned the overall effectiveness of the disclosure requirement in reducing overutilization. These commenters were nonetheless supportive of the reasonable mechanisms used to implement the requirement.

We are finalizing some elements of the proposal without modification. Elements that remain unchanged from the proposed rule include: application of the disclosure requirement to advanced imaging services only; the general disclosure requirements that the notice should be written in a manner sufficient to be reasonably understood by all patients and be given to the patient at the time of the referral; the list must include the requisite number of suppliers; the information about these suppliers must include name, address, and phone number; these suppliers are to be located within a 25-mile radius of the physician's office location at the time of the referral; and the effective date of January 1, 2011.

Elements that we are finalizing with changes include: reducing the number of suppliers that must be included from 10 to 5; removing the requirement that the supplier's distance from the physician's office be listed on the disclosure; clarifying that as long as the requisite number of suppliers are included in the alternate list, the physician may also list providers on the notice; and removing the requirement that the physician obtain the patient's signature on the notice and retain a copy of the disclosure in the patient's medical record.

2. Disclosure Requirement

Based upon the comments received, we have finalized § 411.355(b)(7) in a manner that addresses concerns of the industry while also maintaining the intended purpose of the provision. The comments received during the public comment period are discussed more fully below.

a. Services That Trigger the Disclosure Requirement

We proposed that the disclosure requirement should apply to only the advanced imaging services listed in section 6003 of the ACA (MRI, CT, and PET). We solicited comments regarding whether other radiology or imaging services under section 1877(h)(6)(D) of the Act should be included in the requirement. We are finalizing this element as proposed.

Comment: Most commenters were supportive of our proposal to apply the disclosure requirement only to those advanced imaging services listed in section 6003 of the ACA. A commenter stated that expanding application of the provision beyond the named services would add to confusion and increase negative effects on physician practices. The commenter noted that creating lists of alternate suppliers for the named services will be less burdensome than adding any other radiology services. Multiple commenters who were opposed to expanding the disclosure requirement stated that a disclosure requirement for diagnostic services such as x-rays or ultrasound services would place significant burden on physician groups and could interrupt continuity of care for patients, as these tests are often performed in the office immediately after the physician has ordered the test.

Only one commenter urged CMS to fully exercise the authority granted by the Affordable Care Act and apply the disclosure requirement to all radiology services covered by section 1877(h)(6)(D) of the Act. The commenter stated that the disclosure requirement benefits Medicare beneficiaries through greater transparency regarding their freedom to choose a supplier of medical services and that there is no reason to draw a distinction between MRI, CT, and PET referrals and referrals for other radiology services. This commenter also did not believe that the burden on the referring physicians would be materially different if the list of affected imaging services is expanded to cover all radiology services, as it would only entail expanding the list that will serve as the notice to patients.

Response: We are finalizing this requirement as proposed and applying

the disclosure requirement to only the advanced imaging services specified in section 6003 of the ACA, which are MRI, CT, and PET services. We decline to expand the disclosure requirement to any of the other radiology or imaging services that fall under section 1877(h)(6)(D) of the Act. X-ray and ultrasound services in particular are much more likely to be performed on the same day as the original visit compared to many advanced imaging services. Therefore, disclosures related to these additional services would not be as useful to the patient. We do not find that the benefit of expanding this disclosure requirement to other radiology services would outweigh the additional burden that would be placed on physicians.

Comment: One commenter requested that CMS clarify that any CT imaging service that is furnished integral to a procedure defined as a radiation therapy service for purposes of the physician self-referral law is exempt from this disclosure requirement. The commenter provided the example of CT guidance used to localize tumors and focus the beam during the delivery of external beam radiation therapy treatments. Such imaging, although involving CT, is integral to the performance of radiation therapy treatments that are included in the DHS category of radiation therapy services and supplies.

Response: The disclosure requirement applies to all in-office referrals for CT imaging services that are categorized as "radiology and certain other imaging services" by the list of CPT/HCPCS Codes (as defined in § 411.351). We note, however, that the request by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy does not constitute a "referral," as defined in § 411.351, if certain criteria are satisfied. The disclosure requirement would not apply to any request that is not a "referral" as defined in § 411.351.

Comment: A commenter requested that CMS remove CPT code 77014 (computed tomography guidance for placement of radiation therapy fields) from the DHS category of "radiology and certain other imaging services," and add it to the category of "radiation therapy services and supplies," as such categories are set forth in the list of CPT/HCPCS Codes. The commenter asserts that this would be appropriate because while the code is for a service that involves imaging, the service is distinct from the other radiology codes and integral to the delivery of radiation therapy. The commenter noted that when a radiation oncologist performs

radiation therapy services, it is not considered a referral under the law. However, if CPT code 77014 is included in the list of radiology services, it could be considered a referral and therefore radiation oncologists could be required to fulfill the disclosure requirements for this service if it remains on the list of radiology services codes subject to the new disclosure requirements. According to the commenter, because CPT code 77014 is so integral to the delivery of certain radiation therapy treatments, it would be completely impractical, if not impossible, for a radiation oncologist to fulfill the disclosure requirements for this service.

Response: As noted in section X.B.3 of this preamble, we are removing CPT code 77014 from the list of CPT/HCPCS Codes because the service is always integral to, and performed during, a nonradiological medical procedure. Therefore, under § 411.351, this service is excluded from the definition of "radiology and certain other imaging services" and is not subject to the disclosure requirement. We are not adding this code to the radiation therapy services category on the list of CPT/HCPCS Codes because it does not satisfy the definition of "radiation therapy services and supplies" as set forth in § 411.351. As a practical matter, in many cases the service would not constitute a "referral" (as defined in § 411.351) if requested by a radiation oncologist pursuant to a consultation.

Comment: A commenter requested that CMS stipulate that CPT code 77011, currently defined as "computed tomography guidance for stereotactic localization," is not subject to this disclosure requirement whenever it is furnished as part of a therapeutic or palliative radiation therapy service. This commenter stated that this clarification is essential since CPT code 77011 is not listed in Addendum I to the 2010 PFS final rule with comment period either as a radiology service or as a radiation therapy service.

Response: This code is for a service that is integral to the performance of a nonradiological medical procedure and is performed either during the nonradiological procedure or immediately after the procedure to confirm placement of an item. Therefore, the service is excluded from the DHS category of "radiology and certain other imaging services" and is not subject to the disclosure requirement. The disclosure requirement applies only to MRI, CT, and PET services identified as "radiology and certain other imaging services" on the list of CPT/HCPCS Codes; MRI, CT, and PET services not

identified as such on that list are not subject to the disclosure requirement.

Comment: Other commenters urged CMS to expand the disclosure requirement to other DHS that they perceive to be subject to abuse under the in-office ancillary services exception. These DHS included: physical therapy, anatomic pathology and radiation therapy services.

Response: Section 6003 of the ACA does not grant the Secretary the authority to expand application of this disclosure requirement to DHS other than those in section 1877(h)(6)(D) of the Act. We did not propose expansion beyond these services and did not solicit comments regarding other DHS categories that should have this requirement. The requested expansion to other DHS is beyond the Secretary's authority under this provision and cannot be accomplished in this rulemaking.

Comment: One commenter suggested that CMS expand the disclosure requirement to radiology practices and IDTFs so that they are also required to provide a list of alternate suppliers when self-referring for imaging studies in order to offer a more level playing field. Two commenters suggested that we require the same disclosure for hospitals to avoid the perception of conflict of interest in all settings.

Response: The first comment appears to incorrectly assume that section 6003 of the ACA would never apply to radiology practices and IDTFs. Section 6003 of the ACA applies to physicians who make a "referral" (as defined in section 1877(h)(5) of the Act and § 411.351 of our regulations) for certain advanced imaging services and rely on the in-office ancillary services exception to ensure their compliance with the physician self-referral prohibition. While many requests by radiologists for diagnostic imaging services will not constitute a "referral" as defined in the statute and our regulations, some requests by radiologists for advanced imaging services could implicate the self-referral prohibition, and such referrals would be subject to the disclosure requirement if the referring physician relies on the in-office ancillary services exception to ensure compliance with the physician self-referral prohibition. Similarly, the disclosure requirement would also apply when a physician relies on the in-office ancillary services exception to protect referrals for advanced imaging services furnished and billed by an IDTF that is wholly owned by the physician or his or her group practice.

We have no statutory authority to make the disclosure requirement apply

to requests for advanced imaging services that are not "referrals." Mandating a similar disclosure requirement for hospitals would have to be accomplished under separate rulemaking and authority.

b. General Disclosure Requirements

We proposed that the disclosure notice should be written in a manner sufficient to be reasonably understood by all patients and must, as the ACA requires, be given to the patient at the time of the referral. The notice must indicate to the patient that the services may be obtained from a person other than the referring physician or his or her group practice and include a list of other suppliers who provide the service being referred (MRI, CT, or PET). We are finalizing this proposal without modification.

Comment: One commenter requested CMS to clarify how often the disclosure notice needs to be provided. The commenter asked if a physician can meet the requirement by giving patients the list of suppliers upon initiation of the physician-patient relationship and annually thereafter to ensure updated information is given, or if the information must be disclosed each time a patient is referred for MRI, CT or PET. Another commenter expressed concern regarding informing a patient in person at the time of the referral. This commenter described the situation where diagnostic tests are ordered after the patient has a previous abnormal diagnostic test; often they communicate this to the patient via phone call and do not want to require the patient to come into the office to receive the disclosure. The commenter asked if the disclosure could be mailed to the patient after the verbal notification via phone call.

Response: The statute requires the disclosure to be made "in writing at the time of the referral." In order to satisfy this element of the statute, we believe the disclosure must be presented to the patient each time one of the listed advanced imaging services is referred. Patients should receive the disclosure each time these services are needed, not just for the initial service. The patient should be made aware that he or she may obtain the services from another supplier any time advanced imaging is ordered. For subsequent referrals made via phone call, the written disclosure must still be provided to the patient and adequately documented as further described in the Documentation of Disclosure subsection below. Mailing or e-mailing the disclosure to the patient would be acceptable if verbal notification has also occurred.

Comment: Some commenters requested that CMS post a draft disclosure document that physicians can use as a model to ensure that all notices are drafted in a neutral, comprehensive, and consistent manner.

Response: We do not plan to post standard disclosure language to be used for this requirement. Each physician office will be responsible for drafting the language employed in the notice. Because we are not setting out specific language that must be included in the disclosure, physicians will have more flexibility in drafting the notice.

Comment: Several commenters requested that CMS allow physicians to make it clear on the disclosure that there is no intended endorsement or recommendation of the facilities named on the list furnished by the referring physician.

Response: If the physician chooses to include language informing patients that inclusion of other suppliers is not intended as an endorsement or recommendation of those suppliers, there is nothing in section 6003 of the ACA or this final rule with comment that would preclude him or her from doing so.

c. List of Alternate Suppliers

We proposed that the notice list 10 alternate suppliers (as defined in section 1861(d) of the Act) located within a 25-mile radius of the physician's office at the time of the referral, unless there are fewer than 10 suppliers in the 25-mile radius, in which case the physician must list all suppliers up to ten in that area. In the proposed rule, we required the notice to include the name, address, phone number, and distance from the physician's office at the time of the referral. In this final rule with comment, we are decreasing the number of suppliers that must be listed to 5; and removing the distance from the physician's office from the information about the suppliers that must be listed in the disclosure notice. The final rule does not expand the list of alternate suppliers to include providers as part of the 5 required suppliers but is discussed further below. We are finalizing our proposal that the suppliers be located within a 25-mile radius of the physician's location at the time of the referral.

We solicited comments related to whether there are procedures or circumstances in which it may be difficult or impractical to provide the written disclosure prior to the provision of advanced imaging services. We are finalizing this rule without creating such an exception.

We also solicited comments regarding an alternative notice that includes a "reasonable" list of other suppliers with general requirements for the disclosure to patients, while providing that if the physician meets the more specific requirements set forth in the proposed rule he or she will be deemed to have a "reasonable" disclosure. We are not finalizing this in the final rule as we did not receive comments in support of this alternative.

Comment: A number of commenters asked that the list of alternate suppliers include hospitals. Two commenters stated CMS has taken an overly literal interpretation of "suppliers" and has incorrectly excluded hospitals from the list of alternate sites. The commenters also noted that in many areas, especially rural, the community hospital is the largest or only remaining independent provider of imaging services. Another pair of commenters stated that providing a partial list of options is inconsistent with transparency, inconsistent with collaborative alignment between providers and suppliers, and that including both providers and suppliers would be more consistent with "informing a patient's decision-making regarding his or her own care."

Several commenters urged CMS to allow, and even to require, that physicians include hospitals and CAHs in the written list of alternate suppliers who provide imaging services. The commenters stated that hospitals are often the only provider of this service within the 25-mile radius of the physician's office and allowing physicians to include hospitals and CAHs would provide patients with more options.

Finally, one commenter pointed out that including hospitals in the list of alternate suppliers would be consistent with the integrated and coordinated care models that are of interest to the Federal government, health plans, members of Congress and healthcare delivery reformers. The commenter also believes that this would increase convenience for its patients while preserving their ability to make decisions about their care.

One commenter supported CMS' proposal to limit the required disclosure list to suppliers of services. The commenter stated that this would protect the Medicare program from the higher imaging costs and Part B co-pays for beneficiaries associated with imaging services provided by hospital outpatient departments. The commenter encouraged CMS to finalize the proposed supplier only list.

Response: Section 6003 of the ACA requires physicians to provide patients with a written list of alternate "suppliers" (as defined in section 1861(d) of the Act). The ACA does not afford the flexibility requested by commenters to allow physicians to satisfy the disclosure requirement by furnishing a list that includes hospitals and other providers. However, physicians are not precluded from listing hospitals in the disclosure notice as long as the required number of suppliers is also included. For example, in rural areas where no other suppliers exist in the 25-mile radius, we encourage physicians to list a hospital on the disclosure notice as an alternate location for the patient to receive the referred imaging service if the hospital is the closest option.

Comment: Many of the commenters supported our proposal that the disclosure notice include suppliers located within a 25-mile radius of the physician's location at the time of the referral, rather than in the area in which the patient resides.

Two commenters suggested that CMS set different radii requirements for rural versus urban areas. One of the two commenters stated that in an urban setting, there could be many more than 10 suppliers within a 25-mile setting placing making it difficult for the referring physician to make a decision regarding which providers to include in the written notification. The commenter noted that in a rural setting with fewer than 10 suppliers, the burden of identifying and providing all of the suppliers in the 25-mile radius is excessive for the physician.

Finally, a commenter objected to our concern in the proposed rule preamble that "physicians located in large metropolitan areas will draft a list that includes suppliers located mostly at the edges of the 25-mile radius, thereby increasing the chances that the patient will choose to receive imaging services from the referring physician's practice." The commenter asserted that physicians will strive to create lists that include the highest quality suppliers in the area.

Response: We are finalizing this requirement as proposed. We believe a list of suppliers located within a 25-mile radius of the physician's office is reasonable and large enough to generate a list that will be useful for patients. This same distance has also been used in other physician self-referral exceptions including the intra-family rural referrals exception (§ 411.355(j)) and the physician recruitment exception (§ 411.357(e)). In addition, we are reducing the number of required suppliers on the disclosure notice and

believe this will help address the issue in some rural area settings where there may only be a few suppliers within a 25-mile radius.

Comment: One commenter indicated that requiring a list of 10 suppliers was excessive. Several commenters requested that we decrease the required number of alternate suppliers from 10 to 5 and one commenter suggested we reduce it to 3 in order to meet patient choice and reduce the compliance burden for medical groups and smaller practices. The commenters stated that listing 10 suppliers would be too burdensome on physicians and might be confusing for beneficiaries if too many choices are presented.

Response: We agree with the commenters and are decreasing the required number of alternate suppliers from 10 to 5. We believe a list of 5 suppliers is reasonable, not burdensome, and supports patient choice.

Comment: A commenter supported the inclusion of the proposed information of the disclosure notice because it is easily understood and contains useful information. One commenter recommended that the referring physician provide the name and telephone number for the alternate suppliers and that other information, such as the address and distance, should be included at the referring physician's discretion. A different commenter stated that the distance from the referring physician's office location at the time of the referral should not be included in the notice because it can be measured in a variety of ways and may vary greatly depending on the route taken between the listed supplier and the physician's offices. The commenter believes patients may get upset if the distance noted on the supplier list is different from what they actually encountered and recommends that the list simply state that all of the suppliers are within a 25-mile radius of the referring physician's office.

Response: We are modifying the proposal in the final rule to remove the requirement that the distance from the referring physician's office at the time of the referral be included on the list provided to the patient. All alternate suppliers listed must be located within the 25-mile radius of the physician's office location at the time of the referral. Any reasonable method for measuring distance will be acceptable.

We are finalizing the other information required in the notice as proposed so that it must include the name, address and phone number of each supplier. This provides patients with the most useful information in

making a decision about receiving the service from the referring physician or from another supplier.

Comment: Two commenters requested that CMS provide an exception to providing the disclosure notice to the patient at the time of referral, especially for services furnished on an emergency or time-sensitive basis as the commenters believe it is impractical to think that the list will be given and signed by the patient in an emergency or other time-sensitive case.

Response: We do not believe it is necessary to grant an exception to the disclosure requirement in cases of an emergency or time-sensitive nature. In those situations, physicians should make a reasonable attempt to provide the notice to the patient and document that the attempt was made. We believe the occurrence of emergencies in physician offices that require a referral for advanced imaging under the in-office ancillary services exception is rare enough that it does not warrant granting an exception. We believe having the physician make a reasonable attempt would not prevent or impede beneficiaries from receiving the necessary services. In most emergencies that arise in a physician's office, patients will be transferred to the emergency department of the nearest hospital rather than referred for imaging at the physician's office.

Comment: A commenter asked about compilation of the list of alternate suppliers and how physicians should go about this task. The commenter asked if a search of the internet or a telephone directory would be adequate. Also the commenter asked if Medicare contractors will have a list of entities providing such services. Another commenter recommended that CMS create a publicly available database of providers of the specified services and maintain this information online and in the Medicare provider directory that is published annually because, according to the commenter, it should be less work for CMS to create this list than it is for practices, since much of this information can be gleaned from information already furnished by practitioners to Medicare.

Response: We are not prescribing any one method for physicians to craft the list of alternate suppliers. A physician is able to use any reasonable means that he or she chooses in order to compile the list of five alternate suppliers. We do not plan to create a standard form or a publicly available database for this disclosure requirement nor will we require Medicare contractors to furnish lists of all entities providing such services. Some physicians may choose

to compile the list of suppliers from an internet search, others may know suppliers in the 25-mile radius who provide quality imaging and list these. We are not limiting a physician's methods of creating the list so long as the other requirements of this disclosure requirement are satisfied.

Comment: A commenter requested that CMS emphasize that the list of alternate suppliers must provide the same service for which the patient has been referred, for example a 64-slice CT as opposed to a 16-slice CT.

Response: The disclosure is meant to inform patients that they "may obtain the services for which the individual is being referred" from another supplier who furnishes such services in the area. The referring physician should list suppliers that are able to perform the services for which the patient is being referred. Listing suppliers that are unable to perform the needed test does not provide the patient with meaningful choices about his or her care.

Comment: Several commenters suggested that the quality of alternate suppliers should be indicated on the information provided to patients. Other commenters recommended that only credentialed facilities are listed on the notice, or that credentialed facilities be given special designation on the disclosure notice.

Response: We are not requiring any quality indication on the list of alternate suppliers at this time. Because the referring physician will most likely be reviewing the results of the advanced imaging service that the patient receives, it is reasonable to think that the physician will include quality suppliers on the list. We are not convinced to limit the list of suppliers to those who receive accreditation. Nothing in the statute or this final rule with comment prevents physicians from furnishing a list that designates a supplier's credentialing status.

Comment: Two commenters requested that CMS provide clarification on the frequency with which the physician must review and update the list of suppliers. For example, commenters asked if the notice should be reviewed for accuracy if a supplier relocates or any contact information changes. In addition, one of the commenters asked about the obligation of the referring physician to ensure that the suppliers listed are accepting new Medicare patients.

Response: We suggest that the list of suppliers should be reviewed annually for accuracy and updated at that time, if necessary. We do not believe an annual update would be overly burdensome for physicians. We believe

an inaccurate list of alternate facilities would lead to beneficiary confusion and that annually reviewing and modifying the notice as needed would ensure that patients receive complete and accurate information in accordance with this disclosure requirement.

In addition, referring physicians are not obligated to list only suppliers that are accepting new Medicare patients; however, as the disclosure notice is intended to allow patients to make informed choices, referring physicians should make a reasonable effort to ensure that the suppliers listed in the disclosure are viable options for all of their patients for the services being referred.

d. Documentation of Disclosure

We proposed that, in order to document that this disclosure notice was satisfied, a record of the patient's signature on the disclosure notification must be maintained as an element of the patient's medical record. We are modifying this proposal in this final rule with comment to remove the patient signature requirement.

Comment: Many commenters stated that the burden of obtaining and retaining the patient's signature in the medical record is burdensome. Other commenters noted that, as suppliers move toward maintaining electronic health records, an additional paperwork requirement seems counter to these goals and recommended that CMS include an electronic alternative to the maintenance of a signed copy of the disclosure notice in patients' medical records. Another commenter noted that because the notification of alternate suppliers is not a clinical document, it might not belong in a patient's medical record. A commenter asked if the disclosure document must be maintained in the patient's main medical record or if it could be maintained instead with the patient's radiological documentation, which can be maintained electronically in a PACS system with the physician's orders for the study.

A commenter recommended that CMS accept as sufficient documentation, a note in the patient's chart that a member of the staff provided the letter and explained it to the patient. Another suggestion from a commenter was that physicians maintain a dated notification log at the front desk that patients will sign once they have received and reviewed their disclosure lists. These logs will then be retained and filed by the office for potential review by regulators or accreditors.

One commenter supported the requirement to maintain a copy of the

disclosure in the patient's medical record.

Response: We acknowledge that obtaining the patient's signature and maintaining a copy of such in the medical record may be burdensome. In this final rule with comment we are removing the requirement to obtain the patient's signature on the disclosure and to maintain this documentation in the medical record. Nevertheless, as a matter of prudent business practices, physicians should be able to document or otherwise establish that they have complied with the disclosure requirement. For example, the physician could document in the patient's chart that the notice was given to the patient.

e. Effective Date

We proposed that the new disclosure requirement shall apply only to services furnished on or after the effective date of these final regulations, January 1, 2011. We did not receive any comments suggesting any alternate effective date. We are finalizing the effective date as proposed.

f. Other Comments

Comment: Some commenters submitted comments addressing topics beyond the scope of this proposal. These comments included detailed discussions of the in-office ancillary services exception, services that should be excluded from that exception, MedPAC's analysis on the issue, as well as questions about the anti-markup payment limitation (§ 414.50) and a request that we respond to comments we requested regarding incentive payment or shared savings arrangements.

Response: These comments are beyond the scope of this rulemaking and are not addressed in this final rule with comment. If these issues are addressed in the future, we will publish a notice of proposed rulemaking that will be open to public comment at that time.

U. Section 6404: Maximum Period for Submission of Medicare Claims Reduced to Not More Than 12 Months

1. Background

Sections 1814(a)(1), 1835(a), and 1842(b)(3)(B) of the Act establish time limits for filing Medicare Part A and B claims. Prior to the enactment of the ACA, under sections 1814(a)(1) and 1835(a) of the Act, providers could file for Part A and Part B claims, respectively, " * * * no later than the close of the period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar

months of any calendar year to have been furnished in the succeeding calendar year) except that, where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year * * *. Prior to the enactment of the ACA, CMS was authorized to establish a minimum time limit for provider-submitted Part A and Part B claims of at least 1 calendar year from the date of service, and a maximum time limit not to exceed 4 years and 3 months after the date of service.

Additionally, prior to the enactment of the ACA, under section 1842(b)(3)(B) of the Act, Part B claims for physician and other supplier services could be filed with Medicare * * * no later than the close of the calendar year following the year in which such service is furnished (deeming any service furnished in the last 3 months of any calendar year to have been furnished in the succeeding calendar year) * * *. Therefore, prior to the enactment of the ACA, we were authorized to establish a minimum time limit for filing Part B claims of 15 months and a potential maximum of 27 months after the service was furnished, depending on what month of the year the service was furnished.

Section 424.44 of the regulations implements sections 1814(a)(1), 1835(a), and 1842(b)(3)(B) of the Act. In order to effectively administer the Medicare Program, we, through regulations, modified the potential minimum and maximum time periods for filing Part A claims. At § 424.44(a), we adopted the minimum time limit of 15 months and potential maximum of 27 months after the service was furnished that was permitted under section 1842(b)(3)(B) of the Act for Part B claims and uniformly applied that 15 to 27 month time limit to both Part A and B claims. Also, under § 424.44(b), we allowed providers and suppliers the opportunity to file claims after the 15 to 27 month deadline for filing claims expired when the failure to file * * * was caused by error or misrepresentation of an employee, intermediary, carrier, or agent of the Department that was performing Medicare functions and acting within the scope of its authority.”

2. Provisions of the ACA

Section 6404 of the ACA amended sections 1814(a)(1), 1835(a), and 1842(b)(3)(B) of the Act regarding Medicare fee-for-service (FFS) claims for services furnished on or after January 1, 2010. Under section 6404(b)(1) of the ACA, all claims for services furnished on or after January 1, 2010 must be filed

within 1 calendar year after the date of service. Section 6404 of the ACA did not amend sections 1814(a)(1), 1835(a), and 1842(b)(3)(B) of the Act for services furnished before January 1, 2010. However, section 6404(b)(2) of the ACA created a new requirement that claims for services furnished before January 1, 2010 must be filed on or before December 31, 2010. Thus, the statutory provisions prior to the enactment of the ACA remain in effect for pre-2010 services, subject to this new requirement. The practical effect of this change is that any claims for services furnished before October 1, 2009 will follow the existing regulations. But for services furnished during the last 3 months of 2009, providers and suppliers must file claims no later than December 31, 2010. For services furnished between October 1, 2009 and December 31, 2009, providers and suppliers will only have 12 to 15 months to file a claim, whereas before the ACA amendments, they would have had an additional year to file their claims, or 24 to 27 months.

The majority of the comments that we received for the proposed rule were supportive of our proposed exceptions at § 424.44(b)(2) and (3) concerning retroactive entitlement situations and dual-eligible beneficiary situations. However, some commenters encouraged us to either expand those proposed exceptions or suggested other new exceptions.

Comment: One commenter stated that CMS should instruct Medicare Intermediaries to process claims where provider representatives are submitting retroactive claims within 6 months from the Social Security Administration's (SSA) notification date due to SSA's delay in processing beneficiaries' retroactive Medicare entitlement. Moreover, the commenter cited to an OIG evaluation report dated January 2006 (A-13-05-15028), which stated that the average number of years where beneficiaries are awarded retroactive Medicare benefits is about 8 years. Therefore, the commenter asserted that when SSA corrects the error and sends a notification letter to beneficiaries, providers should be allowed to submit claims to Medicare Intermediaries as long as the claims are submitted within 6 months from the notification letter from SSA and as long as supporting documentation is attached to the claims.

Response: As stated in the CY 2011 PFS proposed rule, if CMS or one of its contractors determines that one of the exceptions to the time limits for filing claims applies, then the time to file a claim will be extended. We will update its internet only manual instructions to

its contractors so that Medicare's contractors are aware of the new timely filing requirements, the exceptions to those requirements, and process claims in accordance with these new requirements.

Comment: Two commenters disagreed that services furnished between October 1, 2009 through December 31, 2009 must be billed by December 31, 2010 and asserted that our proposed language at § 424.44(a) is in contravention of explicit statutory language.

Response: We disagree with the commenter because section 6404(b)(2) of the ACA clearly states that—“In the case of services furnished before January 1, 2010, a bill or request for payment under section 1814(a)(1), 1842(b)(3)(B), or 1835(a) of the Act shall be filed not later than December 31, 2010”. Therefore, because the statute specifically addresses this issue, we must require that services furnished between October 1, 2009 through December 31, 2009 be filed by December 31, 2010.

Comment: Two commenters suggested that CMS create an additional exception to the timely filing rules to permit providers to submit claims for services at the request of a Medicaid State Agency or its agent under the terms of the regulation prior to these current revisions; that is, by the end of the calendar year following the year in which the services were delivered (with services delivered in the last quarter of a calendar year being treated as though they were delivered in the next calendar year). The commenters believe that this type of additional exception would permit Medicaid State Agencies to assure proper billing of services to Medicare, as an appropriate third party payer, without overtaxing providers or Medicare contractors by requiring them to submit multiple claims at varying times. Additionally, a third commenter stated that the third condition of the exception at § 424.44(b)(3) could be interpreted to mean that the Medicaid agency must recover their payment from a provider or supplier prior to the provider or supplier billing Medicare. The commenter believes that it would be a better practice to notify providers of the Medicaid agency's intention to recover prior to performing the actual recovery.

Response: We were not persuaded to modify the rule in order to create an additional exception to permit providers and suppliers to submit claims for services at the request of a Medicaid State Agency prior to the State Medicaid Agency actually recovering the payment. Providers and suppliers do not necessarily have to wait for

Medicaid to recover its payment (see § 424.44(b)(3)) in order to utilize an exception to the timely filing rules in retroactive entitlement situations because the proposed exception at § 424.44(b)(2) may be used by providers and suppliers in order to file claims prior to a State Medicaid Agency recovering its payments. As we stated in § 424.44(b)(2), if CMS or one of its contractors determines that at the time the service was furnished the beneficiary was not entitled to Medicare and the beneficiary subsequently received notification of Medicare entitlement effective retroactively to the date of the furnished service, then the time limit to file a claim may be extended.

Comment: Three commenters suggested that an exception to the timely filing rules should be created for Medicare beneficiaries who are retroactively disenrolled from a Medicare Advantage plan so that all claims for services provided to the beneficiary while enrolled in the Medicare Advantage plan (upon retroactive disenrollment) can be submitted for coverage and payment to original Medicare. The commenters stated that a beneficiary may be retroactively disenrolled from that plan under a variety of circumstances. Moreover the commenters asserted that if a retroactively disenrolled beneficiary is unable to have claims for services submitted to original Medicare because some of those services were delivered more than a year prior to the date of actual disenrollment, then the beneficiary will be unable to be made whole and the ability to disenroll from a Medicare Advantage plan will be rendered pyrrhic at best.

Response: We modified the final rule based on these comments and created an additional exception for retroactive disenrollment from Medicare Advantage plans at § 424.44(b)(4). Although we did not receive a comment requesting an exception for retroactive disenrollment from Program of All-inclusive Care for the Elderly (PACE) provider organizations, we included retroactive disenrollment from PACE in the exception at § 424.44(b)(4) because beneficiaries, providers, and suppliers could also be disadvantaged in retroactive disenrollment PACE situations.

Comment: Two commenters suggested that an exception to the timely filing rules should be created when a private payer recovers its payment from the provider 11 months or more after the date of service. The commenters stated that hospitals routinely experience payment retractions from private payers

that are outside the hospitals' control and that may prevent a Medicare claim from being filed within one year of the date of service.

Response: We were not persuaded to modify the rule by these comments because providers are already required "to maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented". See § 489.20(f). Also, section 1862(b)(6) of the Act states—" * * * no payment may be made for any item or service furnished under part B unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans". Therefore, we are not modifying the rule based on this comment because creating an exception to the timely filing limitations for these situations would allow providers and suppliers to circumvent the statutory and regulatory requirements stated above.

Comment: Two commenters suggested that CMS create an exception to the timely filing rules for Medicare Secondary Payer (MSP) claims when the initial payment determination by the primary payer is not received by the hospital in sufficient time to permit timely filing of the MSP claim. A third commenter recommended that in cases where Medicare is not the primary payer, the filing deadline be extended to 12 months from the date the payment is made for the products or services by the payer immediately primary to Medicare (that is, the primary payer when Medicare is the secondary payer, and the secondary payer when Medicare is tertiary).

Response: We were not persuaded to modify the rule by these comments because Medicare may make conditional payments for services when a payer that is primary to Medicare does not pay promptly. "Prompt" or "promptly", when used in connection with primary payments, except as provided in § 411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim. See 42 CFR part 411 subparts B through H and 411.21 and 411.24 for the definitions of conditional payment and promptly. Moreover, because providers are already required "to maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented" (See § 489.20(f)) we do not

believe a provider's ability to meet the new 1 calendar year timely filing requirement will be compromised by the commenter's concerns.

Comment: Three commenters suggested that CMS create an exception to the timely filing rules so that hospitals are permitted to file inpatient Part B only claims for any inpatient cases that are retrospectively reviewed by a Medicare Recovery Audit Contractor (RAC) or other review entity and determined not to be medically necessary in an inpatient setting. The commenters pointed out that with the reduction of the timely filing period to one year from the date of service, legitimate rebilling opportunities are limited since Medicare RAC's may audit Medicare claims that were paid up to 3 years ago.

Response: We were not persuaded to modify the rule by these comments because Medicare's billing guidelines instruct providers regarding what types of inpatient services may be billed to Part A and to Part B. Therefore, it is the responsibility of a provider to correctly submit claims to Medicare by coding the services appropriately.

Comment: In the CY 2011 PFS proposed rule, CMS solicited comments regarding whether CMS should provide a regulatory definition of "date of service" and, if so, how should it define this term. One commenter suggests that the "date of service" be defined through administrative instructions as the "through date" on the Medicare claim (UB-04 form locator 6, statement covers period). A second commenter stated that CMS should adopt as a final rule the guidance on "Date of Service" provided in MLN Matters Number 7080 and Transmittal 734, Change Request 7080. CMS Manual System, Pub 100-20 One-Time Notification, July 30, 2010. This guidance provides that for institutional claims that include span dates, the "Through" date on the claim will be used to determine the date of service for claims filing timeliness; for professional claims (CMS-1500 Form and 837P) submitted by physicians and other suppliers that include span dates of service, the guidance states that the line item "From" date will be used to determine the date of service and filing.

Response: We decided not to define "date of service" in the final rule because, as we stated in the CY 2011 PFS proposed rule, we recognize that for many Part A and B services it is difficult to craft a uniform rule that will apply a consistent date of service standard. Therefore, we decided to address the "date of service" issue via sub-regulatory guidance. We issued subregulatory guidance on what constitutes the "date

of service" for some items and services on May 7, 2010 via Change Request 6960 and on July 30, 2010 via Change Request 7080 to our Medicare contractors and it is our intention to provide additional sub-regulatory guidance as the need arises for different Part A and B services.

Comment: One commenter believed an exception should be created for claims for consumers who retroactively enroll in original Medicare Part B, such as consumers who successfully apply for equitable relief. For example, a person may choose to take Part A (because it is premium free) but may mistakenly choose not to enroll in Medicare Part B due to cost or because they believe that other insurance for which they already pay a premium, such as retiree coverage or coverage through a group health plan provided by a small employer, will pay medical costs. As a result, insurance that is supposed to pay secondary to Medicare incorrectly pays primary. The commenter goes on to assert that if the insurance plan discovers that a person was eligible for Medicare Part B but did not enroll and therefore the plan was supposed to pay secondary, the insurer can recoup payments made back to the date the enrollee became Medicare Part B eligible. In some instances, a person may obtain a retroactive Medicare Part B start date back to the original date of Medicare eligibility. This retroactive start date can be a few months to a few years and is not limited by statute. As a result, providers from which secondary insurer's recouped payment would need the ability to submit claims to Medicare for services provided over one year in the past. In these cases, because the consumer is already enrolled in Medicare Part A and not Part B, the commenter is concerned that claims would not fall under the language of § 424.44(2)(ii) as the consumer is already entitled to Medicare.

Response: Although this comment was unclear, we believe the commenter wants CMS to create an exception to the time limits for filing claims specifically for Part B services. We were not persuaded to modify the rule by these comments because if a beneficiary is granted equitable relief under section 1837(h) of Act, the beneficiary may still be able to use the exception at § 424.44(b)(2). Of course, all of the conditions for § 424.44(b)(2) will need to be satisfied in order for an exception to be granted in a particular case. It is important to note that all of the exceptions in § 424.44(b) (including the exception for § 424.44(b)(2)) are not limited to just Part A services; the

exceptions may also be granted for Part B services when applicable.

Comment: One commenter asked whether the 4 years from date of service limitation specified in § 424.44(b)(1) applies when the SSA makes an administrative error in determining a beneficiary's retroactive entitlement decision since the SSA is not considered an agent or contractor to CMS. Or, would this be covered under § 424.44(b)(2) or § 424.44(b)(3) without the 4 year limitation? The commenter recommended that CMS clarify in the final rule that the 4 year limitation does not apply when the result of a retroactive Medicare decision was due to SSA's administrative error in incorrectly and untimely processing of beneficiaries eligibility determinations.

Response: Section 424.44(b)(1) only applies to errors or misrepresentations that are made by an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of the Department that was performing Medicare functions and acting within the scope of its authority. It does not apply to errors or misrepresentations made by the SSA; therefore, the 4 year restriction for § 424.44(b)(1) would not apply because § 424.44(b)(2) and (3) could be used in situations where the SSA makes an error. However, it is important to note that errors or misrepresentations by the SSA are not one of the conditions that must be met in order for an extension of time to be granted under § 424.44(b)(2) and (3).

Comment: Two commenters recommended that if the SSA cannot locate a copy of the original retroactive notification letter that was sent to the beneficiary, then CMS should allow providers or beneficiaries to submit the notification letter that they received from SSA that clearly indicates the beneficiary's retroactive entitlement date and the date in which the notification of SSA's retroactive decision was made. Therefore, the regulations and guidelines should address alternate proof of coverage in the event a copy of the actual Notice of Award is unavailable.

Response: We were not persuaded to modify the rule by these comments because we believe these types of documentation or proof of retroactive entitlement issues should be addressed via sub-regulatory guidance. Therefore, we will consider these comments when we update our internet only manual instructions to our contractors.

Comment: One commenter suggested that there should be an exception to account for claims filed for beneficiaries granted Medicare entitlement

retroactively because of the 30+ years of systemic errors of SSA's Special Disability Workload (SDW). The commenter stated that this issue is currently in bill form before both houses of Congress and that failing a legislative solution this proposed rule would bar States from perfecting rightful claims for services provided over the years under Medicaid that should have been provided by Medicare. The commenter goes on to state that States will have great difficulty in reaching out to providers over 30 years of services to recoup third party liability from Medicare. Despite such difficulty, States should retain the right to file claims and they should not be barred by this proposed rule. The proposed rule states that "we believe that limiting this exception to 4 years after the dates of service strikes an appropriate balance between fairness and equity for providers, suppliers, and beneficiaries and administrative finality for the Medicare program". The commenter asserts that the proposed rule does not show any consideration of States' interests in pursuing third party liability against Medicare based on systemic failures by SSA, the agency responsible for determining Medicare eligibility.

Response: The commenter's statement that States should retain the right to file claims is outside the scope of this rule; therefore, we will not address that particular comment. We were not persuaded to modify the rule by the other comments because § 424.44(b)(1) only applies to errors or misrepresentations that are made by an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of the Department that was performing Medicare functions and acting within the scope of its authority. It does not apply to errors or misrepresentations made by the SSA; therefore, the 4 year restriction for § 424.44(b)(1) would not apply in the situation described by the commenter, but § 424.44(b)(2) and (3) could be used in situations where the SSA makes an error. However, it is important to note that errors or misrepresentations by the SSA are not one of the conditions that must be met in order for an extension of time to be granted under § 424.44(b)(2) and (3).

Comment: One commenter suggested that CMS consider allowing the exception for dually-eligible beneficiaries at § 424.44(b)(3) to apply if any one of the three conditions are met as opposed to all of the conditions.

Response: We were not persuaded to modify the rule by this comment because it would make the dual-eligible

exception meaningless. The first condition of § 424.44(b)(3) states—"At the time the service was furnished the beneficiary was not entitled to Medicare". That first condition could apply to every service a person has ever received during his or her lifetime prior to becoming a Medicare beneficiary. Therefore, under the commenter's suggestion the exception would be meaningless.

Comment: One commenter suggested that the first condition of the exception at § 424.44(b)(3) include cases in which Medicare coverage is unknown to the Medicaid agency at the time of service instead of using the condition that at the time the service was furnished the beneficiary was not entitled to Medicare.

Response: We were not persuaded to modify the rule by this comment because if the beneficiary was already entitled to Medicare at the time the service was furnished, then the provider or supplier could have taken the necessary actions to find out that the individual was a Medicare beneficiary. For example, the provider could have asked the beneficiary prior to admission, checked with CMS, etc.

Comment: One commenter stated that the second condition of the exception at § 424.44(b)(3) assumes that because the beneficiary is notified about retroactive Medicare coverage that the provider of service and the State Medicaid Agency is concurrently notified, which may not always be the case. Because this is a direct communication between the Medicare program and its beneficiary, CMS should address how providers and the Medicaid agency will evidence dual eligibility to Medicare's contractors in an effort to meet this condition.

Response: We were not persuaded to modify the rule by these comments even though we agree that it is possible that providers, suppliers, and State Medicaid Agencies may not be notified concurrently about a beneficiary's retroactive Medicare entitlement. However, the exception at § 424.44(b)(3) does not prevent providers and suppliers from requesting an exception to the time limits for filing a claim because the provider or supplier will always be notified about a beneficiary's retroactive entitlement whenever a State Medicaid Agency recovers its payment.

Pursuant to § 424.44(b)(5)(iii), the date when the State Medicaid Agency actually recovers its payment from the provider or supplier is when the extension of time to file the claim through the last day of the 6th calendar month is triggered. In other words, assuming that all three of the conditions for § 424.44(b)(3) are met, providers and

suppliers will possess the ability to file a claim through the last day of the 6th calendar month after the date the State Medicaid Agency recovers its payment. Unlike the 4 year restriction (§ 424.44(b)(5)(i)) placed on the exception at § 424.44(b)(1), which is commonly referred to as the exception for "administrative error," there is no similar time restriction regarding when a provider or supplier may request an exception under § 424.44(b)(3). Therefore, providers and suppliers should note that once the State Medicaid Agency recovers its payment for the services, providers and suppliers will only have through the last day of the 6th calendar month after that recovery date to file a claim (assuming that all three of the conditions for § 424.44(b)(3) are met).

Comment: One commenter recommends that CMS define "retroactive Medicare" for the purpose of these proposed exceptions. The commenter stated that they understand retroactive Medicare to be the extension of benefits to a date in the past but believe that confirmation or clarification of this definition should be issued by CMS.

Response: Although this comment was unclear, we believe the commenter wants CMS to clarify what Medicare entitlement effective retroactively to or before the date of the furnished service means. We were not persuaded to modify the rule by this comment because we did not use the term "retroactive Medicare" in the regulation text. Instead, the regulation text used the following language—"the beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service"—which we believe makes it clear that a beneficiary is receiving his or her Medicare entitlement beginning at some date in the past.

Comment: One commenter recommends that in States which have a contract with the SSA to determine eligibility for Medicaid at the same time a determination is made for receipt of Social Security Income (SSI) benefits (see section 1634(a) of the Act), that CMS should clarify if Medicare retroactivity will include requests for prior month premium payments.

Response: Although this comment was unclear, we believe the commenter wants to know whether the exceptions to the time limits for filing claims is limited to just Part A services. Because the commenter refers to requests for prior month premium payments, we believe that the commenter is concerned about what happens when State

Medicaid Agencies pay Part B premiums on behalf of dual-eligible beneficiaries. If a beneficiary receives notification of Medicare entitlement (Part A) effective retroactively to or before the date of a furnished service and a State Medicaid Agency (or the beneficiary or anyone else) pays for that beneficiary's Part B monthly premium retroactively to or before the date of a Part B furnished service, then those "old" Part B services for that beneficiary may be granted an extension to the time limits for filing as long as the other conditions for that particular exception are also met. In other words, the exceptions for § 424.44(b)(2) and (3) are not limited to just Part A services; the exceptions may also be granted for Part B services when applicable.

Comment: One commenter stated that the ACA provision essentially provides providers with a 12 month period in which to file claims for services for which they have reason to believe Medicare may be responsible. However, in the exceptions proposed by CMS, a provider only has 6 months to file a claim. Consistency with the ACA would suggest that the time to file a claim under each exception should be extended through the last day of the 12th month following the month in which the exception applies. The commenter also stated that with regard to the proposed exceptions, the time limit should be based on the month in which the error or misrepresentation is corrected and the provider is notified of that fact. There may be some time between when the error or misrepresentation is corrected and when the provider is notified of that fact and the extended time limit should begin when the provider becomes aware of the correction. A second commenter stated that the timeframe for filing claims applicable to services provided to beneficiaries who become retroactively entitled to Medicare (regardless of whether they are dual-eligible beneficiaries) should be extended to the later of: (1) The date that is 12 months after the date that the beneficiary is notified of retroactive Medicare entitlement, or (2) the date that is 12 months after the provider or supplier becomes aware of retroactive Medicare entitlement.

Response: We are modifying § 424.44(b)(5)(ii) based on these comments because we agree that in retroactive entitlement situations there could be situations where a provider or supplier may not be notified of a beneficiary's retroactive entitlement in order to utilize the exception at § 424.44(b)(2). Therefore, we are modifying § 424.44(b)(5)(ii) so that

notification to either party (that is, the beneficiary or the provider/supplier) for the first time about a beneficiary's retroactive entitlement will trigger when the extension of time to file the claim through the last day of the 6th calendar month begins. We understand that this rule may result in two extension of time triggers if the beneficiary and the provider/supplier are not notified on the same day (one for when the beneficiary is first notified and one for when the provider or supplier is first notified); however, we agree with the commenter that it would be unfair to providers and suppliers to limit the exception based only on when the beneficiary receives notification.

We are also modifying § 424.44(b)(5)(i) based on these comments because we agree that there may be situations where a provider or supplier may be able to utilize the exception under § 424.44(b)(1) commonly referred to as the "administrative error" exception, but the provider or supplier is not notified about the correction until it is too late to utilize the exception. Therefore, we are modifying § 424.44(b)(5)(i) so that notification to either party (that is, the beneficiary or the provider/supplier) for the first time about the administrative error correction will trigger when the extension of time to file the claim through the last day of the 6th calendar month begins. We understand that this rule may result in two extension of time triggers if the beneficiary and the provider/supplier are not notified on the same day (one for when the beneficiary is first notified and one for when the provider or supplier is first notified); however, we agree with the commenter that it would be unfair to providers and suppliers to limit the exception based only on when the "administrative error" is actually corrected.

However, we were not persuaded to modify the rule for dual-eligible situations (see § 424.44(b)(3)) because the extension of time to file a claim through the last day of the 6th calendar month is triggered in dual-eligible situations when the State Medicaid Agency recovers its payment from the provider or supplier. Therefore, providers and suppliers will always receive sufficient notification in dual-eligible situations because the date that the State Medicaid Agency recovers its payment will be the provider's or supplier's notice that they have through the last day of the 6th calendar month in order to file a claim (assuming of course that CMS or its contractors determines that all the conditions in § 424.44(b)(3) are met and grants an extension).

Also, we were not persuaded to modify the rule based on the comment that the time to file a claim under each exception should be extended through the last day of the 12th month following the month in which the exception applies. Because the triggering events for the exceptions at § 424.44(b)(1), (2), and (3) cannot occur without the provider or supplier actually being notified, we believe that an extension of time to file a claim through the last day of the 6th calendar month after those triggering events gives providers and suppliers sufficient time to submit their claims.

Comment: Two commenters requested that CMS create an additional exception for those instances where the issuance of new Medicare provider numbers are delayed due to no fault of the provider. The commenter stated that numerous Medicare contractors are taking 60 to 120 days or longer to process and finalize CMS enrollment applications. Additionally, and more importantly, many State survey agencies are extremely behind on initial Medicare State surveys. In some cases, it is taking 2 years for the State to conduct the required survey for the providers. These delays significantly restrict a provider's ability to submit claims for services furnished prior to the effective date of the Medicare billing privileges and the commenter hopes that CMS would work with the provider community to process claims under these circumstances. Another commenter recommended that CMS should provide an exception for provider enrollment delays caused by the MAC or CMS Regional Office that are outside the control of the provider. The commenter recommended that CMS should extend the time to file a claim through the last day of the 6th calendar month following the month in which provider enrollment was completed with an additional 30 days allowed for each full or partial month between the effective date of the provider enrollment and the approval date of the provider enrollment. This additional time is necessary to accommodate Medicare's sequential billing requirement.

Response: We were not persuaded to modify the rule based on these comments because regulations at § 424.520, § 424.521, and § 489.13 already establish an effective billing date for providers and suppliers and those regulations have already established limitations on retroactive billing for providers and suppliers.

Comment: Two commenters stated that the Medicare Secondary Payer rules do allow a provider to file with Medicare if the otherwise primary payer is going to take awhile to pay.

Notwithstanding, there have been situations which would warrant enumeration in an exceptions regulation. Providers have experienced situations where an insurance company has executed a retroactive denial of a previously paid claim after a year. When this happens, the timely filing clock should start with the denial date. Thus, the commenter recommends that:

- CMS should continue to allow for payment when a primary payer may take a substantial amount of time to pay;
- CMS should allow for a claim to be considered timely if it is filed within 1 year from the date that the primary payer has made its payment determination; and
- CMS should allow for a claim to be considered timely if it is filed within 1 year from the date that the primary payer retroactively denied a prior previously paid claim.

Response: We were not persuaded to modify the rule by these comments because Medicare may make conditional payments for services when a payer that is primary to Medicare does not pay promptly. "Prompt" or "promptly", when used in connection with primary payments, except as provided in § 411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim. See 42 CFR part 411 subparts B through H and 411.21 for the definitions of conditional payment and promptly.

Also, section 1862(b)(6) of the Act states—" * * * no payment may be made for any item or service furnished under part B unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans". Moreover, because providers are already required "to maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented" (See 489.20(f)) we do not believe a provider's ability to meet the new 1 calendar year timely filing requirement will be compromised by the commenter's concerns.

Comment: One commenter stated that providers have reported that they are experiencing a need to cancel previously processed Part B claims in order to submit benefits exhaust claims. Depending on the time frame for this, providers may be unable to resubmit the Part B charges. Providers need either a mechanism for submitting benefits exhaust claims for older dates of service

that does not require the cancelling of previously processed claims or they need an exception granted for resubmitting claims that had been processed timely but needed to be cancelled to submit benefits exhaust claims. The commenter recommends that CMS should provide a mechanism for submitting benefits exhaust claims for older dates of service that does not require the cancelling of previously processed claim.

Response: We are not aware of the specific scenario described by the commenter; however, we will monitor this issue and determine whether any additional sub-regulatory guidance is needed in this area.

Comment: One commenter stated that there have been cases in which a facility has been under a payment ban and the lifting of the remedy was not communicated to the facility in a timely manner, thus prohibiting the timely filing of claims. The commenter recommended that CMS should start the timely filing clock with the date that the lifting of a payment ban is communicated to the provider.

Response: We were not persuaded to modify the rule by this comment because if the failure to file a claim timely was the result of an error or misrepresentation that was made by an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of the Department that was performing Medicare functions and acting within the scope of its authority, then the provider may be able to utilize the exception under § 424.44(b)(1) commonly referred to as the "administrative error" exception in order to file a claim.

Comment: One commenter stated that when a provider is trying to adjust a claim for the purpose of returning money to the Medicare program, timely filing should not apply. Conversely, when a provider finds an error that had caused an underpayment, the provider should be allowed to file an amended claim and receive the increased compensation. Therefore, the commenter recommends that CMS should provide that timely filing under amended § 424.44 not apply when a provider is trying to adjust a claim for the purpose of returning money to the Medicare program, or, conversely, when a provider finds an error that had caused an underpayment.

Response: We were not persuaded to modify the rule by these comments because the timely filing provision of section 6404 of the ACA and subsequent final rule amending § 424.44 is not intended to address requests for re-

determinations of initial determinations by Medicare contractors such as those described by the commenter. The regulations for such requests are detailed in 42 CFR part 405, subparts G, H, and I.

Comment: One commenter stated that they regularly file claims within 1 calendar year after the date of service that are either rejected or denied and that are subsequently approved after being re-filed. In certain instances, the date of re-filing, because of the time period before the rejection or denial, is more than one year after the date of service. The commenter recommends that the timely filing rule should be and is satisfied when an original claim is timely filed within 1 calendar year after the date of service, regardless of the date of any resubmission.

Response: We were not persuaded to modify the rule by this comment because, for example, if a provider or supplier fails to include a particular item or service on its initial claim, fails to include all the necessary information in order for an initial determination to be made on that claim or fails to file the claim on a form prescribed by us, then a provider or supplier cannot attempt to re-file that claim more than 1 calendar year after the date that the service was furnished. An incomplete or rejected claim cannot act as a placeholder for a claim that has yet to be filed because that would clearly be a way for providers and suppliers to avoid the 1 calendar year requirement stated in section 6404 of the ACA. Moreover, it would create a multitude of problems for CMS to deal with operationally or administratively because CMS would need to have the ability to track all rejected claims or all claims that failed to receive an initial determination and be able to match those rejected or incomplete claims up with all of the complete or valid claims that would eventually be filed months or years later so that an initial determination could be made.

Comment: One commenter stated that it is unnecessary to impose an additional restriction to the exception for claims filed for services provided to dual-eligible individuals. The third condition for the exception at § 424.44(b)(3) that a State Medicaid Agency recovers the Medicaid payment for the furnished service from a provider or supplier 11 months or more after the date of service is too restrictive and CMS should have used a different time period.

Response: We agreed with the commenter that the 11 months or more after the date of service requirement in § 424.44(b)(3)(iii) was too restrictive and

therefore we modified the final rule based on these comments by changing the time period from 11 months to 6 months or more after the service was furnished.

Comment: One commenter suggests that CMS amend the third condition of § 424.44(b)(3) to read as follows— "A State Medicaid agency or Provider recovered the Medicaid payment for the furnished service from the provider or supplier 11 months or more after the date of service." The commenter stated that occasionally providers identify retroactive Medicare coverage after Medicaid has paid without receiving notification from the State Medicaid agency. The provider needs to have the ability to correct the payer order when necessary before their existing payment is recouped.

Response: We were not persuaded to modify the rule by these comments because when a provider refunds a payment that is made to it by a State Medicaid Agency, the provider is not recovering a State Medicaid payment. Instead, when the State Medicaid Agency accepts that refunded payment from the provider, we consider the State Medicaid Agency to actually be recovering that Medicaid payment. Therefore, when a State Medicaid Agency accepts a provider's refunded payment 6 months or more after the service was furnished, then the third condition of § 424.44(b)(3) will be met. Of course, the first two conditions of § 424.44(b)(3) will also need to be met in order for an extension to be granted under § 424.44(b)(3).

Comment: One commenter stated that due to the limited home infusion benefit under Medicare Part B, home infusion suppliers often bill Medicare for the purpose of obtaining Medicare denial billing remittance advices, which are required by other payers. It would be unreasonably costly and confusing for home infusion suppliers to receive timely filing limit denials for services provided to individuals for whom the supplier is unaware of retroactive Medicare entitlement during the allowable filing period. The commenter urged CMS to ensure that infusion suppliers do not have to face this situation.

Response: Although this comment was unclear, we believe the commenter is concerned that home infusion suppliers will be disadvantaged by the exception at § 424.44(b)(2). If the conditions for § 424.44(b)(2) are met, then home infusion suppliers will be able to utilize that exception the same as any other provider or supplier and therefore will not be adversely impacted by this rule.

Comment: One commenter urges CMS to make communication about this new deadline a priority for the Agency. This should include a prominent banner on the CMS Web site home page as well as clear and concise written communications with Medicare providers. It is important that providers not have claims rejected due to lack of awareness of new claims submission deadlines.

Response: Although this comment is outside the scope of this rule, we issued sub-regulatory guidance regarding section 6404 of the ACA on May 7, 2010 via Change Request 6960 and on July 30, 2010 via Change Request 7080. As a result of issuing that sub-regulatory guidance, two provider education articles were posted to CMS's Medlearn Matters Web site educating providers and suppliers about the new 1 calendar year timely filing requirement.

In order to effectuate the changes made by the ACA, we are finalizing our proposed changes to § 424.44, with four modifications. First, we are including another exception at § 424.44(b) by re-designating § 424.44(b)(4) of the proposed rule to § 424.44(b)(5) and designating the new exception for retroactive disenrollment from Medicare Advantage plans or Program of All-inclusive Care for the Elderly (PACE) provider organizations as § 424.44(b)(4). We are adding this new exception so that beneficiaries, providers, and suppliers may be granted an extension to file claims in Medicare Advantage situations when the following conditions are met:

- At the time the service was furnished the beneficiary was enrolled in a Medicare Advantage plan or PACE provider organization.
- The beneficiary was subsequently disenrolled from the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization effective retroactively to or before the date of the furnished service.
- The Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered its payment for the furnished service from a provider or supplier 6 months or more after the service was furnished.

In these situations, if we or one of our contractors determines that all of the conditions are met, then the time to file a claim will be extended through the last day of the 6th calendar month following the month in which the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered

its payment for the furnished service from the provider or supplier.

The second modification changes § 424.44(b)(5)(ii) because in retroactive entitlement situations there could be situations where a provider or supplier may not be notified of a beneficiary's retroactive entitlement in order to utilize the exception at § 424.44(b)(2). Therefore, we are modifying § 424.44(b)(5)(ii) so that notification to either party (that is, the beneficiary or the provider/supplier) for the first time about a beneficiary's retroactive entitlement will trigger when the extension of time to file the claim through the last day of the 6th calendar month begins.

The third modification changes § 424.44(b)(5)(i) because there may be situations where a provider or supplier may be able to utilize the exception under § 424.44(b)(1) commonly referred to as the "administrative error" exception, but the provider or supplier is not notified about the correction until it is too late to utilize the exception. Therefore, we are modifying § 424.44(b)(5)(i) so that notification to either party (that is, the beneficiary or the provider/supplier) for the first time about the administrative error correction will trigger the beginning of the extension of time to file the claim through the last day of the 6th calendar month.

The fourth modification changes the 11 months or more after the date of service requirement in § 424.44(b)(3)(iii) to 6 months or more after the date of service because the 11 months or more requirement was too restrictive.

V. Section 6410 of the Affordable Care Act and Section 154 of MIPPA: Adjustments to the Metropolitan Statistical Areas (MSA) for Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Acquisition Program

In the July 13, 2010 proposed rule we proposed a number of revisions to the DMEPOS CBP as a result of changes to the statute made by both the Medicare Improvements for Patients and Provider Act of 2008 (MIPPA) and the ACA of 2010. Since both MIPPA and the ACA specify requirements for Metropolitan Statistical Area (MSA) selection for Round 2 and subsequent rounds, we outlined our proposals for implementing the statutory requirements related to MSA selection and the phase in of competitive bidding areas under the DMEPOS CBP. First, we proposed to use the authority provided by the statute at section 1847(a)(1)(D)(ii) of the Act, as amended by MIPPA, to subdivide MSAs with populations of

greater than 8,000,000 under Round 2 of the DMEPOS CBP. Second, we proposed to exclude certain areas from competitive bidding after Round 2 as mandated by section 1847(a)(1)(D)(iii) of the Act, as amended by MIPPA. Third, we proposed to implement the requirement of section 6410 of the ACA to expand Round 2 of the program by adding 21 of the largest MSAs based on total population to the original 70 already selected for Round 2.

1. Background

Section VII.H of this final rule provides background on the DMEPOS CBP, including a description of many of the changes made to the program by section 154 of the MIPPA. In this section, we provide additional information regarding changes made by both section 154(a) of the MIPPA and section 6410 of the ACA. In addition to the changes discussed previously in this final rule, MIPPA also added subparagraph (D) to section 1847(a)(1) of the Act. Section 1847(a)(1)(D)(ii) of the Act, as added by MIPPA, addresses Round 2 of the DMEPOS CBP, and section 1847(a)(1)(D)(iii) of the Act addresses subsequent rounds of the Program.

Section 1847(a)(1)(D)(ii)(II) of the Act specifies that the Secretary shall implement DMEPOS competitive bidding in the areas previously selected for Round 2 of the program and also allows the Secretary, in implementing Round 2 of the program, to subdivide MSAs with populations of greater than 8,000,000 into separate CBAs. Section 1847(a)(1)(D)(iii) of the Act imposes new requirements on the Secretary for competitions occurring before 2015 in subsequent rounds of the program. For such competitions (other than national mail order), the following areas are to be excluded from the program: (I) rural areas; (II) MSAs not selected under Round 1 or 2 with a population of less than 250,000; and (III) certain areas with low population density within a selected MSA. These requirements do not apply to a national mail order program.

Finally, MIPPA required that we implement Round 2 of the DMEPOS CBP in the same MSAs that were designated as of June 1, 2008. In 2010, section 6410(a) of the ACA amended sections 1847(a)(1)(B)(i)(II) and (D)(ii) of the Act to expand Round 2 of the program from 70 MSAs to 91 MSAs by adding the next 21 largest MSAs by total population not already selected for Rounds 1 or 2.

2. Subdividing Large MSAs Under Round 2

We have selected MSAs for Round 1 and for Round 2 consistent with MIPPA's requirement. For Round 1, CBAs generally were comparable to MSAs, however, for Round 2 we proposed to subdivide MSAs of 8,000,000 or more in population. The authority to subdivide MSAs into separate areas for competitive bidding purposes is set forth in section 1847(a)(1)(D)(ii)(II) of the Act which states, "[t]he Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes." We have identified three MSAs which, based on the 2009 estimate from the Census Bureau data, we subdivided under section 1847(a)(1)(D)(ii)(II) of the Act: (1) Chicago-Naperville-Joliet, Illinois-Indiana-Wisconsin (IL-IN-WI) MSA with a population of 9,569,624; (2) Los Angeles-Long Beach-Santa Ana, California (CA) MSA with a population of 12,872,808; and (3) New York-Northern New Jersey-Long Island, New York-New Jersey-Pennsylvania (NY-NJ-PA) MSA with a population of 19,006,798. We proposed to divide these MSAs into separate CBAs because we believe this approach would create more manageable CBAs for contract suppliers to serve and allow more small suppliers to be considered for participation in the program.

We considered certain factors when deciding whether to subdivide the MSAs with populations of at least 8,000,000. We considered the geographic, social, and economic integration of each of the MSAs. We applied all of these factors when grouping counties into CBAs and we believe it is also appropriate to use these factors to determine: (1) Whether or not to subdivide an MSA into separate CBAs, and (2) if the decision is made to subdivide the MSA, how to subdivide the MSA. We considered the following factors, generally in the order in which they are listed:

- Geographic size of the MSA and the location of the counties within each MSA compared to neighboring counties.
- The driving distances from north to south and east to west within each MSA and county.
- The total population and the population of FFS Medicare beneficiaries using DMEPOS items subject to competitive bidding.
- The DMEPOS allowed charges for items subject to competitive bidding.

- Comparably sized Round 1 and Round 2 MSAs based on beneficiary counts and allowed charges for competitive bid items.

- The interstate highway infrastructures of the MSAs.
- The current service patterns of suppliers in each county of the MSA.

We used each of the factors to the extent practical to develop initial proposals for reasonable and workable subdivisions of these highly and densely populated MSAs. We believe consideration of these factors will help us meet our goal of subdividing large and densely populated MSAs and creating CBAs that are attractive to suppliers and incentivize them to bid competitively for a contract. With this goal in mind, we proposed to establish CBAs that provide for a good volume of DMEPOS business for winning bidders, avoid obvious geographic obstacles, mimic existing supplier service patterns, and, to the extent possible, do not cross State lines. We stated that we believed the factors we have selected will achieve those objectives.

We found that counties clearly delineate areas within a MSA, and as we have done for Round 1 by identifying CBAs by counties and zip codes, we proposed to subdivide the MSAs at a county level. Since the Office of Management and Budget (OMB) defines the MSAs by counties and county-based subdivisions are stable, we use counties to subdivide CBAs. When subdividing an MSA into counties, we consider counties that share social, economic, and geographic integration. We have first summarized the proposed subdivisions, then summarized the comments and finalized the CBAs.

The Chicago-Naperville-Joliet, IL-IN-WI MSA comprises 14 counties within 3 States: Illinois, Indiana, and Wisconsin. This MSA has 207,106 beneficiaries and \$218,161,562 of DMEPOS allowed charges subject to the DMEPOS CBP. Using the factors that we identified, we proposed to subdivide the Chicago-Naperville-Joliet, IL-IN-WI MSA into four separate CBAs: Indiana-Chicago Metro CBA; South-West-Chicago-Metro CBA; Central-Chicago, Metro CBA; and Northern-Chicago Metro CBA.

The Los Angeles-Long Beach-Santa Ana, CA MSA comprises two counties: Los Angeles County and Orange County. The MSA has 173,631 fee-for-service beneficiaries receiving DMEPOS subject to competitive bidding and \$244,523,957 in DMEPOS allowed charges subject to the DMEPOS CBP. As mentioned previously, we proposed to subdivide MSAs using counties, and since the Los Angeles-Long Beach-Santa

Ana, CA MSA only has two counties, it offers only one subdivision along the county lines. Hence, we proposed to divide the MSA by the two counties creating two CBAs: Los Angeles County CBA and Orange County CBA. We also proposed to use the authority in section 1847(a)(3)(A) of the Act to exclude certain areas within the Los Angeles-Long Beach-Santa Ana, CA MSA. We believe these areas meet the requirement of section 1847(a)(3)(A) of the Act; they are rural areas with a low population density within an urban area that are not competitive. In the April 10, 2007 DMEPOS CBP final rule (72 FR 17992), we finalized our regulations at § 414.410(c) that defined the factors we consider when determining an area is considered a low population density area or an area that would not be competitive. Based on our review of the County Subdivision Population from the 2000 Census from the U.S. Census Bureau, and using the factors set forth in the April 10, 2007 final rule, we proposed to exclude the area of Los Angeles County north of the San Gabriel Mountains. This large geographic area has a population of about 357,000, which is only 4 percent of the total population of Los Angeles County, and is separated from the rest of the county by the San Gabriel Mountains. The area north of the San Gabriel Mountains has one major road and many terrains which make this area remote. The majority of the population in Los Angeles County lives south of the San Gabriel Mountains. We believe that excluding this area will create a more manageable CBA that still provides sufficient volume of DMEPOS items while avoiding the geographic obstacle of the mountains. We believe including this area in the DMEPOS CBP would result in fewer small suppliers being considered for participation under the program, because we would not expect small suppliers to have the resources to serve these more remote areas. As a result, we expect that it will increase the number of bids submitted for the CBAs within the Los Angeles-Long Beach-Santa Ana, CA MSA.

The Los Angeles County includes the two islands of Santa Catalina and San Clemente off the west coast. We proposed that the two islands be included as a part of the Los Angeles County CBA in order to ensure that beneficiaries presently residing on these islands or who move to these islands in the future are ensured access to competitively bid items by contract suppliers. San Clemente Island is a military base with a current population of zero; and therefore, the inclusion of

this area in the CBA would not result in this island being a part of the supplier service area at this time.

The New York-Northern New Jersey-Long Island, NY-NJ-PA MSA comprises 23 counties in three States: New York, New Jersey and Pennsylvania. The MSA has 344,879 FFS beneficiaries receiving DMEPOS subject to the DMEPOS CBP and \$350,449,795 in allowed charges for DMEPOS items subject to competitive bidding. We proposed to subdivide the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA into five CBAs. The proposed Nassau-Brooklyn-Queens CBA would be contiguous to Suffolk County and would consist of the western part of Long Island and extend to the eastern part of New York City. The proposed Suffolk County CBA would consist of the eastern part of Long Island and would encompass most of Long Island. The proposed Bronx-Manhattan NY CBA would include the entire area of Manhattan and the Bronx. The proposed North-West NY Metro CBA would be situated north and west of New York City and would extend into New Jersey and Pennsylvania. The proposed Southern NY Metro CBA included Staten Island and would extend south to Ocean County, New Jersey.

At the March 17, 2010 meeting of the Program Advisory and Oversight Committee (PAOC), we presented these proposals for subdividing these three large MSAs. Various members of the PAOC had the following suggestions for subdividing these MSAs:

- Draw the boundaries of CBAs using the interstate highways rather than the divisions by County.
- Determine the current servicing areas of suppliers by MSA and product category by using a scatter plot.
- Use the Hudson River to divide the CBAs for the New York MSA.
- Carve out Pike and Putnam Counties from the New York MSA due to their location and their low population density.

- Include Manhattan as a separate CBA, due to its unique nature as a self contained area.
- Consider State licensure requirements when we divide the MSAs into CBAs.
- In the LA County CBA, exclude the area north of the San Gabriel Mountains from the CBA.
- Consider traffic patterns when dividing the Los Angeles MSAs into CBAs.

In the July 13, 2010 proposed rule, we stated that we would consider the PAOC's advice and recommendations and further invited comments on the proposed subdivision of the three MSAs.

Comment: One commenter suggested that CMS use main travel arteries to subdivide MSAs. The commenter further explained that using zip codes or county boundaries may be unworkable across a large MSA if the travel arteries do not correspond to the physical boundary lines for counties and zip codes.

Response: We examined travel arteries used by suppliers and supplier service and traffic patterns closely in developing the proposed CBAs. The commenter provided no rationale for use of travel arteries alone to establish CBA boundaries, nor did the commenter provide a specific methodology or information to use in making selections regarding which of the various highways to use as boundaries. We believe it is appropriate to consider travel arteries as one factor when designing CBAs. However, using this factor alone would result in unworkable CBAs. For example, if the interstate highway system in the Chicago-Naperville-Joliet, IL-IN-WI MSA, consisting of 11 different interstate highways (I-55, I-57, I-65, I-80, I-88, I-90, I-94, I-190, I-290, I-294, and I-355), were used as boundaries for CBAs, this would result in approximately 30 different, very small CBAs. As noted above, the numerous highway systems that cut through the MSAs were

considered in determining which counties to include in each proposed CBA; therefore, travel arteries were considered and used to develop the CBAs.

In phasing in the competitive bidding program, we adopted the definition of the term "Metropolitan Statistical Area" consistent with that issued by the OMB. The MSA comprises the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county as measured through commuting. Using OMB's standards for MSAs, we have found that counties clearly delineate areas within a MSA. Therefore, as we have done for Round 1, we will continue to identify CBAs by counties and zip codes. For the large MSAs, although we used the counties as the basis for determining the CBAs, we considered various factors when determining how to subdivide and group each county within the MSA, including which major travel arteries serve which counties or group of counties in a geographic location.

Comment: One commenter suggested that CMS should not finalize regulations expanding the DMEPOS CBP to implement Round 2 until the impact of implementation of Round 1 of the program on Medicare beneficiaries, suppliers and providers is fully evaluated and understood.

Response: Section 1847(a)(1)(B)(i)(II) of the Act mandates that competitions occur in 2011 for Round 2 of the CBP.

We did not receive comments on the specific CBAs proposed for the Chicago-Naperville-Joliet, IL-IN-WI MSA and are finalizing the CBAs in that MSA as proposed. The counties that comprise each of the final CBAs for this MSA are shown in Table 68. The DMEPOS allowed amount, beneficiary count subject to competitive bidding, and the general population that comprise these four final CBAs are shown in this table.

TABLE 68—CHICAGO-NAPERVILLE-JOLIET, IL-IN-WI

CBA name/county	DMEPOS allowed Charles *	DMEPOS beneficiary count subject to competitive bidding *	General population **
Indiana-Chicago Metro CBA:			
Lake, IN	\$18,600,917	16,637	493,800
Jasper, IN	1,238,119	1,191	32,544
Newton, IN	580,842	393	13,933
Porter, IN	4,856,838	4,526	162,181
CBA Total	25,276,716	22,747	702,458
South-West-Chicago-Metro CBA:			
Will, IL	13,523,185	12,522	681,097

TABLE 68—CHICAGO-NAPERVILLE-JOLIET, IL-IN-WI—Continued

CBA name/county	DMEPOS allowed Charles*	DMEPOS beneficiary count subject to competitive bidding*	General population**
Grundyl, IL	1,417,511	1,405	47,958
Kendall, IL	978,215	1,052	103,460
DeKalb, IL	2,358,319	2,323	106,321
Kane, IL	9,273,504	9,082	507,579
CBA Total	27,550,734	26,384	1,446,415
Central-Chicago Metro CBA:			
Cook, IL	124,854,279	116,360	5,294,664
DuPage, IL	16,945,135	18,492	930,528
CBA Total	141,799,414	134,852	6,225,192
Northern-Chicago Metro CBA:			
Lake, IL	12,352,802	12,482	712,453
McHenry, IL	7,020,768	6,852	318,641
Kenosha, WI	4,161,128	3,789	164,465
CBA Total	23,534,698	23,123	1,195,559
MSA Total	218,161,562	207,106	9,569,624

* Source: Medicare claims from 10/1/08 to 9/30/09 for items subject to competitive bidding.

** Source U.S. Census Bureau 2009 population estimates.

We did not receive comments on the specific CBAs proposed for the Los Angeles-Long Beach-Santa Ana, CA MSA and are finalizing the CBAs in that MSA as proposed, with one exception, based on further consideration of issues raised by the PAOC. We will not include Santa Catalina Island and San Clemente Island in the Los Angeles County CBA as initially proposed. We discussed the factors to consider when excluding low population density areas from a CBA in the April 10, 2007 DMEPOS CBP final rule (72 FR 17992). Exclusion of low population density areas results in smaller CBAs that may reduce supplier costs in servicing the CBAs. Lower supplier costs may result in lower bids, which would increase savings under the program. Although an area may be a low population density area, in accordance with existing regulations at § 414.410(c), it cannot be excluded from a CBA unless a determination is made that the area is non-competitive based on one or more of the following factors: Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas; low number of DMEPOS suppliers relative to similar geographic areas; or low number of Medicare fee-for-service beneficiaries relative to similar geographic areas. The island of

San Clemente has a population of zero and including the island in the program would therefore result in no savings. Approximately 70 Medicare beneficiaries receiving \$57,000 in DMEPOS items and services reside on the island of Santa Catalina. This area can therefore be considered a non-competitive area given the low number of Medicare beneficiaries and low level of DMEPOS utilization, especially considering that the total allowed charges for DMEPOS for Los Angeles County as a whole is over \$200 million. We took into consideration, when deciding whether to finalize this proposal, comments from the March 17, 2010, meeting of the PAOC, during which a supplier of DMEPOS highlighted the high costs of furnishing items to Santa Catalina Island, 20 miles off the coast of mainland California and accessible only by boat, helicopter, or amphibious aircraft. Contract suppliers, and in particular small suppliers, that do not have a location near the ferry ports for this island would be burdened by having to serve this area in accordance with their contract, and we expect that this may have an impact on the bids submitted for this CBA. Medicare beneficiaries who are residents of Santa Catalina Island and require delivery of DMEPOS items must currently make special arrangement

with suppliers for delivery of those DMEPOS items. Suppliers are not currently obligated to serve this island, so it is the beneficiary and not the supplier that bears the cost of any additional expense associated with delivery of items. Under the DEMPOS CBP, the supplier would be obligated to serve this island, if it were included in the CBA, and the additional expense of delivering items to this remote island are therefore transferred from the beneficiary to the supplier. Although we originally proposed to include Santa Catalina Island in the Los Angeles CBA to ensure access to DMEPOS items for these beneficiaries, we have further examined this issue and believe that beneficiaries will continue to have the ability to make special arrangements for delivery of these items if this area is not included in the CBA. We therefore believe that excluding the islands of San Clemente and Santa Catalina from the Los Angeles CBA is consistent with existing regulations at § 414.410(c).

The counties that comprise each of the final CBAs for this MSA are shown in Table 69. The DMEPOS allowed amount, beneficiary count subject to competitive bidding, and the general population that comprise these two final CBAs are shown in this table.

TABLE 69—LOS ANGELES-LONG BEACH-SANTA ANA, CA

CBA name	DMEPOS allowed amount*	DMEPOS beneficiary count*	General population**
Los Angeles County CBA***	\$201,244,121	137,408	9,862,049
CBA Total	201,244,121	137,408	9,862,049
Orange County CBA	43,279,836	36,223	3,010,759
CBA Total	43,279,836	36,223	3,010,759
MSA Total	244,523,957	173,631	12,872,808

* Source: Medicare claims from 10/1/08 to 9/30/09 for items subject to competitive bidding.
 ** Source U.S. Census Bureau 2009 population estimates.
 *** The counts and amounts are not adjusted for the area excluded north of the San Gabriel Mountains.

We did not receive comments on the specific CBAs proposed for the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA. However, we have decided to make three changes based on further consideration of issues raised by the PAOC. We carefully considered the PAOC suggestion noted in the proposed rule to exclude Pike and Putnam counties from the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA in order to result in a smaller and more manageable CBA than the proposed North-West NY Metro CBA. This proposed North-West NY Metro CBA is a large area situated north and west of New York City and covering the three states of New York, New Jersey, and Pennsylvania. Pike County, Pennsylvania is a low population density area and makes up only 0.3 percent of the total DMEPOS utilization for the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA. Therefore, we believe that excluding Pike County from the North-West NY Metro CBA is consistent with existing regulations at § 414.410(c). In addition, the PAOC pointed out that excluding Pike County, PA, would help reduce the burden of suppliers having to comply with different state licensure requirements. As noted in the proposed rule, the PAOC also suggested that CMS consider state licensure requirements when dividing the MSAs into CBAs. To eliminate the complexity of complying

with different state licensure requirements, we have decided to split the proposed North-West NY Metro CBA into two CBAs: One containing the New Jersey counties of Bergen, Essex, Hudson, Morris, Passaic, and Sussex; and one containing the New York counties of Putnam, Rockland, and Westchester. To summarize, with regard to the proposed North-West NY Metro CBA, the PAOC suggested excluding Pike and Putnam counties to reduce the size of this large CBA we proposed for the area in the north and west of the MSA. It was noted by the PAOC that removing Pike County would also reduce complications of multi-state licensing as Pennsylvania licensing rules and requirements would no longer be an issue. Based on the advice to reduce the size of the proposed North-West NY Metro CBA and reduce multi-state licensure complexities, we are removing Pike County from the CBA and are splitting the CBA into two new CBAs: A fairly large CBA containing the New Jersey counties from the proposed North-West NY Metro CBA; and a smaller CBA containing the New York counties from the proposed North-West NY Metro CBA. As a result of this change, there is now no need to remove Putnam County from the CBA as the three county area of Putnam, Rockland, and Westchester counties in New York will be served by suppliers contracted to furnish items in this area, which is now

significantly smaller than the proposed North-West NY Metro CBA. In further response to the PAOC's advice to consider State licensure requirements when subdividing the MSAs into separate CBAs, we have decided to remove Richmond County, NY from the proposed South New York Metro, leaving this CBA to be comprised of six counties in New Jersey. We are therefore moving Richmond County, NY to the Nassau-Brooklyn-Queens-County Metro CBA and have changed the name of the CBA to Nassau-Brooklyn-Queens-Richmond County Metro CBA. We note that Hudson River is in between Richmond County and the other counties in the Nassau-Brooklyn-Queens-Richmond County Metro CBA but we took into consideration the social integration of this area in that there is a major bridge/highway connecting Richmond County to Long Island. Also, we believe that for each final CBA set forth in this rule, the supplier servicing patterns supports our decision. We determined that both large and small suppliers in the MSA generally furnish items within the CBAs we proposed. The counties, DMEPOS allowed amount and beneficiary count subject to competitive bidding and the general populations that comprise each CBAs based on our final provisions are shown in Table 70.

TABLE 70—NEW YORK-NORTHERN NEW JERSEY-LONG ISLAND, NY-NJ-PA

CBA name/county	DMEPOS allowed amount*	DMEPOS beneficiary count*	General population**
Nassau-Brooklyn-Queens-Richmond County Metro CBA:			
Nassau, NY	\$30,888,889	29,857	1,351,625
Kings, NY	47,044,915	44,893	2,556,598
Queens, NY	33,406,236	32,798	2,293,007
Richmond, NY	7,054,863	6,626	487,407
CBA Total	118,394,903	114,174	6,688,637
Suffolk County CBA:			

TABLE 70—NEW YORK-NORTHERN NEW JERSEY-LONG ISLAND, NY-NJ-PA—Continued

CBA name/county	DMEPOS allowed amount*	DMEPOS beneficiary count*	General population**
Suffolk, NY	31,950,806	31,476	1,512,224
CBA Total	31,950,806	31,476	1,512,224
Bronx-Manhattan NY CBA:			
Bronx, NY	19,791,646	17,002	1,391,903
New York, NY	26,483,792	26,414	1,634,795
CBA Total	46,275,438	43,416	3,026,698
Northern NJ Metro CBA:			
Hudson, NJ	13,622,910	12,644	595,419
Bergen, NJ	19,948,837	20,278	894,840
Passaic, NJ	10,266,137	10,233	490,948
Essex, NJ	9,911,767	10,735	770,675
Morris, NJ	9,094,758	9,830	487,548
Sussex, NJ	2,905,240	2,819	150,909
CBA Total	65,749,650	66,540	3,390,339
North East NY CBA Metro:			
Putnam, NY	1,997,668	1,876	99,244
Rockland, NY	6,421,317	6,265	298,545
Westchester, NY	16,971,210	17,220	953,943
CBA Total	25,390,195	25,361	1,351,732
Southern NY Metro CBA:			
Hunterdon, NJ	2,709,880	2,356	129,031
Union, NJ	10,466,838	10,654	523,249
Middlesex, NJ	15,803,473	16,649	789,102
Monmouth, NJ	14,979,747	15,110	642,448
Ocean, NJ	20,913,022	21,600	569,111
Somerset, NJ	4,941,838	5,425	324,563
CBA Total	69,814,798	71,794	2,977,504
MSA Total	358,968,794	354,235	19,006,798

In summary, we are finalizing our proposal to divide the Chicago-Naperville-Joliet, IL-IN-WI MSA into four CBAs. We are finalizing, with the modification discussed above, two CBAs in the Los Angeles-Long Beach-Santa Ana, CA MSA. Lastly, we are finalizing, with modifications discussed above, six CBAs in the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA.

3. Exclusions of Certain Areas after Round 2 and Prior to 2015

Section 154(a) of MIPPA amended the statute by requiring that competition under Round 2 takes place in 2011 and by adding section 1847(a)(1)(D)(iii) of the Act that requires us to exclude the following areas from the competitive bid program for competitions after Round 2 of the program and before 2015:

- Rural Areas.
- Metropolitan Statistical Areas not selected under Round 1 or Round 2 with a population of less than 250,000.
- Areas with a low population density within a MSA that is otherwise selected consistent with section 1847(a)(3)(A) of the Act.

We proposed to incorporate these requirements and timeframes in proposed § 414.410(c).

We received no comments on this proposal and therefore are finalizing this provision without modification.

4. Expansion of Round 2

Section 6410(a) of the ACA expanded the areas to be included in Round 2 of the program. As amended by section 6410(a) of the ACA, section 1847(a)(1)(B)(i)(II) of the Act requires that the competition for Round 2 of the

program occur in 91 of the largest MSAs in 2011. Prior to this change, Round 2 was to include 70 MSAs. Section 1847(a)(1)(D)(ii)(II) of the Act, as added by section 6410(a) of the ACA, specifies that the additional 21 MSAs to be included in Round 2 "include the next 21 largest metropolitan statistical areas by total population" (after those already selected Round 2). The 2009 annual population estimates from the U.S. Census Bureau are the most recent estimates of population that will be available prior to the Round 2 competition mandated to take place in 2011. Therefore, we proposed to use these estimates to determine the additional 21 MSAs to be included in Round 2 of the program. Table 71 is a list of the additional 21 MSAs added to Round 2.

TABLE 71—ADDITIONAL 21 MSAs ADDED TO ROUND 2

21 Additional MSAs	2009 Total population
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	5,968,252
Washington-Arlington-Alexandria, DC-VA-MD-WV	5,476,241
Boston-Cambridge-Quincy, MA-NH	4,588,680
Phoenix-Mesa-Scottsdale, AZ	4,364,094

TABLE 71—ADDITIONAL 21 MSAS ADDED TO ROUND 2—Continued

21 Additional MSAs	2009 Total population
Seattle-Tacoma-Bellevue, WA	3,407,848
St. Louis, MO-IL	2,828,990
Baltimore-Towson, MD	2,690,886
Portland-Vancouver-Beaverton, OR-WA	2,241,841
Providence-New Bedford-Fall River, RI-MA	1,600,642
Buffalo-Niagara Falls, NY	1,123,804
Rochester, NY	1,035,566
Tucson, AZ	1,020,200
Honolulu, HI	907,574
Albany-Schenectady-Troy, NY	857,592
Worcester, MA	803,701
Oxnard-Thousand Oaks-Ventura, CA	802,983
Springfield, MA	698,903
Bradenton-Sarasota-Venice, FL	688,126
Poughkeepsie-Newburgh-Middletown, NY	677,094
Stockton, CA	674,860
Boise City-Nampa, ID	606,376

We received no comments on this proposal and therefore are finalizing this provision without modification.

W. Section 10501(i)(3): Collection of HCPCS Data for Development and Implementation of a Prospective Payment System for the Medicare Federally Qualified Health Center Program

The Omnibus Budget Reconciliation Act (OBRA) of 1989 amended the Act by creating new FQHC benefit programs under both Medicare and Medicaid. The Medicare FQHC benefit provides coverage for a full range of primary care services, including physician and certain nonphysician services (PAs, NPs), clinical social worker, psychologist services, and preventive services. FQHCs are “safety net” providers (for example, community health centers and programs serving migrants, the homeless, public housing centers, and tribal groups). The main purpose of the FQHC program is to enhance the provision of primary care services in underserved urban and rural communities. FQHCs typically enhance the availability of care to vulnerable populations, including Medicare, Medicaid, SCHIP, and the uninsured. Most of these health centers receive HRSA grants for services to the uninsured.

Medicare pays FQHCs on the basis of reasonable cost, subject to an upper payment limit on the reasonableness of incurred cost. Actual Medicare reasonable cost is determined based upon a Medicare cost report filed by the FQHC after the end of its fiscal year. Prior to the start of the year, an interim all-inclusive per-visit payment amount, based upon an estimate of Medicare reasonable costs, is calculated for each

Medicare FQHC. During the year, this interim all-inclusive per-visit payment amount is paid for each covered visit between a Medicare beneficiary and an FQHC health professional. After the end of the Medicare FQHC’s cost reporting year, interim per-visit payments are reconciled to actual Medicare reasonable costs based upon the Medicare cost report filed by the FQHC. Section 10501(i)(3) of the ACA now amends this current Medicare FQHC payment policy with an entirely different payment system, effective with cost reporting periods beginning on or after October 1, 2014.

Section 10501(i)(3)(A) of the ACA amended section 1834 of the Act by adding a new subsection (o), Development and Implementation of Prospective Payment System. This subsection provides the statutory framework for development and implementation of a prospective payment system for Medicare FQHCs. Section 1834(o)(1)(B) of the Act, as established by the ACA, addresses collection of data necessary to develop and implement the new Medicare FQHC prospective payment system. Specifically, section 1834(o)(1)(B) of the Act, Collection of Data and Evaluation, grants the Secretary of HHS the authority to require FQHCs to submit such information as may be required in order to develop and implement the Medicare FQHC prospective payment system, including the reporting of services using HCPCS codes. Section 1834(o)(1)(B) of the Act requires that the Secretary impose this data collection submission requirement no later than January 1, 2011. Accordingly, we proposed to add a new paragraph (d) to § 405.2470 to require Medicare FQHCs to begin reporting all services furnished

using HCPCS codes for these services starting January 1, 2011. Beginning January 1, 2011, we proposed that the Medicare FQHC would be required to report on Medicare FQHC claims all pertinent service(s) provided for each Medicare FQHC visit (defined in § 405.2463). This additional reporting would include the information needed to develop and implement a PPS for FQHCs. For example, corresponding HCPCS code(s) would be required to be reported along with the presently required Medicare revenue code(s) for the Medicare FQHC visit(s). We noted in our proposal that our Medicare FQHC claims processing system would be revised to accept the addition of the new reporting requirements effective January 1, 2011. In our proposal, we also noted that the proposed new data collection effort would be for informational and data gathering purposes only, and would not be utilized to determine Medicare payment to the FQHC. Until the FQHC prospective payment system is implemented in 2014 and the Medicare claims processing system is revised to reflect such a system, we noted that Medicare FQHC payment would continue in the current manner (utilizing revenue codes and the interim per-visit payment rate methodology).

In our proposed rule, we further noted that Medicare FQHCs would be required to adhere to the information collection requirements in accordance with the content and terms of their Medicare agreement as stipulated at § 405.2434. We indicated in the proposed rule that failure to do so could result in the termination of the FQHC’s Medicare agreement in accordance with § 405.2436 of the Medicare FQHC regulations.

At the time of publication of the proposed rule, we noted that we did not foresee additional claims or other information collection needs beyond collection of HCPCS codes.

Accordingly, we did not propose additional information collection requirements at that time. However, we solicited public comment on any additional information FQHCs believe may be necessary in order to develop and implement a prospective payment system for Medicare FQHCs.

We received a number of comments on the proposed information collection requirements. We address these comments as follows:

Comment: One commenter requested that CMS ensure that its systems are appropriately updated to be able to accept HCPCS codes from Medicare FQHCs.

Response: CMS will work to assure that its contracts are provided with adequate notice allowing for claims processing systems to accept these new reporting requirements.

Comment: One commenter requested that health centers be given adequate time to learn the new reporting requirements, and to work with health centers that might need additional assistance.

Response: CMS, through its Contractors, presently works to assist and train all providers in Medicare reporting requirements, particularly new requirements such as the collection of HCPCS information from Medicare FQHCs. Medicare contractors have a variety of assistance measures at their disposal to train Medicare FQHCs in HCPCS coding. Assistance measures include seminars, web learning portals, and telephone information lines. We note that there are numerous private sector training and educational opportunities in HCPCS coding as well. With the specific language regarding HCPCS data collection from Medicare FQHCs included in the ACA itself, and the resultant lead time prior to January 1, 2011 implementation of the reporting requirements, we believe health centers have had sufficient time to prepare themselves to meet these requirements.

Comment: One commenter suggested that data collection begin with a representative sample of health centers, and that it generally be phased in across the nation, in order to ensure that CMS not penalize health centers that might need additional assistance.

Response: With the tight ACA implementation time frames for implementation of a Medicare FQHC prospective payment system, as well as the limited total number of FQHCs, we believe both provider sampling and

phase-in approaches to information collection requirements would jeopardize CMS' ability to meet statutory requirements for the Medicare FQHC PPS. Accordingly, we cannot accept comments to delay or limit collection of Medicare FQHC data we believe necessary to meet the statutory requirements.

Comment: One commenter suggested that HHS estimate the additional administrative burden placed on FQHCs and, if that is significant, increase reimbursement proportionately during the proposed collection period.

Response: Medicare FQHCs are paid on the basis of reasonable cost. Administrative costs attributable to added information collection requirements that might be incurred by Medicare FQHCs are already to be reported by the Medicare FQHC on its Medicare costs report and included as part of its Medicare FQHC all-inclusive rate.

Comment: One commenter suggested that HHS use the quality measures reported to CMS as part of its meaningful use of electronic health record requirements, instead of coding additional information into the claims.

Response: We do not believe that quality measures reported to CMS as part of meaningful use requirements would be sufficient in scope or representative in breadth in order to establish a National Medicare PPS sample which would be representative of the entire population of Medicare FQHCs. Accordingly, we cannot accept this comment.

As a result of these comments, we are making no changes to our proposal to require FQHCs to begin the reporting of services using HCPCS codes. Accordingly, we are finalizing this provision without modification. We will add a new paragraph (d) to § 405.2470 to require Medicare FQHCs to begin reporting all services furnished using HCPCS codes for these services starting January 1, 2011.

We received no public comment suggesting collection of additional information collection requirements beyond HCPCS codes. Therefore we add no additional Medicare FQHC information collection requirements, beyond the collection of the aforementioned HCPCS data requirements, in this final rule.

VII. Other Provisions of the Proposed Regulation

A. Part B Drug Payment: Average Sales Price (ASP) Issues

1. "Carry Over" ASP

The average sales price (ASP) payment methodology is authorized under section 303(c) of the MMA, which amends Title XVIII of the Act by adding section 1847A. This section establishes the use of the ASP methodology for payment for Medicare Part B drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. For purposes of this part, unless otherwise specified, the term "drugs" will hereafter refer to both drugs and biologicals. The ASP methodology applies to most drugs furnished incident to a physician's service, drugs furnished under the DME benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

Sections 1847A and 1927(b) of the Act specify quarterly ASP data reporting requirements for manufacturers. Specific ASP reporting requirements are set forth in section 1927(b) of the Act. Although delays in reporting have been uncommon, they create a risk that: (1) Could result in the publication of payment limits that do not reflect prices for drug products, and (2) could result in inaccurate payments, the need for correction of files and unintentional ASP payment limit variability.

As a result of these concerns, we sought to establish a process for addressing situations where manufacturers fail to report manufacturer ASP data in a timely fashion, that is within 30 days after the end of a quarter. The proposal in CY 2011 PFS proposed rule was intended to allow us to calculate and report ASP payment limits for a given quarter within the existing timelines and would not affect CMS or the OIG's authority to assess civil monetary penalties associated with untimely or false ASP reporting. Manufacturers who misrepresent or fail to report manufacturer ASP data will remain subject to civil monetary penalties, as applicable and described in sections 1847A and 1927(b) of the Act.

For the purposes of reporting under section 1847A of the Act, the term "manufacturer" is defined in section 1927(k)(5) of the Act and means any entity engaged in the following: production, preparation, propagation, compounding, conversion, or processing of prescription drug product, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical

synthesis, or by a combination of extraction and chemical synthesis; or packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. However, manufacturers that also engage in certain wholesaler activities are required to report ASP data for those drugs that they manufacture. Note that the definition of manufacturers for the purposes of ASP data reporting includes repackagers.

In accordance with section 1847A of the Act, manufacturers are required to report data on the National Drug Code (NDC) level, which include the following elements: the manufacturer ASP for drugs; the Wholesale Acquisition Cost (WAC) in effect on the last day of the reporting period; the number of units sold; and the NDC. Currently, when manufacturer ASP data or specific data elements are not available, we calculate an ASP price for a billing code based on other applicable and available pricing data from manufacturers for that drug. This alternative method used when manufacturer data are not available for a billing code includes WAC prices from compendia. WAC prices tend to be higher than manufacturer ASP prices.

Although problems with reporting have been uncommon, we have recently encountered situations where delays in manufacturer ASP reporting could have led to significant ASP payment limit fluctuations for highly used HCPCS codes. The greatest potential impact occurs when data for high volume drug products within a HCPCS code that is represented by a limited number of NDCs have not been reported and cannot be included in the ASP volume

weighted calculations described in section 1847A(b) of the Act. For multisource drugs, such a situation is likely to artificially increase or decrease Medicare ASP payment limits, which in turn would affect beneficiary cost sharing amounts. Such artificial fluctuations of the ASP payment limit could provide the appearance of instability unrelated to market forces and could also create access issues for providers and beneficiaries and confusion that could ultimately affect product demand in the marketplace.

In order to minimize the possibility of ASP payment limit fluctuations due to missing data, we proposed a process, consistent with our authority in section 1847A(c)(5)(B) of the Act, to update ASPs based on the manufacturer's ASP calculated for the most recent quarter for which data is available. Specifically, we proposed to carry over the previously reported manufacturer ASP for an NDC(s) when missing manufacturer ASP and/or WAC data could cause significant changes or fluctuations in ASP payment limits for a billing code, and efforts by CMS to obtain manufacturer-reported ASP before Medicare ASP payment limits publication deadlines are not successful. For example, the most recently reported manufacturer ASP prices for products on the market would be carried over to the next quarter if a manufacturer's entire submission were not received, manufacturer ASP price data for specific NDCs have not been reported, or when only WAC data has been reported; however, NDCs that have zero sales or are no longer being manufactured will not be subjected to this process. Also, we proposed to apply the carryover process only in cases where missing data results in a 10 percent or greater change in the ASP

payment limit compared to the previous quarter. Based on experience with ASP methodology since 2004, we believe that this percentage threshold constitutes significant change. We specifically sought comments on our use of 10 percent as the threshold amount. In order to better represent actual market trends, that is, actual increases or decreases in manufacturer reported ASP for the group of NDCs that represent the HCPCS code, we also proposed that the manufacturer ASP payment amounts for the individual NDCs that are carried over will be adjusted by the weighted average of the change in the manufacturer ASP for the NDCs that were reported during both the most recently available quarter and the current quarter. We requested comments about whether other methods to account for marketplace price trends could be a better substitute for applying the weighted average change. The previous quarter's sales volumes will be carried over. An example of the proposed process appears in Table 72.

We proposed to apply this process to both single source drugs and multiple source drugs. However, we are concerned that including single source drugs in the carry over process could create an incentive for nonreporting in situations where ASPs for a single source drug are falling and the manufacturer stops reporting ASPs in an effort to preserve a higher payment amount despite the risk of significant statutory penalties for such an action. Therefore, we specifically requested comments on this option and the effect of limiting this proposal to multiple source drugs only. We noted that we would consider these comments carefully before including both single source and multisource drugs in the process.

TABLE 72—ASP CARRYOVER EXAMPLE FOR NDCs IN A SPECIFIC HCPCS CODE

Previous quarter reported NDCs	Previous quarter reported volume	Previous quarter ASP	Current quarter reported NDCs	Current quarter reported volume	Current quarter ASP	Current quarter NDCs for calculation	Current quarter volume for calculation	Current quarter price for calculation
12345-6789-10	2000	\$1.000	12345-6789-10	2500	\$0.980	12345-6789-10	2500	\$0.980
12345-6789-11	3000	1.000	12345-6789-11	1700	0.980	12345-6789-11	1700	0.980
12345-6789-12	5000	1.000	12345-6789-12	5500	0.980	12345-6789-12	5500	0.980
45678-1234-90	9000	1.100	(2)	(2)	(2)	45678-1234-90	9000	1.078
45678-1234-99	27000	1.100	(2)	(2)	(2)	45678-1234-99	27000	1.078

¹ This result is obtained by calculating the weighted average price change in NDCs available (that is, 12345-6789-10 thru 12345-6789-12) in both the previous and current quarters, which is -2% [(0.98-1.00)*100], and applying that change to the previous quarter's manufacturer ASP for the missing NDCs (that is, 45678-1234-90 and 45678-1234-99). The last two columns on the right would be used to calculate the weighted ASP and payment limits for the 5 NDCs as a HCPCS code and accounts for missing prices for two high volume NDCs that represent most of the units sold within the HCPCS code and therefore heavily influence the price calculation for the HCPCS code.

² Missing.

Our proposed approach was intended to establish a straightforward and

transparent solution that minimizes the effect of missing manufacturer ASP data

on Medicare ASP payment limits. We believe that the availability of a

mechanism to minimize non-market-related price fluctuations is desirable when efforts to obtain manufacturer's ASP data by deadlines have not been successful. Our proposed mechanism was not intended to alter or adjust reported prices and will not be used to do so, but instead is intended to more accurately represent prices in the marketplace in the rare circumstance where manufacturer ASP data for particular drug product(s) is missing. Based on our experience with ASP reporting since 2004, we do not believe that this process will be used frequently. However, as we stated previously, recent concerns about delays in reporting of manufacturer ASP data have led to this proposal.

We also remind manufacturers that significant civil monetary penalties (CMP) for not reporting or misrepresenting manufacturer ASP data are authorized under sections 1847A(d)(4) and 1927(b)(3)(C) of the Act and codified in regulations at § 414.806. This proposal should not be interpreted to mean that CMS and the OIG will refrain from collecting such penalties for ASP reporting violations. Late or missing reports will not be tolerated. This proposed policy would be implemented regardless of any efforts by the OIG to impose CMPs for nonreporting.

We would also like to remind manufacturers that additional specific information about reporting ASP data to us is available. (For examples, see the following: 69 FR 17936, 69 FR 66299, 70 FR 70215, 71 FR 69665, 72 FR 66256, 73 FR 69751, and 74 FR 61904.) Also, Frequently Asked Questions are posted in the related links inside CMS section of the ASP Overview Web page at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp#TopOfPage, and the downloads section of the same Web page contains a link to the ASP Data Form (Addendum A), which includes examples of how ASP data must be reported and formatted for submission. In particular, we would like to remind manufacturers to report sales volume in quantities of NDC units sold (not vials or other units of sale), and to use a zero (that is, the character "0") instead of a blank when reporting items that did not have any sales in a particular quarter. In addition, manufacturers should report both the ASP and the WAC for each NDC, the expiration date for the last lot sold, if applicable, and the date of first sale for an NDC.

We received several comments about our proposals. In general, comments supported our proposal, including the

use of a weighted average when calculating the carry over amounts, but the comments also requested clarification about certain details. We did not receive any comments that would lead us to reconsider the 10 percent threshold that we proposed.

Comment: Several commenters specifically requested that CMS clarify what will be done to obtain a manufacturer's ASP information before carrying over previous manufacturer ASP information. The comments recommended that CMS establish contact with manufacturers using contact information from the manufacturer's submission before applying the carryover policy.

Response: We follow a routine internal quality check process that prompts communication with contacts listed on manufacturers' ASP submissions when we believe that ASP data may be late, missing, or incomplete. The process includes contacting the manufacturer as recommended above. Our experience with using the reported contact information to reach the manufacturer generally has been satisfactory, and we plan to continue using it to manage and track submissions and to coordinate follow-up action by CMS or other agencies. However, we also believe that the carryover policy will serve as a backup in the event information cannot be obtained in a timely manner. Again, we reiterate that sections 1847A and 1927 of the Act require manufacturers to report ASP quarterly, and that that section 1847A(d)(5) of the Act provides for significant CMPs in situations when misreporting of ASP data occurs.

Comment: A few commenters requested that we clarify how we determine whether products are no longer being sold. The comments agreed with our approach to exclude from the carryover process products with no sales or those products that are no longer manufactured.

Response: In most cases, the manufacturers' ASP reports clearly establish whether a product is still being sold because manufacturers are required to report NDCs with zero sales. As noted above, CMS also contacts the manufacturers, as needed, in order to clarify information. If a situation arises where the product's sales status is not clear and we are unable to get clarification from the manufacturer, we use multiple sources of information, including but not limited to internal quality checks, compendia data, and public information about drug products to determine the product's status. Our experience has shown that this approach is effective, and we would use

this approach to determine whether to apply the carryover policy if information supplied by the manufacturer was not available or not clear. Based on our experience, we believe that this approach will be sufficient to prevent the use of carryover data from products that are not sold during a quarter. We also would like to reiterate that manufacturers have a reporting obligation for NDCs with zero sales (71 FR 69676). In other words, the reporting obligation for an NDC ends only after the expiration date of the last lot sold. As mentioned above, a zero (the character "0") should be used to report the number of units of a drug product sold if that product had no reportable sales for a quarter.

Comment: A commenter requested that CMS announce the exact deadline for the application of the carryover policy each quarter.

Response: The ASP reporting deadline is specified in regulation text at § 414.804, which states that data must be submitted to CMS within 30 days after the close of a quarter. We decline to provide an additional "grace period" beyond the stated statutory and regulatory deadline—not only have we not proposed such a grace period, but also we believe such a policy could be misconstrued as permitting late submission of manufacturer data. As we stated earlier, our proposal was not intended (nor should it be construed) to affect manufacturers' obligations to submit ASP data timely, and penalties for noncompliance with the timely reporting requirement continue to apply. For these reasons, we decline to adopt the commenter's suggestion.

Comment: A commenter recommended that the carryover policy not be used for more than one quarter due to a concern about the accuracy of payment amounts based on data that is more than 2 quarters old.

Response: We will not specify the duration for the carryover policy at this time in order to prevent a situation where prolonged nonreporting of ASP data could influence ASP payment limit calculations. Based on our experience, reporting problems and delays with a duration of 2 or more quarters would be unlikely.

Comment: Commenters recommended that CMS carry over prices only if there is a manufacturer rebate agreement in place and a "track record" of four or more quarters of data have been reported.

Response: We disagree with these comments. First of all, the carryover process is unrelated to the manufacturer's reporting obligations under sections 1847A and 1927 and the

ASP regulations—in other words, our proposal does not serve to relieve manufacturers of any reporting obligations. Rather, our proposal is intended to solve the problem of how to accurately calculate ASP in instances where we do not have complete information. Thus, applying the carryover process only to certain manufacturers as the commenter suggests is not only unnecessary, but also, in our view, not appropriate. In addition, although we appreciate the commenter's desire to establish a baseline, for the reasons stated above, we do not believe that implementing a standard whereby we apply the carryover process only after a manufacturer has submitted four or more quarters of data is advisable. Such a policy would be contrary to our intent in making this proposal, which is to provide us with a standard procedure for addressing missing data. Further, we have no information indicating that manufacturers with four or more quarters of reporting are any more or less likely to fail to submit data for a particular product in future reporting periods. Therefore, we will not be modifying our policy based on these comments.

Comment: One commenter agreed with carrying over a weighted average price, but suggested that the carryover weighting calculation be based on the manufacturer's own NDCs within the given HCPCS code rather than the NDCs for all manufacturers within a given HCPCS code instead of weighting based on all manufacturers NDCs in the HCPCS code. The commenter believes that price changes for the manufacturer's own NDCs in the same HCPCS code will better represent price changes for the manufacturer's missing NDCs.

The commenter also recommended that CMS only use all other manufacturers' NDCs in the carryover weighting calculation as proposed if a manufacturer has not reported any data for any NDCs in the code.

Response: We disagree with these comments. We believe that basing weighting calculations on all of the reported NDCs in the code is the best approach because it permits us to maintain ASP stability without potentially providing manufacturers with an incentive not to report their ASP data. We are concerned that basing the carryover weighting calculation solely on the manufacturer's own NDCs in the applicable code could incentivize manufacturer non-reporting, particularly in situations where a manufacturer has multiple NDCs that comprise a large share of sales for a

HCPCS code. Indeed, we are aware of situations where a very wide variety of price changes have been reported for a single manufacturer's multisource products for a single code. If we were to calculate the weight for the carryover data using only the NDCs that the manufacturer reported, then a manufacturer might decide to risk sanction and purposefully report only a subset of NDCs for the quarter in order to increase the ASP payment limit for the HCPCS code, and this would result in inaccurate payment limits. For example, if a manufacturer omitted data for a single NDC in a code that had a price decrease and only reported one or two NDCs in that code that had price increases, the carryover weighting calculations could be skewed toward overpayment if only the manufacturer's own price changes were used in the carryover calculation. Again, we reiterate that that Section 1847A of the statute requires manufacturers to report ASP quarterly, and that that section 1847A(d)(5) of the Act provides for significant CMPs in situations when misreporting of ASP data occurs.

Comment: Two commenters recommended that CMS expand our proposed regulation text at § 414.904(i) to include more detail such as the 10 percent threshold, a requirement that we make contact with a manufacturer before applying the carryover policy, and that the policy not be applied to products with zero sales or products that are no longer being manufactured.

Response: Based on these comments, we will update the regulation text at § 414.904(i) to state that the carryover policy will apply only if the ASP payment limit change due to missing data is significant. Our threshold for a "significant" change is 10 percent up or down. We do not believe that adding further detail to the regulation text is necessary at this time because the preamble language and the clarifications sufficiently detail our approach.

Comment: In the proposed rule, we specifically requested comments about the applicability of our proposals to single source and multiple source drugs. One commenter agreed with our concerns that despite the potential for civil monetary penalties, single source drug manufacturers still could perceive an incentive not to report ASPs in order to maximize the margin between the ASP payment and the actual price for which providers acquire drugs. The commenter stated that the carryover process, if applied to single source drugs, could provide purchasers with an incentive to buy increased quantities of the product because of the widening gap between their purchase price and

Medicare payments. Further, because of the potential for increased sales volume, manufacturers of single source drugs may determine that the gains in volume outweigh the statutory penalties. The commenter recommended applying the carryover policy only to multiple source drugs because the absence of data for one product within a multiple source code could result in payment rate instability from quarter to quarter unrelated to market forces.

Response: We are persuaded by the comment to finalize our proposal with limitation that the carryover policy applies to multiple source drugs only because we agree that including single source drugs in the policy could result in inappropriate ASP payment limits for a HCPCS code and may unintentionally provide an incentive for nonreporting of single source drugs despite the likelihood of CMPs. In contrast, we believe that for multiple source drugs the carryover process can improve payment stability and keep the payment calculation more in line with market forces. Moreover, multiple source drugs present less risk for nonreporting because data from more than one manufacturer is used in pricing calculations and thus, the impact of one manufacturer's missing data is decreased. For these reasons and based on the comment we received, we will limit our carryover policy to multisource drugs. However, we will continue to monitor manufacturers' reporting practices for single source drugs, biologicals, and multiple source drugs.

In summary, we are finalizing our proposal as follows: When a manufacturer's reported data for a multiple source drug product with sales during a quarter is missing, and efforts by us to obtain manufacturer reported ASP data before Medicare ASP payment limits publication deadlines have not been successful, we will use the following process to calculate the payment limit for that drug product's billing code: First, we will determine whether calculating the payment limit without accounting for the missing data would result in a 10 percent or greater change in the ASP payment limit compared to the previous quarter. In that event, we will use (that is, carry forward) the most recent data available for that multiple source drug product(s) (that is, the individual NDCs), adjusted by the weighted average of the change in the manufacturer ASP for the NDCs that were reported during both the most recently available quarter and the current quarter. The previous quarter's sales volumes also will be carried over for the NDCs with missing data. The

carryover process as described above applies, for example, if a manufacturer's entire submission was not received, manufacturer ASP price data for specific multiple source NDCs has not been reported, or when WAC data only has been reported. However, single source drugs and biologicals, and multiple source drug NDCs that have zero sales or that have been permanently discontinued by the manufacturer will not be subject to this process. We are also finalizing § 414.804(i) with minor modifications as described elsewhere in this section.

Our process is intended to more accurately represent prices in the marketplace if manufacturer ASP data for particular drug product(s) is missing. Based on our experience with ASP reporting since 2004, we do not believe that this process will be used frequently.

2. Partial Quarter ASP Data

Section 1847A(c)(4) of the Act states that, "In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—(A) the wholesale acquisition cost; or (B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals."

When a new drug product enters the market, the first date of sale rarely coincides with the beginning of a calendar quarter. Therefore, the ASP data for many new drug products falls into partial quarter status during the first quarter of sales. We are taking this opportunity to describe our policy regarding how we use data from the first quarter of sales in the calculation of ASP payment limits.

In accordance with section 1847A(c)(4)(A) of the Act, our policy has been to price new single source drugs and biologicals at WAC for the first quarter (unless the date of first sale is on the first day of the quarter), and to add new NDCs for multisource drugs and product line expansions of single source drugs and biologicals to the ASP calculation for a quarter as soon as these products are reported.

We believe that the approaches for single source drugs, biologicals, and multisource drugs are consistent with the statute, particularly section 1847A(c)(4) of the Act, and we intend to continue this policy.

Although this section of the rule did not contain any proposals, we received several comments about our description of current policy.

Comment: Several commenters asked that CMS clarify how our policy coincides with previously published preamble language from the CY 2005 PFS rule (69 FR 66302) that states that the initial period "start[s] on the date that sales of the drug begin and end[s] at the beginning of the quarter after we receive information from the manufacturer regarding ASP for the first full quarter of sales."

Response: We believe our clarification is consistent with previously published materials referenced by the commenters, and we appreciate the opportunity to better explain our approach. The CY 2011 PFS proposed rule discussion pertains to our determination of the ASP-based payment limits under section 1847A of the Act using data from the drug's first quarter of sales—in other words, how we calculate payment once we have received ASP data from the manufacturer for a drug. These payment limits become effective two quarters after the drug's first quarter of sales. In contrast, our preamble discussion in the CY2005 PFS rule pertained to payment under section 1847A of the Act in quarters before sufficient ASP data that is needed to calculate payment limits has been reported to CMS—that is, the CY2005 preamble discusses payment for drugs that are administered on dates of service during their first or second quarter of sales.

The ASP reporting and publishing time table has a two quarter lag, so payment limits calculated using data reported from the first quarter of sales become effective two quarters later. By way of example only, a manufacturer's prices for a new single source drug first sold on January 10 would be reflected in the ASP data that a manufacturer reports to CMS no later than April 30, and that data would be considered partial quarter data because sales began after the first day of the quarter. If CMS determines that the drug should be added to the national price files (that is, the drug is not priced by a contractor/MAC), payment limits using the data from January 10 to March 31 would then be calculated and become effective for the first quarter of sales from July 1 to September 30 of that year. In this example, the first full quarter of sales of the new drug would take place between April 1 and June 30. ASP data from the new drug's first full quarter of sales would be reported to CMS no later than July 30, and payment limits calculated using this data would become effective

for the period October 1 to December 31. Our approach is consistent with the initial period for ASP based payment limit calculations described in the CY 2005 PFS final rule (69 FR 66302), which states that the "time period will start on the date that sales of the drug begin and end at the beginning of the quarter after we receive information from the manufacturer regarding ASP for the first full quarter of sales."

Comment: Commenters also requested that CMS clarify whether we use 100 percent or 106 percent of WAC to set payment limits after new drugs are introduced.

Response: As we mentioned above, our discussion of partial quarter data in the 2011 PFS proposed rule is limited to situations where national payment limit determinations under section 1847A of the Act are being made using reported data from the first quarter of a drug's sales.

The national payment limits for single source drugs that are calculated from partial quarter data and are published in CMS's quarterly ASP price files use 106 percent of WAC. This percentage is consistent with sections 1847A(c)(4)(A) and 1847A(b) of the Act and is also described in Chapter 17 Section 20.1.3 of the Medicare Claims Processing Manual.

Comment: Commenters requested that CMS make regulation text changes to clarify that 106 percent of WAC is applied as a payment limit for the period that starts on the date that sales of the drug begin and ends at the beginning of the quarter after we receive information from the manufacturer regarding ASP for the first full quarter of sales.

Response: Our policy is consistent with existing regulation text language at § 414.904, the manual, and preamble language. Therefore, we are not making any regulation text changes.

Comment: One commenter asked that CMS clarify what "product line expansions of single source drugs" means.

Response: For the purpose of the discussion of partial quarter ASP data above, the term "line expansion" refers to an additional package size or sizes of a single source drug or biological; by way of example only, a new larger vial size of a new antibiotic that is introduced for sale nine months after the drug's initial sales begin would represent a line expansion. Sales data for such new, additional NDCs is incorporated into the weighted ASP payment limit calculation for single source drugs beginning with the first quarter of sales that is reported to CMS. In other words, data for NDCs added to

a single source drug code that is already priced using the weighted average calculations is not considered partial quarter data.

Comment: CMS received several comments that request other changes to the regulations in connection with the first quarter of sales. These comments included recommendations that CMS—

- Develop regulation text changes that describes an apparent expansion of the initial period described in section 1847A(c)(4)(A) of the Act;
- Define when invoice pricing may be used if payments are made under section 1847A;
- Discuss the determination of payment amounts made under section 1847A for dates of service during the first or second quarter of a drug's sales;
- Add additional information requirements to ASP reporting templates used by manufacturers; and
- Clarify how payments are calculated when a drug leaves the market.

Response: As noted previously, our discussion of partial quarter data is limited to and pertains to the use of less than a full quarter's worth of data to calculate an ASP-based payment limit, not to other issues such as the payment limit for drugs administered during the first quarter of sales, or reporting procedures. Thus, these comments are outside the scope of this rule.

We will continue to apply the policy as previously clarified in this section and described in the proposed rule.

3. Determining the Payment Amount for Drugs and Biologicals Which Include Intentional Overfill

The methodology for developing Medicare drug payment allowances based on the manufacturers' submitted ASP data is specified in 42 CFR part 414, subpart K. We initially established this regulatory text in the CY 2005 PFS final rule with comment period (69 FR 66424). We further described the formula used to calculate the payment amount for each HCPCS billing code in the CY 2006 PFS proposed rule (70 FR 45844) and final rule with comment period (70 FR 70217). With enactment of the Medicare, Medicaid and SCHIP Extension Act (MMSEA) (Pub. L. 110-173), the formula we use changed beginning April 1, 2008. Section 112(a) of the MMSEA amended section 1847A(b) of the Act to require CMS to calculate payment amounts using a specified volume-weighting methodology. In addition, section 112(b) of the MMSEA sets forth a special rule for determining the payment amount for certain drugs and biologicals. We addressed these changes in the CY 2009

PFS proposed and final rules (73 FR 38520 and 69571, respectively).

For each billing code, we calculate a volume weighted, ASP based payment amount using the ASP data submitted by manufacturers. Manufacturers submit ASP data to CMS at the 11-digit National Drug Code (NDC) level, including the number of units of the 11-digit NDC sold and the manufacturer's ASP for those units. We determine the number of billing units in an NDC based on the amount of drug in the package. For example: A manufacturer sells a box of 4 vials of a drug. Each vial contains 20 milligrams (mg); the billing code is per 10 MG. The number of billing units in this NDC for this billing code is (4 vials × 20mg)/10mg = 8 billable units.

Beginning April 1, 2008, we use a two step formula to calculate the payment amount for each billing code. We sum the product of the manufacturer's ASP and the number of units of the 11 digit NDC sold for each NDC assigned to the billing and payment code, and then divide this total by the sum of the product of the number of units of the 11 digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code. This process is discussed further in the CY2009 Physician Fee Schedule rule at 73 FR 69752.

The provisions in section 112 of the MMSEA were self implementing for services on and after April 1, 2008. Because of the limited time between enactment and the implementation date, it was not feasible to undertake and complete rulemaking on this issue prior to implementing the required changes. As a result of the legislation, we revised § 414.904 to codify the changes to the determination of payment amounts consistent with section 112 of the MMSEA.

Since that time, we have become aware of situations where manufacturers, by design, include a small amount of "intentional overfill" in containers of drugs. We understand that this "intentional overfill" is intended to compensate for loss of product when a dose is prepared and administered properly. For instance, a hypothetical drug is intended to be delivered at a 0.5 mg dose that must be drawn into a syringe from a vial labeled for single use only. The vial is labeled to contain 0.5 mg of product but actually contains 1.5mg of product. The additional 1.0 mg of product is included, by design, and is intended to be available to the provider so as to ensure a full 0.5 mg dose is administered to the patient.

Our ASP payment calculations are based on data reported to us by manufacturers. This data includes the

"volume per item". In our "Appendix A—Average Sales Price Reporting Data Elements" available on our Web site at <http://www.cms.gov/McrPartBDrugAvgSalesPrice/>, we define "volume per item" as, "The amount in one item (ex., 10 ml in one vial, or 500 tablets in one bottle). Enter "1" for certain forms of drugs (for example, powders and sheets) when "Strength of the Product" indicates the amount of the product per item." In order to accurately calculate Medicare ASP payment limits under section 1847A of the Act, we interpret "the amount in one item" to be the amount of product in the vial or other container as indicated on the FDA approved label.

It has been longstanding Medicare policy that in order to meet the general requirements for coverage under the "incident to" provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies (See Medicare Benefit Policy Manual (Publication # 100-02), Chapter 15, Sections 50.3, 60.1.A). Such physicians' services and supplies include drugs and biologicals under section 1861(s)(2)(A) of the Act. In accordance with this policy, providers may only bill for the amount of drug product actually purchased and that the cost of the product must represent an expense to the physician.

We further understand that when a provider purchases a vial or container of product, the provider is purchasing an amount of drug defined by the product packaging or label. Any excess product (that is, overfill) is provided without charge to the provider. In accordance with our current policy as explained above, providers may not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursable, and providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.

Because such overfill is currently not included in the calculation of payment limits under the methodology in section 1847A of the Act and does not represent an incurred cost to a provider, we proposed to update our regulations at 42 CFR part 414 Subpart K to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We also proposed to update our regulations at Subpart J to clearly state that payment for amounts

of free product, or product in excess of the amount reflected on the FDA-approved label, will not be made under Medicare.

We received several comments supporting our proposal. Several other comments raised concerns about whether our proposal attempts to regulate or even prohibit the use of overfill. Our policy is not intended to limit the use of intentional overfill during the care of beneficiaries or in medical practice; such measures are beyond CMS' authority. Rather, we are clarifying our ASP pricing and payment policies, describing how we utilize manufacturer reported data, and updating our regulations at 42 CFR part 414. The following is a summary of the comments we received and our responses.

Comments: Several commenters supported our proposal, agreeing that a provider does not incur a cost in obtaining the intentional overfill amount. One commenter noted that statute, regulations, and policies effective since CY 1965 regarding the "incident to" provision have required the provider to incur costs in order to receive Medicare payment. Another commenter supported the proposal because it protects the Medicare Trust Fund and the taxpayer, reduces fraud and abuse, and ensures quality patient care by reducing the influence of profit rather than clinical efficacy on medical decisions for the patient. One commenter agreed with the CMS proposal because of the variations in the amount of overfill that could be found in each vial or packaging. This commenter also noted previous OIG reports that expressly excluded intentional overfill in the calculation of acquisition costs because of variability in the amount of and different practices for the use of overfill. Some commenters, in support of the proposal, mentioned ongoing litigation which alleges that some manufacturers provided kickbacks to providers by marketing and furnishing intentional overfill and encouraging providers to bill federal health care programs to increase the providers' profits and sales volumes for the drugs.

Response: We appreciate the comments in support of our proposal. We believe these comments help to illustrate the variety of perspectives regarding overfill.

Comments: Several commenters expressed concern that our proposed regulation changes are, in effect, a restriction on providers' ability to use intentional overfill. Comments emphasized that intentional overfill is provided to account for loss of drug

during dosage preparation, and some comments noted that the FDA allows for intentional overfill to be included in the packaging to account for this loss of drug. Similarly, comments noted that current United States Pharmacopeia (USP) 797 standards for compounding sterile injections also allow for the use of overfill during drug preparation. Some comments suggested we work closely with the FDA and the USP to address the issue of intentional overfill in the manufacturing and packaging of the drugs. One comment suggested that we require providers to comply with USP 797 standards regarding the use of overfill. Commenters asserted that any regulation of intentional overfill should be imposed upon manufacturers rather than providers.

Response: We disagree with the commenters that believe our proposal would restrict the clinical use of intentional overfill. The comments that suggest that we impose requirements or implement standards regarding the amount or clinical use of overfill are beyond the scope of this rulemaking. In response to the commenters' concerns, however, we believe it is necessary to reiterate the distinction between the amount of drug product that is contained in a vial or other packaging for use in the care of a beneficiary and the amount of drug product that manufacturers report to CMS for pricing purposes and used to calculate payment limits under section 1847A of the Act. Our policy discussion is limited to the latter issue. Our policy is not intended to allow, prohibit, or otherwise regulate the amount of overfill that manufacturers include in a container, or how that overfill is used in clinical practice. Indeed, we do not have the authority to regulate the manufacturing of drugs or biologicals or the practice of medicine. The appropriate use of drug products, including sterile products, depends on numerous factors, including, but not limited to: approved labeling, State law, the setting in which the product is prepared and used, how the product is stored, sterility, and chemical stability. For many drugs, overfill quantities are small and are not completely used. In many settings, harvesting small amounts of overfill, when appropriate, can make up for doses that are lost or are discarded because of an error, short stability, or accidental contamination, for example. Our proposal does not pertain to, or apply to, any of these issues. The intent of this proposal is merely to clarify that the Medicare ASP payment limit is based on the amount of drug conspicuously indicated on the FDA

label, and that no payment will be made for any intentional overfill included as free drug for the proper preparation of a single therapeutic dose.

Comments: Some commenters estimated significant increases in Medicare costs if the proposal is finalized. These estimates were based on concerns that our policy would prohibit the use of overfill. These commenters emphasized that providers would be required to use additional vials and drugs if the use of intentional overfill were prohibited. They stated that the proposal will not reduce Medicare costs, but will transfer the costs associated with intentional overfill from the pharmaceutical companies to the providers and, in turn, to the Medicare and its beneficiaries. Several commenters stated that providers minimize wastage and cost through the use of intentional overfill and efforts to schedule patients efficiently.

Response: Because we disagree that our proposal limits utilization of overfill, we accordingly disagree that our proposal will increase costs. We are not prohibiting the use of overfill, thus we do not anticipate providers or other entities buying additional amounts of drug as a result of this policy. Further, we do not believe that our policy will require significant changes in procedures or practices for most providers and suppliers because most providers and suppliers use overfill in clinically appropriate circumstances, and we therefore do not believe that our policy will cause them to incur significant costs on that basis.

However, as we stated in our proposal, we believe it is inappropriate for a provider or supplier to bill Medicare for any amount of intentional overfill beyond the labeled amount in a single-use vial or package, and we agree with the commenters that such inappropriate billing does not occur routinely.

Comments: Several commenters expressed concern that the proposed intentional overfill policy may cause lower reimbursement rates for overhead costs relating to procurement, preparation, and dispensing of affected drugs. Several comments expressed concern about the burden of tracking doses that are prepared as a service for providers who bill under Medicare Part B. Some commenters stated that the intentional overfill proposal is impossible to apply to multi-dose vials or packages, and will cause unnecessary administrative burden to maintain accurate inventory and medical records regarding overfill and drug wastage from single-dose vials.

Response: We disagree with these comments. As we stated previously, our policy on intentional overfill pertains to payment under section 1847A of the Act—it is not an attempt to mandate or direct how the contents of a drug product package are used. Our policy relates to the providers and suppliers who furnish drugs or biologicals under Part B and who bill for such services. We have no authority under section 1847A of the Act to dictate how entities that prepare and sell doses of drugs for use in various clinical settings set their rates. We would expect that providers and suppliers who purchase prepared doses from these entities have incurred a cost for them. For these reasons, we do not anticipate that our policy will affect entities that do not bill separately for Part B drugs, such as entities that prepare doses of sterile products for sale to providers or suppliers who bill Medicare for the drug.

This proposal also is not intended to affect the current cost or waste-saving batch processes in place when using multiple-dose vials or packages. Instead, the intent of this proposal is to clarify that the ASP payment limit is currently based on the amount of drug indicated on the FDA label, and that no payment will be made for any intentional overfill.

We expect that providers will continue to maintain accurate medical records for all beneficiaries as well as accurate inventory records of all drugs that were actually purchased and appropriately billed to Medicare.

Comment: One commenter noted an increased burden upon CMS to examine the beneficiaries' records to verify that no intentional overfill was billed to Medicare.

Response: For the reasons stated above, we do not believe that our proposal will significantly affect procedures used in most clinical settings. We therefore do not expect an additional burden for the agency to track and monitor this policy beyond the procedures that are in place right now.

Comment: One commenter noted that the proposal is contrary to our current policy regarding discarded drugs and specifically stated that billing Medicare for discarded drug is only appropriate for single-use vials, and that the provider must make good faith efforts to schedule patients to efficiently deliver the drugs to patients in a clinically appropriate manner, and that any discarded drug amount billed to Medicare must not be used on any other patient.

Response: We disagree with this comment. Although our policy on discarded drugs may appear to be

similar to our proposed policy for overfill (in that they both pertain to how providers and suppliers deal with drug product that remains in a package after a dose has been administered), there is a key distinction. Our policy on discarded drugs acknowledges that providers and suppliers acting in good faith to minimize wastage should not be financially burdened when, for clinical reasons, it is not possible or advisable to use the full labeled amount of drug product in a single-use vial—in other words, we permit, in limited circumstances, billing for drugs for which the provider or supplier incurred a cost, but that the provider or supplier did not administer. In contrast, our policy on intentional overfill applies to drug product for which the provider or supplier did not incur a cost, that is, amounts of drug that are beyond the labeled amount. Thus, in addition to complying with the overfill policy, we expect providers to continue to make good faith efforts to efficiently minimize the amount of discarded drug by facilitating clinically appropriate methods of administering the required dose to each beneficiary and is consistent with the discarded drug policy in Chapter 17 Section 40 of the Medicare Claims Processing Manual (<http://www.cms.gov/manuals/downloads/clm104c17.pdf>).

Comments: Several commenters agreed with our position that intentional overfill is considered free product for which the provider did not incur a cost. However, other commenters stated that the purchase of a drug includes not only the amount of drug identified on the FDA label, but also encompasses the entire package including accompanying items such as syringes, diluents, and intentional overfill that is required to assure the drug is prepared and administered properly. One commenter suggested that it is more appropriate to see any excessive overfill as an in-kind discount that reduces the per-unit price of a drug. This commenter believes that manufacturers have factored overfill into the pricing of their products and that providers indirectly pay for overfill regardless of its use. Some commenters also that intentional overfill is within the Discount Exception and Safe Harbor under the Anti-Kickback statute. These commenters believe that CMS should similarly interpret intentional overfill as a discount and require accurate reporting of the price of the item (taking into consideration the discount) by the manufacturer, but not should not require the provider to reduce the amount billed or refrain from billing for the overfill.

Response: We acknowledge that drugs and biologicals are supplied in various containers or kits that include accessories and diluents, as well as a variable amount of intentional overfill to ensure that the single dose is prepared and administered appropriately. Sections 1847A(b)(2) and (b)(5) of the Act require that payment limit calculations be carried out without regard to any diluents or special packaging for the drug. We believe these statutory provisions support our position that overfill is not an in-kind discount. Further, we have authority under section 1847A(c)(3) of the Act to identify price concessions that must be included in the ASP calculation. However, we have a practical reason for declining to consider overfill to be a discount for purposes of the ASP calculation—namely, operational feasibility. The amount of overfill in vials varies from drug to drug and often is not easily or consistently quantifiable because actual fill amounts may also vary slightly due to the manufacturing process. In contrast, manufacturer sales data, ASP calculations, and ASP payment limits use exact quantities of drug that are represented by exact monetary values. Payment limits are currently calculated using the amount of drug that is reported by manufacturers to CMS each quarter. We base our price, in part, on the quantity indicated on the drug package, which does not indicate an overfill amount. The calculation of the Medicare payment limit is based on the reported data from the manufacturer. We do not have access to information that would permit us to account for overfill in the ASP calculation. Further, we are concerned that attempting to account for a variable amount of overfill could result in price instability or inaccuracy.

The application of safe harbor provisions to this proposal is outside the scope of this rule.

Comments: Some commenters suggested the issue of intentional overfill should be addressed in the ASP calculations. One commenter specifically suggested that the ASP calculation methodology be changed to consider intentional overfill when defining the units relevant to the calculation of the Medicare payment limit per billing code.

Response: Manufacturers are currently reporting ASP and sales data based on the labeled amount of the drug product. The intent of this proposal is to clarify that the ASP payment limit is based on the amount of drug clearly identified as the amount on the FDA label and packaging. We do not intend to change the ASP calculation

methodology to include intentional overfill because of the operational difficulty in accurately identifying the amount of overfill.

Comments: Many commenters suggested CMS clarify the applicability of the proposal to specific providers. Other commenters suggested that the proposal be applied and enforced prospectively only in the physician office setting and not in hospitals or other provider settings. Another commenter noted that drugs furnished in the outpatient department are reimbursed based on ASP when separately payable, and requests clarification regarding whether this proposal must be required of hospital outpatient clinics paid under the Hospital Outpatient Prospective Payment System (OPPS). This commenter also requested that CMS clarify whether this proposal applies to acute care hospitals, skilled nursing facilities, dialysis facilities and other providers or suppliers of services under bundled payment methodologies. Another commenter requested the proposal not be applied to dialysis facilities. The commenter stated that intentional overfill is included in their costs reports, that the "incident-to" provision does not apply to dialysis facilities, and that the policy may cause confusion during the transition into the new End Stage Renal Disease payment bundle.

Response: Section 1847A(a)(1) of the Act specifies that the ASP methodology applies to drugs or biologicals described in section 1842(o)(1)(C) of the Act, which indicates that the ASP-based payment limit in 1847A of the Act affects a physician, supplier or any other person that bills for Part B covered drugs that are not paid under a cost or prospective payment system. We did not propose to change the manner in which we calculate ASP-based payment limits to reflect the setting in which the drug was provided, and we believe that not only would such a policy be unduly complicated, but also would likely be beyond our authority under the ASP statute. We note that regardless of the benefit category for a drug or biological, if it is paid under section 1847A of the Act, we calculate the payment limit without regard to overfill—thus, the fact that certain providers or suppliers do not furnish drugs on an "incident to" basis is irrelevant to our policy for the ASP calculation. This rule's scope is limited to the payment of overfill under section 1847A of the Act.

Comment: One comment suggested that we encourage providers to the use intentional overfill and bill Medicare only for the amount administered to the

patient, but not the wasted amount. The commenter also suggested that drug billing code increments be reduced for those drugs that are dosed in smaller amounts than what is currently on the billing code. For example, if a patient dose is 710mg but the billing increment is 100mg, then the provider must bill Medicare for 800mg and waste the left over 90mg.

Response: We are continuing to work closely to review all billing codes to assure that such codes describe drugs at the most clinically appropriate dosage descriptors. As stated in the discarded drug policy (Chapter 17 Section 40 of the Medicare Claims Processing Manual; <http://www.cms.gov/manuals/downloads/clm104c17.pdf>), Medicare will continue to make payment for the administered amount of drug plus any appropriately discarded drug that sums to the labeled amount on a single-use vial or package.

Comments: Some commenters disagree that Medicare has a longstanding policy that an expense must be incurred by the provider in order for payment to be made by Medicare. One commenter stated that there is no existing law or regulation that prohibits a provider from billing for intentional overfill or for any free product. This commenter further discussed previous OIG reports that identified providers were using intentional overfill which would alter their costs, and added that CMS did not express any concerns about these overfill utilization practices. Another commenter recommended that CMS determine overfill amounts for all injectable drugs and validate whether excess product pooled from more than one container and billed to Medicare does not represent a cost to the provider.

Response: We believe our preamble adequately describes the longstanding Medicare policy based upon section 1861(s)(2)(A) of the Act. We maintain that services or supplies reimbursed by Medicare under the "incident-to" provision should represent an expense incurred by the physician or entity billing for the drugs, services or supplies. Our policy clarifies that we will not pay for intentional overfill. For reasons described elsewhere in this preamble, we do not intend to track overfill amounts for injectable drugs.

Comments: Some commenters requested that CMS define what is meant by "intentional" overfill since many injectable drugs include a variable amount of overfill to allow the labeled dose to be appropriately prepared and administered to the patient. One comment cited that the USP

recommends a 10 percent overfill by volume for liquid medicines, and stated that the example in the proposal describing a 100 percent overfill is inconsistent with USP guidelines.

Response: We described "intentional" overfill in the proposed rule (75 FR 40155) and we agree that the amount of intentional overfill may vary from product to product; however, we are not aware of an absolute limit on the amount of overfill. In summary, the preamble describes intentional overfill as any amount of drug greater than the amount identified on the conspicuous FDA approved label on the outside of the package, and characterizes overfill as excess or free product that does not represent a cost to the provider.

After reviewing the public comments, we are finalizing our proposal to update our regulations at 42 CFR part 414 Subpart J to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label, and Subpart K to clearly state that payment for amounts of product in excess of the amount reflected on the FDA-approved label will not be made under Medicare. We are finalizing the regulations as proposed. These provisions will be effective January 1, 2011.

4. Widely Available Market Price (WAMP)/Average Manufacturer Price (AMP)

Section 1847A(d)(1) of the Act states that "The Inspector General of HHS shall conduct studies, which may include surveys to determine the widely available market prices (WAMP) of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate." Section 1847A (d)(2) of the Act states, "Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the ASP under this section for drugs and biologicals with—

- The widely available market price (WAMP) for these drugs and biologicals (if any); and
- The average manufacturer price (AMP) (as determined under section 1927(k) (1) of the Act) for such drugs and biologicals."

Section 1847A(d)(3)(A) of The Act states, "The Secretary may disregard the ASP for a drug or biological that exceeds the WAMP or the AMP for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B))." Section 1847A(d)(3)(C) of the Act states that if the Inspector General (OIG) finds that the ASP for a drug or

biological is found to have exceeded the WAMP or AMP by this threshold percentage, the OIG "shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological, the lesser of—(i) the widely available market price for the drug or biological (if any); or (ii) 103 percent of the average manufacturer price. * * *

The applicable threshold percentage is specified in section 1847A(d)(3)(B)(i) of the Act as 5 percent for CY 2005. For CY 2006 and subsequent years, section 1847A(d)(3)(B)(ii) of the Act establishes that the applicable threshold percentage is "the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the WAMP or the AMP, or both." In the CY 2006 (70 FR 70222), CY 2007 (71 FR 69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904) PFS final rules with comment period, we specified an applicable threshold percentage of 5 percent for both the WAMP and AMP. We based this decision on the fact that data was too limited to support an adjustment to the current applicable threshold percentage.

For CY 2011, we proposed to specify two separate adjustments to the applicable threshold percentages. When making comparisons to the WAMP, we proposed the applicable threshold percentage to remain at 5 percent. The applicable threshold percentage for the AMP is addressed below in this section of the preamble. Although the latest WAMP comparison was published in 2008, the OIG is continuing to perform studies comparing ASP to WAMP. Based on available OIG reports that have been published comparing WAMP to ASP, we do not have sufficient information to determine that the 5 percent threshold percentage is inappropriate. As a result, we believe that continuing the 5 percent applicable threshold percentage for the WAMP is appropriate for CY 2011. Therefore, we proposed to revise § 414.904(d)(3) to include the CY 2011 date.

As we noted in the CY 2010 PFS final rule with comment period (74 FR 61904), we understand that there are complicated operational issues associated with this policy. We continue to proceed cautiously in this area. We remain committed to providing stakeholders, including providers and manufacturers of drugs impacted by potential price substitutions with adequate notice of our intentions

regarding such, including the opportunity to provide input with regard to the processes for substituting the WAMP for the ASP.

We solicited comments on our proposal to continue the applicable threshold percentage at 5 percent for the WAMP for 2011.

The following is a summary of the comments we received and our responses:

Comment: Several commenters supported maintaining the threshold at 5 percent. Other commenters commended CMS for the cautious approach toward determining price substitutions based on WAMP to ASP comparisons, and supported the exclusion of WAMP from the price substitution proposal discussed elsewhere in this rule. One comment suggested the AMP threshold be increased to reflect recent changes to the definition of AMP but did not provide a specific percentage. One commenter suggested that OIG also review whether existing discrepancies in the various reporting rules for bundled arrangements and price concessions have impacted the reported pricing for the same products under AMP and ASP.

Response: We appreciate the comments supporting the continuation of the 5 percent threshold. As we noted in the CY 2010 PFS rule (74 FR 61904), we understand there are complex operational issues associated with potential payment substitutions. We will continue to proceed cautiously in this area and provide stakeholders, particularly manufacturers of drugs impacted by potential price substitutions, with adequate notice of our intentions regarding such, include the opportunity to provide input with regard to the processes for substituting the WAMP or the AMP for the ASP. As part of our approach we intend to continue to work closely with the OIG to develop a better understanding of the issues that may be related to certain drugs for which the WAMP and AMP may be lower than the ASP over time.

After reviewing the public comments, we are finalizing our proposal to continue the 5 percent WAMP threshold for CY 2011.

5. AMP Threshold and Price Substitutions

As mentioned elsewhere in this final rule with comment period, when making comparisons of ASP to AMP, the applicable threshold percentage for CY 2005 was specified in statute as 5 percent. Section 1847A(d)(3) of the Act allows the Secretary to specify adjustments to this threshold percentage for years subsequent to 2005, and to

specify the timing for any price substitution. For CY 2006 (70 FR 70222) CY 2007 (71 FR 69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904), the Secretary made no adjustments to the threshold percentage; it remained at 5 percent.

For CY 2011, we proposed with respect to AMP substitution to apply the applicable percentage subject to certain adjustment such that comparisons of ASP to AMP will only be made when the ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter. We further proposed to apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that is, "complete" AMP data).

Furthermore, we proposed a price substitution policy to substitute 103 percent of AMP for 106 percent of ASP for both multiple and single source drugs and biologicals as defined respectively at section 1847(A)(c)(6)(C) and (D) of the Act. Specifically, we proposed that this substitution:

- Would occur when the applicable percentage has been satisfied for a number of calendar quarters as discussed elsewhere in this rule (that is, for two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter);
- Would permit for a final comparison between the OIG's volume-weighted 103 percent of AMP for a billing code (calculated from the prior quarter's data) and the billing code's volume weighted 106 percent ASP, as calculated by CMS, for the current quarter to avoid a situation in which the Secretary would inadvertently raise the Medicare payment limit through this price substitution policy; and
- That the duration of the price substitution would last for only one quarter.

We also sought comment on other issues related to the comparison between ASP and AMP, such as:

- Any effect of definitional differences between AMP and ASP, particularly in light of the revised definition of AMP per the ACA;
- The impact of any differences in AMP and ASP reporting by manufacturers on price substitution comparisons; and,
- Whether and/or how general differences and similarities between

AMP and manufacturer's ASP would affect comparisons between these two.

Comment: CMS received a number of comments pertaining to its proposals regarding the AMP threshold. Some commenters generally agreed that any proposal should be transparent, cautious, and should account for inter-quarter price fluctuations. Some commenters also supported our proposal to limit the price substitution to those HCPCS codes for which ASP and AMP comparisons are based on the same set of NDCs. One commenter requested that CMS specifically note that the volume used to calculate the volume-weighted AMP is identical to that used in the calculation of the volume-weighted ASP. Other commenters supported maintaining the applicable threshold at 5 percent for CY 2011.

Response: We appreciate the comments regarding our proposed AMP threshold policies. Since the publication of the PFS proposed rule, the preliminary injunction issued by the United States District Court for the District of Columbia in *National Association of Chain Drug Stores et al. v. Health and Human Services*, Civil Action No. 1:07-cv-02017 (RCL) is still in effect. Additionally, CMS continues to expect to develop regulations that will implement the provisions of section 2503 of the ACA, which amended the definition of AMP. Moreover, section 202 of the Federal Aviation Administration Air Transportation Modernization and Safety Improvement Act (Pub. L. 111-226), (enacted on August 10, 2010) has further amended section 1927(k) of the Act. Finally, on September 3, 2010, we proposed to withdraw certain provisions of the AMP final rule published on July 17, 2007 (75 FR 54073).

In light of these factors and comments received, we are finalizing our proposal that the AMP applicable threshold be 5 percent for CY 2011. However, we are not finalizing our proposed adjustments to the 5 percent AMP threshold that would specifically apply the applicable percentage such that comparisons of ASP to AMP will only be made when—

- The ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter; and
- For those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that is, "complete" AMP data).

We appreciate the submitted comments and will take them into account when we revisit the price

substitution and AMP threshold issues in future rulemaking.

Comment: We received a number of comments regarding our price substitution proposed policies. Some commenters supported our proposal that any substitution would last only for a single quarter. The majority of commenters requested that any proposal should not be implemented until after CMS published regulations on the revised definition of AMP. A few commenters also recommended that CMS provide adequate notice to manufacturers prior to making a price substitution. One commenter suggested that additional OIG comparison studies are needed to examine the impact of the new definition of AMP. Several commenters requested clarification on and suggested changes to our proposed regulatory language. Another commenter requested clarification on the timing of price substitutions and suggested that any price substitution policies should not be implemented until the lag time between when the comparison is made and when the substitution would be implemented was decreased. One commenter noted that the OIG studies are not a reliable indicator of predicted savings since the substitution timeframes within the studies differed from that in our proposal. All commenters agreed that any price substitution policy should not be implemented until after the preliminary injunction is vacated.

Moreover, several commenters provided additional information related to the comparison between ASP and AMP, including:

- How ASP and AMP each encompass different sales and rebate data and are calculated based on differing statutory definitions;
- The impact of restated AMP data on comparisons; and
- The effect of price substitutions on physician acquisition of drugs.

Response: We appreciate the comments submitted regarding our price substitution proposal. As discussed above, recent legislative and regulatory changes have further affected this issue.

After careful review and consideration of the comments received, we will not be finalizing our price substitution proposal at this time and thus we will not be finalizing the proposed regulation text at section 414.904(d). Specifically, we are not finalizing our proposal for a policy to substitute 103 percent of AMP for 106 percent of ASP for both multiple and single source drugs and biologicals as defined respectively at section 1847(A)(c)(6)(C) and (D) of the Act. This proposal specifically would have—

- Occurred when the applicable percentage had been satisfied for a number of calendar quarters as discussed elsewhere in this rule;

- Permitted for a final comparison between the OIG's volume-weighted 103 percent of AMP for a billing code (calculated from the prior quarter's data) and the billing code's volume weighted 106 percent ASP, as calculated by CMS, for the current quarter to avoid a situation in which the Secretary would inadvertently raise the Medicare payment limit through this price substitution policy; and

- Had the duration of the price substitution lasting for only one quarter.

We are finalizing the portion of our proposal that sets the AMP threshold at 5 percent CY2011 and have revised the regulations text accordingly. We remain committed to proceeding cautiously as we continue to evaluate the impact of any future policy developments in this area.

6. Out of Scope Comments

We received comments pertaining to: (1) Part B payment for insulin; (2) bona fide service fees; (3) price concessions and bundled arrangements in the calculation of manufacturer ASP data; (4) updating supplying and dispensing fees for Part B drugs; (5) developing standards for manufacturers to not submit related ASP data; (6) low reimbursement in a HCPCS-based claims systems for pharmacies; (7) claims processing, claims rejection, and payment delays in Medicare Part B as compared to Part D; and (8) publishing reimbursement rates for radiopharmaceuticals on contractor Web sites. These comments are outside the scope of this rule, and therefore are not addressed in this final rule with comment period.

B. Ambulance Fee Schedule Issue: Policy for Reporting Units When Billing for Ambulance Fractional Mileage

Under the ambulance fee schedule, the Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated and all other applicable medical necessity requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the following levels of service:

- For Ground—
 - ++ Basic Life Support (BLS) (emergency and nonemergency).
 - ++ Advanced Life Support, Level 1 (ALS1) (emergency and nonemergency).

- ++ Advanced Life Support, Level 2 (ALS2).
- ++ Specialty Care Transport (SCT).
- ++ Paramedic ALS Intercept (PI).
 - For Air—
- ++ Fixed Wing Air Ambulance (FW).
- ++ Rotary Wing Air Ambulance (RW).

1. History of Medicare Ambulance Services

a. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplementary Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt. 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

b. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations as specified in § 410.40 and § 410.41. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

2. Mileage Reporting—Provisions of the CY 2011 Proposed Rule

In the CY 2011 PFS proposed rule (75 FR 40159–40161, issued July 13, 2010), we proposed that, effective for claims with dates of service on and after January 1, 2011, ambulance providers

and suppliers would be required to report mileage rounded up to the nearest tenth of a mile on all claims for mileage totaling up to 100 covered miles, as further discussed below. We stated that we would revise the instructions set forth in our Claims Processing Manual to reflect the revised billing procedures. In this section, we describe our proposals in the CY 2011 PFS proposed rule, including the background and current process for reporting ambulance mileage, the proposed fractional mileage billing policy, and our reasons for proposing revisions to the current mileage reporting policy.

a. Background and Current Process for Reporting Ambulance Mileage

Historically, the Medicare FFS claims processing system lacked the capability to accept and process fractional unit amounts reported in any claim format. Therefore, the standard for reporting units for ambulance mileage was to bill in whole number increments. Thus, if the total units of service for ambulance mileage included a fractional amount, providers and suppliers of ambulance services (hereafter referred to collectively as “providers and suppliers”) were instructed to round the fraction up to the next whole number. Claims billed with fractional units of service were, at that time, returned as unprocessable as CMS' claims processing systems could not accept nor adjudicate fractional unit amounts properly.

Consequently, in Change Request (CR) 1281 (Transmittal AB–00–88, issued on September 18, 2000), we instituted an operational procedure requiring whole-unit reporting of mileage on ambulance claims. Specifically, we instructed providers and suppliers that “If mileage is billed, the miles must be whole numbers. If a trip has a fraction of a mile, round up to the nearest whole number.” Our instructions also stated that “1” should be reported for trips totaling less than a single mile. This was an operational instruction based on Medicare's FFS system limitations and capabilities at the time, as our claims processing systems were not capable of accepting and processing claims submitted with fractional units of service. Since then, our claims processing system functionality has evolved to the point where this rounding process is no longer necessary for ambulance transports, as it is now possible for our FFS systems to capture and accurately process fractional units on both paper and electronic forms.

Based on our prior instructions, providers and suppliers continue to

report loaded mileage as whole-number units on both paper and electronic claims. Providers and suppliers utilize the appropriate HCPCS code for ambulance mileage to report the number of miles traveled during a Medicare-covered trip rounded up to the nearest whole mile at a minimum of 1 unit for the purpose of determining payment for mileage. Transmittal AB–00–88 established a list of HCPCS codes accepted by Medicare for the purpose of billing mileage. Providers and suppliers were instructed to use these specific HCPCS codes and enter the total number of covered miles in the “units” field of the claim form. For example, if a covered trip from the point of pickup (POP) to the Medicare-approved destination (see § 414.40 for a list of approved destinations) totaled 9.1 miles, the provider would enter the appropriate HCPCS code for covered mileage and a “10” in the units field. Providers and suppliers billing for trips totaling, for example, 0.5 covered miles, would enter “1” in the units field along with the appropriate HCPCS code for mileage.

b. Concerns Regarding the Potential for Inaccuracies in Reporting Units and Associated Considerations

Often an ambulance provider will transport a distance that is either not an exact whole number of miles or less than one whole mile during a covered trip. Based on our current instructions, providers and suppliers billing for ambulance services must round up the total billable mileage to the nearest whole mile for trips that include a fraction of a mile or less than one whole mile. Because of those instructions, a provider or supplier is required to bill as much as 0.9 of a mile more than what was actually traveled.

We have been contacted by suppliers on several occasions with concerns regarding our current instructions for reporting ambulance mileage. Certain suppliers believe that our instructions require them to bill inaccurately. One company in particular stated that they routinely need to bill for trips totaling less than 1 mile. The beneficiaries that are being transported by this company live in the immediate vicinity of the facility to which they are being transported, and therefore, the number of loaded miles for each trip totals approximately one half of a mile. The company was concerned that since Medicare requires that they enter a “1” in the units field of their claims for mileage, they are being overpaid by Medicare for mileage based on the service they actually provided.

However, the company's main concern revolved around the risk of creating an appearance of impropriety. Although our instructions clearly state that providers and suppliers should, as a matter of procedure, round up fractional mileage amounts to the nearest whole mile, some providers and suppliers indicated that they wanted to bill as accurately as possible and that they only wanted to be paid for the service they actually provided. We thoroughly considered these concerns while reevaluating the procedure for reporting units for fractional mileage amounts.

As we stated in the CY 2011 PFS proposed rule (75 FR 40160), our first priority in considering the issues raised by ambulance providers and suppliers was to ascertain the basis for the current mileage reporting instructions. As previously discussed, the original instructions for reporting fractional mileage were published in Transmittal AB-00-88, issued on September 18, 2000. We instructed providers and suppliers to round fractional mileage amounts "up to the nearest whole mile" and to enter "1" for fractional mileage totaling less than one mile. This particular process had also been in place prior to issuance of the transmittal. The reason for the procedure was that our claims processing systems were not capable of accepting and processing claims submitted with fractional units of service—even if the service was commonly measured in fractional amounts, as with ambulance mileage.

In the CY 2011 PFS proposed rule (75 FR 40160), we then explored whether a change in our procedure would be: (1) Appropriate; (2) possible considering our current system capabilities and industry standards of measurement; and (3) applicable to any service other than ambulance mileage. As to the appropriateness of changing the procedure for reporting units of service on provider claims for fractional ambulance mileage, we stated in the proposed rule (75 FR 40160) that we believe that we should make every effort to create and implement policies and processes that create the best opportunity for accuracy in billing. It is not our intention to put providers and suppliers in a position where they are required to bill inaccurately for the service they provide. We continue to strive toward ensuring that providers and suppliers bill and are paid only for services actually provided. In the CY 2011 PFS proposed rule (75 FR 40160), we stated that we believe that changing our current procedure for reporting units of service to require reporting of

fractional mileage will help to ensure that providers and suppliers can submit claims that more precisely reflect actual mileage, and are reimbursed more accurately for the services they actually provided. We originally instituted a policy of accepting and processing only whole units because at that time system limitations prevented us from accepting and processing fractional ambulance mileage.

Second, we considered in the CY 2011 PFS proposed rule (75 FR 40160) whether it is currently possible for our claims processing systems to accept and process fractional unit amounts on both paper and electronic claims. Upon reevaluating our system capabilities, we found that technological advancements in Optical Character Recognition (OCR) and electronic claim submission have made it possible for our FFS systems to capture and accurately process fractional units on both paper and electronic claims. We note that our systems currently have the capability to accept fractional units with accuracy up to as much as one thousandth of a unit (that is, to 3 decimal places).

We also considered in the CY 2011 PFS proposed rule (75 FR 40160) whether ambulance providers and suppliers have the capability to measure fractional mileage. This was an important point because if providers and suppliers are not able to measure mileage with any more specificity than the nearest whole number mile, then there would be no need to modify the current procedure for billing fractional mileage. In that case, providers and suppliers would continue to report mileage as whole numbers since they could measure no more accurately than that. We stated in the proposed rule that both analog and digital motor vehicle odometers are designed to measure mileage accurately to within a minimum of a tenth of a mile. While we found that some vehicle odometers measure mileage more accurately than a tenth of a mile, most odometers are accurate to the nearest tenth of a mile. Additionally, aircraft geographic positioning system (GPS) technology provides the means to accurately determine billable mileage to the tenth of a mile.

Third, we considered whether a policy of billing fractional units would be applicable to any other service besides ambulance mileage. The units of service field on both the electronic and paper claim is used to report the quantity of services or supplies provided to Medicare beneficiaries and is used to report a wide range of services and supplies including, but not limited to: number of office visits; anesthesia minutes; quantity of drugs

administered; covered miles. Although Medicare currently makes payment based on fractional units for some services (for example, calculation of payment after conversion of anesthesia time reported in minutes to time units), there is currently no requirement that providers bill fractional units on the claim. We stated that if we were to implement a policy of requiring reporting of fractional units for other types of services or supplies, we would first need to evaluate whether it is possible to do so considering industry standards of measurement. As discussed in the CY 2011 PFS proposed rule (75 FR 40160), we found that providers and suppliers of ambulance services have the capability to determine fractional mileage using standard onboard equipment, that is, an odometer, GPS, and/or other similar equipment used to measure distance traveled. We stated that this would enable us to readily implement a fractional unit billing policy for ambulance mileage; whereas applicability to other areas (such as anesthesia, drugs, etc.) would require more analysis to determine whether a fractional unit billing policy is feasible, efficacious, and cost effective. Additionally, this issue was first raised by ambulance suppliers who were concerned about overbilling and being overpaid by Medicare. Therefore, we stated in the proposed rule (75 FR 40160) that we believe it is most reasonable to first address the area where concerns have been raised (that is, ambulance mileage) and consider applicability of this procedure to other types of services and items in the future.

Finally, and perhaps most importantly, we considered that our claims processing system should be configured to process claims as accurately as possible so as to provide for more accurate payments and to safeguard Medicare dollars. As previously discussed, we found that ambulance providers and suppliers currently have the capability to measure mileage accurately to within a minimum of a tenth of a mile using devices (for example, odometers, and GPS technology, etc.) already equipped onboard their vehicles. We stated in the CY 2011 PFS proposed rule (75 FR 40160) that we believe that requiring ambulance providers and suppliers to round (and report) fractional ambulance mileage up to the next tenth of a mile strikes a proper balance between ensuring that the claims processing system adjudicates a claim as accurately as the system will permit without unduly burdening the ambulance community.

Based on all of the considerations noted previously, we proposed that our claims processing instructions for submission of claims for ambulance mileage should be revised to reflect the current functionality of our claims processing systems so as to maximize the accuracy of claims payment, as further discussed in this section (75 FR 40160).

c. Billing of Fractional Units for Mileage

It is both reasonable and prudent that, in order to ensure accuracy of payment, we facilitate and allow submission of the most accurate information on all Medicare ambulance claims. Furthermore, since our claims processing systems are currently capable of accepting and processing fractional units of service, we believe that ambulance mileage should be billed to and paid by Medicare in fractional amounts to enhance payment accuracy. Based on all the considerations discussed previously, in the CY 2011 PFS proposed rule (75 FR 40161), we proposed to require that claims for mileage submitted by ambulance providers and suppliers for an ambulance transport (ground and air) be billed in fractional units; by rounding up to the nearest tenth of a mile (with the exception discussed below). As previously discussed, we believe that requiring ambulance providers and suppliers to round (and report) fractional mileage up to the next tenth of a mile would allow us to provide for more accurate claims payment without unduly burdening the ambulance community.

Therefore, in the CY 2011 PFS proposed rule (75 FR 40161), we proposed that, effective for claims with dates of service on and after January 1, 2011, ambulance providers and suppliers would be required to report mileage rounded up to the nearest tenth of a mile for all claims for mileage totaling up to 100 covered miles. Providers and suppliers would submit fractional mileage using a decimal in the appropriate place (for example, 99.9). Since standard vehicle mileage (analog, digital, and GPS) is or can be calculated accurately to the nearest tenth of a mile, we proposed that the mileage billed to Medicare by ambulance providers and suppliers be reported by rounding up to the next tenth of a mile.

We also stated in the proposed rule (75 FR 40161) that although the electronic claim formats can accommodate fractional mileage when mileage is equal to or greater than 100 covered miles (for example, 100.0), the paper claim cannot. Because the Form CMS-1500 paper claim currently only

supports four characters (including the decimal point) in the units field (Item 24G), we also proposed that mileage equal to or greater than 100 covered miles continue to be reported in whole number miles on both paper and electronic claims. We proposed that providers and suppliers would round up fractional mileage to the next whole number for mileage that exceeds 100 covered miles and report the resulting whole number in the units' field. We stated that we would revise the instructions set forth in our Claims Processing Manual to reflect the revised procedures for submitting and paying claims for fractional ambulance mileage.

3. Analysis of and Responses to Public Comments

We received approximately 131 comments in response to the proposed rule. We received comments from, among others, public and private ambulance companies, national ambulance organizations, local fire and EMS departments as well as other interested parties such as attorneys and consultants. The responses we received pertained primarily to the proposed rule's financial and administrative impact, the impact on patient care, and the overall impact on the ambulance services industry. A summary of the comments and our responses are included below.

a. Basis for Reconsideration of the Ambulance Mileage Reporting Requirements

Comment: A few commenters believed that the concerns discussed in the proposed rule regarding certain suppliers' belief that the current mileage reporting requirement forced them to bill inaccurately, were an attempt by CMS to achieve budgetary savings by using the concerns of a few companies as justification. These commenters stated that CMS should have addressed the suppliers' concerns by educating providers and suppliers about its current policy of rounding up to the next whole mile so that they would be aware that this billing practice is appropriate, and suggested that CMS include the current whole mile billing policy in the regulations to further reinforce this, rather than implement the new fractional mileage policy. They stated that any change to the ambulance mileage reporting requirement would be unreasonable and unfounded. The commenters believed that if accuracy was a priority, then CMS should have implemented the fractional mileage billing policy in Transmittal AB-00-88, issued September 18, 2000.

Response: While the impetus for reconsidering our policy on ambulance mileage billing was the concerns raised by ambulance suppliers wishing to bill accurately, our basis for moving forward with the proposed policy was that the conditions that dictated the original mileage billing policy have now changed. As we stated in the proposed rule (75 FR 40160), technological advancements in our system capabilities enabled us to reconsider our policy for reporting ambulance mileage. We were originally not capable of receiving or processing fractional unit amounts on electronic or paper claims, and thus, initially, it was necessary to implement a policy that required providers and suppliers to round mileage up to the nearest whole mile—even though that amount exceeded the miles actually traveled. As discussed in the CY 2011 PFS proposed rule (75 FR 40159), under the current policy, the result could be overpayment for mileage of up to 0.9 of a mile.

Therefore, this change to our policy regarding ambulance mileage billing represents a reasonable and appropriate change to improve payment accuracy. The fact that we did not implement such a policy in the Transmittal cited by commenters does not negate the fact that the change is both needed and appropriate. Again, the original policy for rounding mileage up to the nearest whole number mile was based on the fact that we could not capture and process fractional mileage on a Medicare claim. To ignore the current systems' capability to more accurately process claims than what was possible 10 years ago would unnecessarily perpetuate a less accurate method of processing claims and would result in less accurate payments than is possible with current system capabilities.

For the reasons discussed previously and in the CY 2011 PFS proposed rule, we continue to believe that it is reasonable and appropriate to revise our claims processing instructions as discussed in the proposed rule to require that ambulance mileage be reported in fractional amounts by rounding up to the next tenth of a mile.

b. Appropriateness of Fractional Mileage Reporting Policy

As we discussed in the CY 2011 PFS proposed rule (75 FR 40160), we believe that reporting of and payment based on fractional ambulance mileage is appropriate because it permits ambulance providers and suppliers to submit claims that more precisely reflect actual mileage and to be reimbursed more accurately for the services they provide. Although many

commenters agreed that billing and payment accuracy are important, commenters cited various concerns regarding the appropriateness of the policy.

(1) Statutory Compliance and Financial Impact of Fractional Mileage Policy

Comment: Many commenters believed that the fractional mileage reporting policy does not adhere to the "budget neutrality principles" set forth in 42 U.S.C. 1395m(l)(3)(B). These commenters interpreted 42 U.S.C. 1395m(l)(3)(B) as requiring that CMS pay the same amount for ambulance services after implementation of the fee schedule as it did prior to the fee schedule with an inflation adjustment, and stated that in order to comply with this statute, the fractional mileage policy must be implemented in a manner such that any savings generated by this policy are reinvested in the ambulance fee schedule.

Furthermore, commenters asked that CMS comply with the "requirement and commitment made during negotiated rulemaking to ensure that no money is taken out of the system." Commenters cited to the February 27, 2002 final rule implementing the ambulance fee schedule, in which we stated that we would monitor payment data and make adjustments to the conversion factor (CF) if the actual experience under the fee schedule is significantly different from the assumptions used to establish the original CF. (67 FR 9102 and 9102). Several commenters stated that the fractional mileage policy alters the fee schedule and therefore requires reconsideration of the conversion factor (CF) used to set the ambulance fee schedule payment amounts so that no money is removed from the system. Some commenters believed that the policy will have a greater effect on ground ambulance services and recommended a greater proportional increase to the CF for ground ambulance transports versus air ambulance rates.

Response: Section 1834(l)(3)(B) of the Act (42 U.S.C. 1395m(l)(3)(B)) does not require that we pay the same aggregate amount for ambulance services after implementation of the fee schedule as we did before implementation of the ambulance fee schedule, or that we ensure that any savings generated by the fractional mileage policy be put back into the ambulance fee schedule. Rather, this statutory section sets forth the ambulance inflation factor to be used to update the ambulance fee schedule rates each year. Section 1834(l)(3)(B) of the Act requires that we set the ambulance fee schedule rates each year at the same

level as the previous year increased by the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending in June of the previous year (as discussed in section VI.P. of this final rule with comment period, effective January 1, 2011, the annual update to the fee schedule rates is subject to a productivity adjustment). We have interpreted this provision at § 414.610(f) as requiring that the CF, the air ambulance rates and the mileage rates be updated annually by the ambulance inflation factor set forth in the statute. The fractional mileage billing policy does not alter the payment rates set under the ambulance fee schedule; rather, it is a change to our operational instructions for reporting ambulance mileage intended to improve billing and payment accuracy. After implementation of the fractional mileage billing policy, we will continue to update the rates each year as required by section 1834(l)(3)(B) of the Act, and thus we believe this policy is consistent with section 1834(l)(3)(B) of the Act. Furthermore, we note that while section 1834(l)(3)(A) of the Act required the Secretary to ensure that the aggregate amount of payments made for ambulance services during 2000 (originally expected to be the first year of the ambulance fee schedule) did not exceed the aggregate amount of payments that would have been made for such services during such year absent the fee schedule, it did not set forth a budget neutrality requirement for subsequent years.

While some commenters stated that the fractional mileage billing policy alters the fee schedule and therefore requires reconsideration of the conversion factor (CF) used to set the ambulance fee schedule payment amounts so that no money is removed from the system (citing to the February 27, 2002 final rule implementing the ambulance fee schedule), we believe that commenters have misunderstood our statements in the February 27, 2002 final rule. In the February 27, 2002 final rule, we stated that we would monitor payment data and make adjustments to the conversion factor (CF) if the actual experience under the fee schedule is significantly different from the assumptions used to establish the original CF as discussed in the February 27, 2002 final rule (67 FR 9102 and 9103).

As stated previously, the fractional ambulance mileage billing policy does not change the rates under the ambulance fee schedule. Rather, it is a change to our operational procedures for reporting ambulance mileage intended to improve billing and payment

accuracy. We do not believe that it is appropriate to adjust the CF or air ambulance rates as a result of this policy, as further discussed below.

In the February 27, 2002 final rule implementing the ambulance fee schedule (67 FR 9102–9103, 9127, 9134), we stated that we would monitor the payment data and adjust the CF and the air ambulance rates if actual experience under the fee schedule proved to be significantly different from the assumptions used to determine the initial CF and air ambulance rates (for example, the relative volumes of the different levels of service (service mix) and the extent to which providers and suppliers charge below the fee schedule (low billers)). Thus, in the February 27, 2002 final rule, we finalized § 414.610(g), which at that time stated, in part, that the "Secretary will annually review rates and will adjust the CF and air ambulance rates if actual experience under the fee schedule is significantly different from the assumptions used to determine the initial CF and air ambulance rates."

In each of the 4 years following implementation of the ambulance fee schedule, we reevaluated the effects of the relative volume of different levels of ambulance service (service mix) and the extent to which ambulance providers and suppliers bill less than the ambulance fee schedule (low billers) to determine whether the assumptions used to set the CF were accurate when compared to actual billing data. We found only insignificant differences in the observed data versus our assumptions. The differences observed in any single year were not significant enough to warrant a change to the CF in any of the years we monitored. (See 71 FR 69624, 69717, and 69718). Consequently, in the December 1, 2006 final rule (71 FR 69717–69718), we discontinued our annual review of the original CF assumptions and the air ambulance rates, and revised § 410.610(g) to state, in part, that the "Secretary monitors payment and billing data on an ongoing basis and adjusts the CF and air ambulance rates as appropriate to reflect actual practices under the fee schedule."

We do not believe that adjustments to the CF or the air ambulance rates are appropriate as a result of the fractional mileage billing policy. First, as discussed previously, the fractional mileage billing policy has no effect on the fee schedule rates; rather, it is an operational procedure for reporting ambulance mileage. Second, the purpose of this policy is to improve billing and payment accuracy for ambulance mileage. As discussed

previously, under the current whole mile reporting policy, ambulance providers and suppliers are billing as much as 0.9 of a mile more than what is actually traveled. Commenters suggest that adjustments to the CF and the air ambulance rates are necessary to make up for the fact that ambulance providers and suppliers will be permitted to round up only to the nearest tenth of a mile rather than the nearest whole mile, resulting in lower mileage reimbursement on some claims compared to under the current policy. The purpose of the fractional mileage billing policy is to provide for more accurate billing and payment for ambulance transports, which we do not believe can be achieved if we were to make the adjustments suggested by commenters. Furthermore, we note that the current regulation at § 410.610(g) requires us to monitor billing and payment data and adjust the CF and air ambulance rates "as appropriate" to reflect actual practices under the fee schedule. This regulation does not require that we adjust the fee schedule rates prospectively each time we adopt operational procedures that differ from those in place prior to implementation of the fee schedule.

Furthermore, we believe that the policy does not have a significant bearing on the original CF assumptions that were discussed in the February 27, 2002 final rule (67 FR 9102-03, 9115-16), and for this reason too, we do not believe that adjustments to the CF and air ambulance rates would be appropriate. Having reevaluated the CF during the 4 years after implementation of the ambulance fee schedule and finding no significant differences in the observed data versus our original assumptions, we believe that we will continue to find insignificant differences, if any at all, after implementation of the fractional mileage billing policy, such that changing the CF or air ambulance rates would be unnecessary.

However, as required by § 410.610(g), we will continue to monitor the billing and payment data on an ongoing basis, and will consider adjusting the CF and air ambulance rates in the future if (and to the extent) we determine appropriate to reflect actual experience under the fee schedule after the policy is implemented.

Comment: The commenters believed that the proposed rule would lower ambulance reimbursement that is already too low and noted that the fee schedule rates have not been increased in the last 2 years. Most of the same commenters cited a May 2007 Government Accountability Office

(GAO) report detailing GAO's research findings which indicated that Medicare's reimbursement for ambulance services averages between 6 percent and 17 percent less than the cost to ambulance companies for the services they provide.

Response: We reiterate that the fractional ambulance mileage billing policy does not change the ambulance fee schedule rates. The base payment rate and mileage reimbursement rate will not be changed by the fractional mileage billing policy. The fractional mileage billing policy is strictly an effort to improve billing and payment accuracy, and as such, we believe that it is both reasonable and appropriate to implement this policy.

In response to the comment that the fee schedule rates have not been increased in the past 2 years, we note that the ambulance inflation factor for CY 2008 was 2.7 percent and in CY 2009 it was increased to 5 percent, and thus the CF, air ambulance rates and mileage rates were increased by 2.3 percent over the previous calendar year in accordance with the section 1834(l)(3)(B) of the Act. However, we recognize that the fee schedule rates were not increased in CY 2010 because the CPI-U for the 12 month period ending with June 2009 was negative, resulting in no increase to the rates under the statutory formula set forth in section 1834(l)(3)(B) of the Act.

The 2007 GAO report cited by commenters estimated that between 39 percent and 56 percent of ambulance providers and suppliers will realize a profit under the ambulance fee schedule after expiration of the temporary payment provisions in the MMA. The GAO also noted in the same report that providers' expected Medicare margins will vary greatly depending on their ability to keep their operating cost low, and because of that variance, they were not able to conclude with any certainty whether providers and suppliers would see a decrease, increase, or no change in their profitability as it relates to the Medicare reimbursement rates after expiration of the temporary payment provisions in the MMA.

We seriously considered the findings in the May 2007 GAO report and, although we were not bound to the GAO findings, we agreed with their recommendation that CMS monitor utilization of ambulance transports to ensure that Medicare payments are adequate to provide for beneficiary access to ambulance services, particularly in "super rural" areas. We note that in the years since the May 2007 GAO report, certain temporary payment provisions originally set forth

in § 414 of the MMA have been increased and extended in subsequent legislation to address these issues. Specifically, § 414(d) of the MMA added section 1834(l)(13) of the Act which set forth payment increases of 1 percent and 2 percent for urban and rural ground transports, respectively. Section 146(a) of the MIPPA modified section 1834(l)(13) of the Act to increase these percentages to 2 percent and 3 percent for urban and rural transports, respectively, and to extend these increases through December 31, 2009. Subsequently, sections 3105(a) and 10311(a) of the ACA extended these increases through December 31, 2010. Furthermore, section 414(c) of the MMA added section 1834(l)(12) of the Act which provided a "super rural" bonus for certain ground transports that originate in qualified rural areas effective through December 31, 2009. Sections 3105(c) and 10311(c) of the ACA extended this super rural bonus through December 31, 2010. Finally, we note that section 146(b)(1) of the MIPPA, as amended by sections 3105(b) and 10311(b) of the ACA, provides that any area that was designated as a rural area for purposes of making payment for air ambulance services furnished on December 31, 2006, shall continue to be treated as a rural area for purposes of making payment for air ambulance services furnished during the period July 1, 2008 through December 31, 2010. We have implemented these payment add-ons in § 414.610(c)(1), (c)(5)(ii) and (h), respectively.

Comment: Several commenters stated that cutting already low reimbursement rates for ambulance providers and suppliers would result in cutbacks that would make it difficult to stay in business and would, therefore, have a negative impact on patient care. Many commenters also noted that smaller companies would be impacted the most by lowered reimbursement rates, stating that small companies need the extra revenue to stay in business. Some commenters suggested that mileage charges are the only means ambulance providers and suppliers have of recovering increasing, variable costs for ancillaries—such as oxygen supplies, disposable supplies, etc.—that are not separately payable under the fee schedule. Other commenters believed that reporting mileage more accurately will be too costly and would increase the cost of doing business. Another commenter responded that the payment made for mileage represents payment for the variable cost of transporting patients and that even short trips have a cost associated with them. The same

commenter pointed out that lowering the mileage reimbursement would not adequately reimburse ambulance providers and suppliers for the cost of transporting their patients.

Response: As previously stated, the fractional mileage billing policy is an effort to improve billing and payment accuracy. The policy does not modify the reimbursement rates under the ambulance fee schedule. While we remain cognizant of the need for ambulance providers and suppliers to remain financially solvent, we must also ensure that providers and suppliers bill accurately and that we pay accurately. We believe the payment implications of the fractional mileage billing policy are modest when considering the difference in reimbursement on a claim by claim basis, and should not have a significant impact on the overall financial viability of individual ambulance providers and suppliers or on patient care. We recognize that there is a cost of doing business. However, as discussed previously, we believe that it is both reasonable and appropriate to implement the policy to provide for more accurate billing and payment for ambulance mileage under Medicare. We do not believe that it is appropriate to continue the current whole mileage reporting procedure, which results in less accurate billing and payment, in order to provide extra revenue for providers and suppliers.

Comment: One commenter responded that the lower reimbursement would "trickle down" to other payers. In other words, the commenter believes that other payers would follow CMS' lead by adopting similar mileage reporting requirements, thereby potentially lowering reimbursement from other payers as well.

Response: While other payers may choose to adopt similar requirements for reporting ambulance mileage, we would not have any involvement in that decision. As previously discussed, we believe that it is reasonable and appropriate to implement the fractional mileage billing policy under Medicare to provide for more accurate billing and payment for Medicare ambulance services.

c. Administrative Impact

Comment: Many commenters stated that the fractional mileage policy would be administratively burdensome for medical and billing staff and would distract their medical staff from their first priority which is caring for the patient. The same commenters also suggested that the policy would be particularly burdensome for small ambulance companies. One commenter

stated that imposing a requirement to capture fractional mileage would complicate the already overwhelming documentation requirements that they face. Another commenter believed that the fractional mileage billing policy creates undue hardship on an ambulance industry which is already overburdened and underfunded.

Response: We believe that capturing fractional mileage amounts in trip documentation and on claims will not create any undue burden on the ambulance industry. Proper documentation of trip details, including mileage traveled, is already a longstanding Medicare requirement that remains unchanged and, we believe, uncompromised by the requirement to capture the additional digit beyond the decimal point. As we stated in the proposed rule, we believe that implementation of the policy is a reasonable and appropriate measure to ensure that claims are adjudicated and paid as accurately as possible.

Comment: Many commenters responded that the fractional mileage billing policy would make it difficult for ambulance providers and suppliers to comply with State and local laws which prohibit billing fractional mileage. Several commenters cited the City of Los Angeles as an example of a locality requiring that mileage be rounded to a whole number.

Response: We are not aware of any State or local law(s) that regulate how claims must be submitted to Medicare. We did not find any language in the City of Los Angeles or the Los Angeles County ordinances that governs claims submission to other payers, including Medicare. Further, even if there were a State or local law that specified a billing requirement that differed from Medicare's requirement, the Medicare requirement would, nevertheless, be controlling for claims submitted to Medicare payment. We note that the fractional mileage billing policy applies only to claims submitted to Medicare and does not dictate how a provider or supplier reports mileage to other payers. Thus, while we recognize the possibility that the requirements for billing ambulance mileage to State-funded or other payers may differ, we believe that the fractional mileage billing policy is reasonable and appropriate to ensure that claims submitted to Medicare more accurately reflect the service(s) rendered and that our payments to providers and suppliers are as accurate as possible.

Comment: Several commenters stated that, if the fractional mileage billing policy is implemented, the requirements for billing ambulance mileage to Medicare will be different than for other

payers, and it would make it difficult for ambulance providers and suppliers to maintain compliance with the differing billing requirements. One commenter stated that since other payers allow whole number reporting of mileage, their ambulance company would be forced to manually change claims in order to submit fractional mileage to Medicare.

Response: We understand that payer requirements may, and often do, vary, and that providers and suppliers may need to comply with different payer billing requirements. Each payer sets its own requirements for billing and payment. We believe that most billing systems are capable of accommodating the reality of varying billing requirements amongst different payers. While additional changes to billing systems or procedures may be necessary in some cases to enable mileage to be reported differently for different payers, as we stated previously, we continue to believe that implementation of the fractional mileage billing policy is reasonable and appropriate to ensure more accurate reporting and payment of ambulance mileage under Medicare.

After considering the comments, for the reasons discussed previously and in the CY 2011 PFS proposed rule, we continue to believe that it is reasonable and appropriate to revise our claims processing instructions to require reporting of and payment based on fractional mileage, as further discussed below.

(2) Technical and Other Considerations (A) Ability To Measure Fractional Miles

Comment: Many commenters responded that most ambulance companies do not have the ability to measure fractional mileage because their odometer does not show tenths of a mile. These commenters stated that 67 percent of all new ambulances are Ford models which do not have a tenths display on the odometer. One commenter stated that digital odometers, in particular, only show whole miles. Another commenter asked that CMS prove its assertion that most vehicle odometers display tenths of a mile. Yet another commenter suggested that we provide guidance for ambulances that do not display tenths of a mile on the odometer. We also received a response from a commenter who believed that GPS can sometimes be unreliable.

Response: Based on the statement from many commenters that most new ambulances are Ford models, we reviewed owner's manuals for the Ford E250, E350, E450 as well as the F350

and F450 vehicles. Our research revealed that Ford E series and F series vehicle (typically trucks or vans) chassis typically provide the base for the Ford ambulance prep package. We reviewed Ford's gauge specifications for model years 1996 through 2010. In model years prior to 2004, the standard analog odometer reflected tenths of a mile. Model years 2004 and later include standard digital odometers that show fractional miles as well as a separate trip odometer that also displays mileage to the tenth of a mile. Additionally, the ambulance prep package includes an optional onboard trip computer and navigation system.

We also researched other vehicle chassis models that may provide the base for other ambulance prep packages and may currently be in use by some providers or suppliers. We reviewed owner's manuals for the Dodge Ram 3500 and 4500 for model years 2008 and 2009 and we also researched GM/Chevrolet G4500 and 3500 for model years 2009 and 2010. We found that both Dodge and Chevrolet model vehicle gauges include odometers and/or trip odometers that display fractional mileage. Chevrolet models also include a retroactive reset feature on the trip odometer that will calculate the distance traveled since the engine was last started in the event the trip odometer is not reset at the beginning of the trip.

We found through our research that in many cases, trip odometers are mentioned as separate devices from the basic odometer, particularly in newer model cars that utilize both digital gauges. We also found that in some cases, the basic digital odometer does not, in fact, have a tenths display. In those cases, we found that the tenths display appears only on the trip odometer. In the proposed rule, we did not specify the types of odometers that that may be used to measure fractional mileage, and thus we are clarifying in this final rule with comment period that mileage may be measured using a separate trip odometer as well.

In light of our review of Ford vehicle chassis and the assertion that most new ambulances are Ford vehicles as well as our review of the other vehicle chassis models as discussed above, we believe that most ambulance companies have the ability to measure fractional mileage to the tenth of a mile. However, we recognize that there may be some ambulance companies that have a small number of vehicles wherein the gauges are damaged, missing, or otherwise unusable, or that may be using non-standard vehicles that do not have a fractional mileage display on the

odometer, trip odometer, GPS navigation, trip computer, or other onboard device that measures distance traveled. We believe that tools used to measure distance traveled (such as GPS navigation equipment) are readily available to the average consumer at a low cost. As such, ambulance providers and suppliers are responsible for ensuring that they have the necessary equipment to measure fractional mileage to the tenth of a mile, and ensuring that onboard vehicle gauges measuring trip mileage are in working order. If they are not able to repair said gauges, they are responsible for ensuring that they have the necessary equipment to measure mileage accurately to the tenth of a mile. Additionally, for those ambulance providers and suppliers who have vehicles that include a separate trip odometer, ambulance providers and suppliers are still responsible for ensuring that trip mileage is measured and reported accurately—even if they fail to reset the trip odometer at the beginning of a trip. For example, if the driver fails to reset the trip odometer at the beginning of the trip, he or she would simply document the mileage at the end of the trip and subtract the mileage for the previous trip from the total which would leave a remaining balance that should correspond to the distance of the current trip.

With regard to the statement that GPS can sometimes be unreliable, CMS is not aware of data that confirms or refutes this statement. However, in order to continue to provide ambulance providers and suppliers with flexibility in how they can measure fractional mileage, use of GPS devices will continue to be acceptable for the purpose of measuring fractional mileage.

(B) Ambulance Provider Versus Supplier Billing

Comment: We received responses from several commenters who believe that the fractional mileage billing policy establishes different requirements for Part A versus Part B ambulance providers and suppliers. These commenters stated that neither electronic nor paper institutional claims can accommodate fractional unit amounts. They cited 42 U.S.C. 1395m(l)(1) which requires that all ambulance services be paid under the same fee schedule. Many commenters believed that Part A providers and Part B suppliers, respectively, will be treated differently under the fractional mileage billing policy and will, therefore, be paid differently.

Response: Per the version 4010A1 Implementation Guide and the version

5010 TR3 specifications, the ANSI 8371 (institutional) electronic claim format has the capability to accept fractional unit amounts up to 3 decimal places, and thus both ambulance providers and suppliers will be able to bill fractional mileage on electronic claims. The commenters are correct that the Form UB-04 paper institutional claim does not currently support fractional unit amounts. However, the National Uniform Billing Committee (NUBC) has recently approved a change to the Form UB-04 that will allow fractional unit billing, and this change is scheduled to take effect in July 2011. Currently, less than 0.5 percent of all institutional providers bill Medicare using the paper Form UB-04. Based on the low number of providers billing ambulance services on the Form UB-04 and the fact that the form is expected to be capable of accepting fractional unit amounts in July 2011, we are delaying the implementation date for ambulance providers billing on the paper Form UB-04. If the Form UB-04 is capable of accepting fractional mileage unit amounts by the end of July 2011 as scheduled, ambulance providers billing on the paper Form UB-04 will be required to submit fractional mileage in accordance with this final rule with comment period for dates of service on and after August 1, 2011. If paper Form UB-04 is not capable of accepting fractional mileage by July 31, 2011, then implementation of the fractional mileage policy for these ambulance providers will be further delayed until January 1, 2012 to allow ample time for any changes to the UB-04 to be implemented. As with other claim types, ambulance providers billing on the paper Form UB-04 will report fractional mileage on all claims for mileage totaling up to 100 miles.

We note that delayed implementation of the fractional mileage billing policy for the small number of providers using Form UB-04 does not result in suppliers and providers receiving different rates under the ambulance fee schedule. As discussed previously, the fractional mileage billing policy does not change the rates under the ambulance fee schedule for providers or suppliers. It is strictly a change to our operational instructions for reporting ambulance mileage intended to improve billing and payment accuracy. Thus, after implementation of the fractional mileage billing policy, providers and suppliers will continue to be paid under the same fee schedule and there will be no differentiation in rates between providers and suppliers.

(C) Billing Software

Comment: We received a few comments stating that billing systems will need to be modified to accommodate the fractional mileage billing policy. Three commenters stated that modification of billing software would be too costly, with one commenter further stating that the change would create a hardship for the billing software developer. Another commenter believed that changing their billing system would mean that they would have to report fractional mileage to all payers, not just Medicare.

Response: While minor changes to billing software may be required, any billing software that is compliant with ANSI 837 electronic claim standards should have the capability to accept and submit fractional unit amounts in the appropriate field. For providers and suppliers using paper claim forms to submit claims to Medicare, again, we believe that only minor changes to the units field will be required in order to submit fractional mileage amounts.

As discussed previously, we understand that payer requirements may—and often do—vary, and that providers and suppliers may need to comply with different payer billing requirements. However, the requirement to bill fractional mileage to Medicare does not necessarily mean that providers and suppliers will have to also submit fractional mileage to other payers. Each payer sets its own requirements for billing and payment. We believe that most billing systems are capable of accommodating the reality of varying billing requirements amongst different payers. While additional changes to billing systems or procedures may be necessary in some cases to enable mileage to be reported differently for different payers, as we stated previously, we continue to believe that implementation of the fractional mileage billing policy is reasonable and appropriate to ensure more accurate reporting of and payment for ambulance mileage under Medicare.

(D) Enforcement and Compliance

Comment: One commenter stated that the fractional mileage billing policy would be impossible to verify and/or enforce.

Response: Upon implementation of the fractional mileage billing policy, ambulance providers and suppliers will still be subject to the same statutory and regulatory requirements regarding documentation, fraudulent billing, and pre- and post-payment review.

Comment: One commenter requested guidance for providers and suppliers

who cannot comply with the fractional mileage billing policy.

Response: We believe that providers and suppliers are capable of complying with the new policy. As discussed above, we believe that most ambulance companies have the ability to measure fractional mileage using standard onboard devices. Furthermore, we believe that tools used to measure distance traveled (such as GPS navigation) are readily available to the average consumer at a low cost. Thus, in those instances where gauges are damaged, missing or otherwise unusable, or where companies are using non-standard vehicles that do not include a device to measure fractional mileage, ambulance providers and suppliers are responsible for ensuring that they have the necessary equipment to measure fractional mileage to the tenth of a mile. Furthermore, billing software that is compliant with the ANSI 837 electronic claim format is capable of capturing and submitting fractional unit amounts, and fractional mileage units can be captured on paper claims (with the exception of paper Form UB04 claims as discussed previously). We believe that implementing the fractional mileage policy is a reasonable and appropriate measure to ensure more accurate billing and payment of Medicare ambulance transports and thus, ambulance providers and suppliers (except for providers billing on Form UB-04 as discussed previously) are expected to comply effective January 1, 2011 with the fractional mileage billing policy finalized in this final rule with comment period.

(E) Air Ambulance

Comment: One commenter responded that the air ambulance segment of the ambulance industry is overpaid by Medicare and suggested that we look to generate savings by changing the reimbursement for air ambulance mileage to be based on nautical miles instead of statutory miles.

Response: As we stated in the proposed rule, our claims processing system should be configured to process claims as accurately as possible so as to provide more accurate Medicare payments. Thus, we believe that the fractional mileage billing policy is a reasonable and appropriate measure to enhance billing and payment accuracy for both air and ground transports. The issue of basing air ambulance reimbursement on nautical miles versus statutory miles was not discussed or proposed in the CY 2011 PFS proposed rule, and thus we are not addressing this

issue in this final rule with comment period.

Comment: A few commenters suggested that the fractional mileage billing policy will affect ground ambulance transports but not air ambulance transports.

Response: The fractional mileage billing policy will be applied in the same manner to, and will affect, both ground and air ambulance transports. However, since the fractional mileage billing policy does not apply to mileage exceeding 100 miles, we recognize that it may impact a greater percentage of ground transports than air transports, as a larger percentage of air transports may exceed 100 miles. We analyzed claim payment data for all Part B ambulance claims paid in 2008. If the fractional mileage billing policy had been implemented in 2008, approximately 92 percent of all claims for air ambulance mileage would have been impacted versus 99 percent of all claims for ground ambulance mileage. However, since air ambulance companies receive higher mileage reimbursement rates, we found that the average financial impact per claim would have been greater for air ambulance versus ground ambulance transports. Thus, when we consider both factors together, it is not clear whether the overall impact will be greater for ground ambulance companies than for air ambulance companies. Regardless of any potential differential impact, we believe that implementation of the fractional mileage billing policy is a reasonable and appropriate measure to ensure more accurate reporting of mileage and more accurate payments under Medicare for both ground and air transports.

(F) Miscellaneous Comments

Comment: One commenter questioned whether the new rounding rule would create no reimbursement for 0.49 miles.

Response: No. The correct rounding, based on the fractional mileage billing policy, would be to always round up the hundredths place. Therefore, the provider or supplier in the commenter's example would bill 0.5 miles. Likewise, if the provider or supplier traveled 0.43 miles, they would bill 0.5 miles on their claim. CMS would apply the normal calculations for determining the payment amount using the fractional mileage units reported.

4. Applicability of the Fractional Billing Policy to Other Services

We received no comments regarding the applicability of the fractional unit billing policy to other services. Therefore, for the reasons discussed in the CY 2011 PFS proposed rule (75 FR

40160). we are applying the fractional unit billing policy only to ambulance mileage.

5. Final Fractional Mileage Billing Policy

For the reasons discussed above and in the CY 2011 PFS proposed rule (75 FR 40159), we believe that it is reasonable and appropriate to implement the fractional mileage billing policy as proposed in the CY 2011 PFS proposed rule effective for claims with dates of service on and after January 1, 2011 (with the exception discussed below relating to providers billing on paper Form UB-04).

Therefore, effective for claims with dates of service on and after January 1, 2011, ambulance providers and suppliers (except for providers billing on paper Form UB-04) are required to report mileage rounded up to the nearest tenth of a mile on all claims for mileage totaling up to 100 covered miles. Providers and suppliers must submit fractional mileage using a decimal in the appropriate place (for example, 99.9). For example, if the total miles traveled equals 1.59 miles, then the provider or supplier must report "1.6" on the claim for mileage. Likewise, if the total mileage equals 1.53 miles, the provider or supplier must report "1.6" on the claim.

Although the electronic claim formats can accommodate fractional mileage when mileage is equal to or greater than 100 covered miles (for example, 100.0), as discussed in the proposed rule, the paper claim cannot. The Form CMS-1500 paper claim currently only supports four characters (including the decimal point) in the units field (Item 24G). Therefore, we are finalizing our proposal that mileage equal to or greater than 100 covered miles must continue to be reported in whole number miles on both paper and electronic claims. Providers and suppliers must round up fractional mileage to the next whole number for mileage that exceeds 100 covered miles and report the resulting whole number in the unit field. The instructions set forth in our Claims Processing Manual will be updated to reflect the revised procedures for submitting and paying claims for fractional ambulance mileage.

Because the changes to the paper Form UB-04 necessary to accommodate fractional units are scheduled to be completed in July 2011, implementation of this policy for ambulance providers that are permitted to bill using the Form UB-04 is delayed until August 1, 2011 (that is, ambulance providers permitted to bill on paper form UB-04 will be required to report fractional mileage in

accordance with this final rule with comment period for dates of service on and after August 1, 2011). If the paper Form UB-04 is not capable of accepting fractional mileage by July 31, 2011, then implementation of this policy for these ambulance providers will be further delayed until January 1, 2012. As with other claim types, upon implementation of the fractional mileage policy for providers billing on the paper Form UB-04, these providers will report fractional mileage on all claims for mileage totaling up to 100 miles.

As discussed previously, providers and suppliers are responsible for ensuring that they have the necessary equipment to measure fractional mileage to the tenth of a mile, and ensuring that onboard vehicle gauges measuring trip mileage are in working order. If they are not able to repair said gauges, they are responsible for ensuring that they have the necessary equipment to measure mileage accurate to the tenth of a mile. Tools that may be used to measure trip mileage include, but are not limited to: Digital or analog odometers, trip odometers, GPS navigation, onboard trip computers or navigation systems.

C. Clinical Laboratory Fee Schedule: Signature on Requisition

In the March 10, 2000 **Federal Register**, we published the "Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services" proposed rule (65 FR 13082) announcing and soliciting comments on the results of our negotiated rulemaking committee tasked to establish national coverage and administrative policies for clinical diagnostic laboratory tests under Part B of Medicare. In our final rule published in the November 23, 2001 **Federal Register** (66 FR 58788), we explained our policy on ordering clinical diagnostic laboratory services and amended § 410.32 to make our policy more explicit. Our regulation at § 410.32(a) states the requirement that "[a]ll diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary." In the November 23, 2001 final rule, we added paragraph (d)(2) to § 410.32 to require that the physician or qualified nonphysician practitioner (NPP) (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners (NPs), and physician assistants (PAs)) who order the service must maintain documentation of medical necessity in the beneficiary's medical record (66 FR 58809). In the preamble discussions to

the March 10, 2000 proposed rule and November 23, 2001 final rule (65 FR 13089 and 66 FR 58802, respectively), we noted that "[w]hile the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered." In those preambles, we described the policy of not requiring physician signatures on requisitions for clinical diagnostic laboratory tests, but implicitly left in place the existing requirements for a written order to be signed by the ordering physician or NPP for clinical diagnostic laboratory tests, as well as other types of diagnostic tests. We further stated in the preambles of the proposed and final rules that we would publish an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test (65 FR 13089 and 66 FR 58802).

On March 5, 2002, we published a program transmittal implementing the administrative policies set forth in the final rule, including the following instruction: "Medicare does not require the signature of the ordering physician on a laboratory service requisition. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the service, it is not the only permissible way of documenting that the service has been ordered. For example, the physician may document the ordering of specific services in the patient's medical record." (Transmittal AB-02-030, Change Request 1998, dated March 5, 2002).

On January 24, 2003, we published a program transmittal in order to manualize the March 5, 2002 Transmittal. (Transmittal 1787, Change Request 2410, dated January 24, 2003). The cover note to the transmittal states, "Section 15021, Ordering Diagnostic Tests, manualizes Transmittal AB-02-030, dated March 5, 2002. In accordance with negotiated rulemaking for outpatient clinical diagnostic laboratory services, no signature is required for the ordering of such services or for physician pathology services." In the manual instructions in that transmittal in a note, we stated: "No signature is required on orders for clinical diagnostic services paid on the basis of the physician fee schedule or for physician pathology services." The manual instructions did not explicitly reference clinical diagnostic laboratory tests as the cover note did. Rather, the transmittal seemed to extend the policy set forth in the **Federal Register** (that no

signature is required on requisitions for clinical diagnostic laboratory tests paid under the CLFS) to also apply to clinical diagnostic tests paid on the basis of the PFS and physician pathology services. In addition, the manual instructions used the term "order" instead of "requisition," which some members of the industry have asserted caused confusion.

When we transitioned from paper manuals to the current electronic Internet Only Manual system, these manual instructions were inadvertently omitted from the new Benefit Policy Manual (BPM).

In August 2008, we issued a program transmittal (Transmittal 94, Change Request 6100, dated August 29, 2008) to update the BPM to incorporate language that was previously contained in section 15021 of the Medicare Carriers Manual. The reissued language states, "No signature is required on orders for clinical diagnostic tests paid on the basis of the CLFS, the physician fee schedule, or for physician pathology services." Based on further review, we determined that there are no clinical diagnostic laboratory tests paid under the PFS. After Transmittal 94 was published, we received numerous inquiries from laboratory, diagnostic testing, and hospital representatives who had questions about whether the provision applied to all diagnostic services, including x-rays, MRIs, and other nonclinical laboratory fee schedule diagnostic services.

To resolve any existing confusion surrounding the implementation of the policy in 2001 and subsequent transmittals, we restated and solicited public comments on our policy in the CY 2010 PFS proposed rule (74 FR 33641). Our current policy is that a physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS. However, it must be evident, in accordance with our regulations at § 410.32(d)(2) and (3), that the physician ordered the services.

We note that we solicited and received comments on this signature requirement during the notice and comment period for the March 10, 2000 proposed rule in the context of our proposal to add paragraph (d)(2)(i) to § 410.32 to require that the practitioner who orders a diagnostic laboratory test must maintain documentation of medical necessity in the beneficiary's medical record. The majority of comments supported the adoption of a policy that the signature of the practitioner on a requisition for a clinical diagnostic laboratory test paid under the CLFS is not the only way of

documenting that the test has been ordered and, thus, should not be required provided such documentation exists in an alternate form.

This policy regarding requisitions for clinical diagnostic laboratory tests does not supersede other applicable Medicare requirements (such as those related to hospital Conditions of Participation (CoPs)) which require the medical record to include an order signed by the physician who is treating the beneficiary. Nor do we believe that anything in our policy regarding signatures on requisitions for clinical diagnostic laboratory tests supersedes other requirements mandated by professional standards of practice or obligations regarding orders and medical records promulgated by Medicare, the Joint Commission (TJC), or State law; nor do we believe the policy would require providers to change their business practices.

We also restated and solicited public comment on our longstanding policy consistent with the principle in § 410.32(a) that a written order for diagnostic tests including those paid under the CLFS and those that are not paid under the CLFS (for example, that are paid under the PFS or under the OPSS), such as X-rays, MRIs, and the TC of physician pathology services, must be signed by the ordering physician or NPP. That is, the policy that signatures are not required on requisitions for clinical diagnostic laboratory tests paid based on the CLFS applies only to requisitions (as opposed to written orders) (74 FR 33642).

Additionally, we solicited public comments about the distinction between an order and a requisition (74 FR 33642). We note that an "order" as defined in our IOM, 100-02, Chapter 15, Section 80.6.1, is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (for example, if test X is negative, then perform test Y). As set forth in the CY 2010 PFS final rule (FR 74 61930), an order may be delivered via any of the following forms of communication:

- A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility.
- A telephone call by the treating physician/practitioner or his or her office to the testing facility.

- An electronic mail, or other electronic means, by the treating physician/practitioner or his or her office to the testing facility.

If the order is communicated via telephone, both the treating physician/practitioner, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

In the CY 2010 PFS proposed rule (74 FR 33642), we defined a "requisition" as the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. It may contain patient information, ordering physician information, referring institution information, information about where to send reports, billing information, specimen information, shipping addresses for specimens or tissue samples, and checkboxes for test selection. We believe it is ministerial in nature, assisting laboratories with billing and handling of results, and serves as an administrative convenience to providers and patients. We believe that a written order, which may be part of the medical record, and the requisition, are two different documents, although a requisition that is signed may serve as an order. We welcomed comments from the public about the distinction between requisitions and orders.

During the proposed and final rulemaking process for CY 2010, we received numerous comments on these issues, including, among others: Expressions of continued confusion over the difference between an "order" and a "requisition"; requests that we develop a single policy for all outpatient laboratory services, without the distinction for those paid under the CLFS or the PFS; and concerns about reference laboratory technicians who believed compelled to perform a test in order to protect the viability of the specimen although they did not have the proper documentation. (See 74 FR 61929 through 61931 for a complete discussion of the comments received and responses to these issues.) In the CY 2010 PFS final rule with comment period (74 FR 61931), we stated that, in light of the issues and concerns raised during the comment period, and our desire to create policy that will address the concerns in a meaningful, clear and thoughtful way, we would continue to carefully consider the issues of physician signatures on requisitions and orders and that we plan to revisit these issues in the future paying particular attention to the definitions of order and requisition.

Since the publication of the CY 2010 PFS final rule with comment period, we have considered an approach that would address the concerns raised. Therefore, in the CY 2011 PFS proposed rule (75 FR 40162), we proposed to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the CLFS. We stated that we believe that this policy would result in a less confusing process because a physician's signature would then be required for all requisitions and orders, eliminating uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature. We also stated that we believe that it would not increase the burden on physicians because it is our understanding that, in most instances, physicians are annotating the patient's medical record with either a signature or an initial (the "order"), as well as providing a signature on the paperwork that is provided to the clinical diagnostic laboratory that identifies the test or tests to be performed for a patient (the "requisition") as a matter of course. Further, we stated that this policy would make it easier for the reference laboratory technicians to know whether a test is appropriately requested, and potential compliance problems would be minimized for laboratories during the course of a subsequent Medicare audit because a signature would be consistently required. We stated in the CY 2011 OPSS/ASC proposed rule that this minimizes confusion and provides a straightforward directive for laboratories to meet.

Comment: Some commenters stated that physicians continue to be unfamiliar with when a signature is required and when it is not required on requisitions for physician pathology services, x-ray services, and services other than clinical diagnostic laboratory tests paid under the CLFS. The commenters also asked for consistency in signature requirements between services required under the CLFS and the Physician Fee Schedule (PFS).

Response: We proposed to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS. We did not propose to change, and we are not changing, the signature requirements for other services. One of the reasons we made this proposal is because we believed that it would be less confusing for a physician's signature to be required for all requisitions and orders, eliminating

uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature.

Comment: Some commenters were supportive of our proposal.

Response: We appreciate the commenters' support of our proposed policy, which we are finalizing in this rule.

Comment: The commenters seemed to interpret the proposed policy to mean that clinical diagnostic laboratory tests requested by telephone or electronic means would not be acceptable because they would not contain a signature. The commenters stated that there must be a way to validate electronic requests for services by the physician or NPP and that, as the medical world moves toward electronic records, everything must be annotated (that is, "signed") in some way to authenticate that the service is ordered by the physician.

Response: Our proposed policy does not concern electronic or telephonic requests, because we do not consider these types of requests to be requisitions. As we discussed previously, a requisition is the actual paperwork, such as a form, that is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. It may contain patient information, ordering physician information, referring institution information, information about where to send reports, billing information, specimen information, shipping addresses for specimens or tissue samples, and checkboxes for test selection. We believe it is ministerial in nature, assisting laboratories with the billing and handling of results, and serves as an administrative convenience to providers and patients. When a physician or NPP chooses to use a requisition to request a clinical diagnostic laboratory test paid under the CLFS, under the policy we are adopting in this rule, the physician or NPP must sign the requisition.

Comment: The commenters pointed out that it should be evident from the medical record that the physician actually ordered the service.

Response: We did not propose to change any requirements with respect to orders. As discussed above, a requisition is the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. Our proposal only applies to signatures on requisitions for clinical diagnostic laboratory tests paid under the CLFS. A

signature on a requisition should be sufficient for a clinical diagnostic laboratory to verify that a physician or NPP is requesting a clinical diagnostic laboratory test.

Comment: The commenters stated that the patient rarely takes the requisition to the laboratory himself/herself because the patient does not go to the laboratory. These commenters seemed to believe that, in those cases, a paper request for clinical diagnostic laboratory services would have to be created where there may not have been a need for one to exist. The commenters suggested that only the medical record, and not any other paper materials, should be signed or initialed by the physician.

Response: As stated previously, a requisition is the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. Under our proposed policy, which we are finalizing in this rule, if a physician or NPP chooses to use a requisition to request a clinical diagnostic laboratory test paid under the CLFS, the physician or NPP must sign the form. However, this policy does not require a physician or NPP to use a requisition to request a clinical diagnostic laboratory test paid under the CLFS. Many physicians and NPPs currently request clinical diagnostic laboratory tests using an order, such as an annotated medical record or documented telephonic request, and they may continue to do so without being impacted by our new policy for requisitions.

Comment: The commenters suggested that physicians would need to be educated about the new signature requirement on requisitions for clinical diagnostic laboratory tests paid under the CLFS to alleviate problems such as physician non-compliance with this policy because they are unaware of it or do not understand it. Some commenters stated that they firmly believe that the physician will neglect to sign any document that directs the clinical diagnostic laboratory to perform a service. In order to incentivize physicians to provide a signature, some commenters suggested tying the physician's ability to bill for a service to the requirement to provide a signature.

Response: We understand the need to educate physicians and NPPs. As such, in addition to updating our manuals, we will direct the Medicare contractors to educate physicians and NPPs concerning this issue. We did not propose to adopt a policy linking the physician's ability to bill for a service to the requirement to provide a signature

and we are not adopting such policy in this final rule.

Comment: The commenters believe that medical personnel are already required to provide an extensive amount of identifying information on the requisition. The commenters stated that either the physician or NPP is completing the paperwork but then, in most cases, not signing it or initialing it to confirm that the requested service was documented by a medical practitioner.

Response: If physicians and NPPs are completing extensive written documentation concerning each beneficiary on requisitions, the addition of a signature should not be an issue.

Comment: The commenters expressed continued confusion over the terms "requisition" and "order." The commenters stated that CMS should define "requisition" and "order" in the CMS Internet Only Manual (IOM) system.

Response: We recognize that there is confusion around the definition of these terms. However, as we stated above, we define an "order" (IOM, 100-02, Chapter 15, Section 80.6.1) as a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. We further provided that an order may be delivered via any of the following forms of communication: (1) A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility; (2) a telephone call by the treating physician/practitioner or his or her office to the testing facility; or (3) an electronic mail, or other electronic means, by the treating physician/practitioner or his or her office to the testing facility. If the order is communicated via telephone, both the treating physician/practitioner, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records. We define a "requisition" as the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. It may contain patient information, ordering physician information, referring institution information, information about where to send reports, billing information, specimen information, shipping addresses for specimens or tissue samples, and checkboxes for test selection. We believe it is ministerial in nature, assisting laboratories with billing and handling of results, and serves as an administrative convenience to providers and patients. We believe that a written order, which may be part

of the medical record, and the requisition, are two different documents, although a requisition that is signed may serve as an order. We are revising our manuals to reflect our new requirement for physicians' and NPPs' signatures on requisitions for clinical diagnostic laboratory tests paid under the CLFS.

Comment: The commenters note that there is no corresponding suggested change in the language of the Code of Federal Regulations (CFR) concerning the physician signature issue.

Response: We have determined that a change to § 410.32(d)(2) is not necessary with respect to this issue because this provision involves orders not requisitions. We articulated our policy regarding requisitions for clinical diagnostic laboratory tests in our manuals and in preamble language. Therefore, we are changing our manuals to reflect our new policy.

Comment: The commenters suggested that the requirement to provide some type of signature represents an undue burden on the clinical diagnostic laboratory, especially in the long term care world where standing orders in the form of a "plan of care" are maintained in the beneficiary's records onsite and tests are ordered by the long term care staff as required based on directions provided by the physician. The commenters asserted that the physician rarely appears onsite at the facility to sign requests for medical services and, as a result, an exception for these types of facilities is warranted. However, commenters also pointed to a Drug Enforcement Administration (DEA) requirement for long term care facilities which states that, "The facility must provide or obtain laboratory services only when ordered by the attending physician."

Response: Again, the change in policy discussed in this final rule only affects requisitions and does not affect orders. The policy that we proposed and are adopting as final in this rule is that a physician's or NPP's signature is required on requisitions for clinical diagnostic laboratory tests paid under the CLFS.

Comment: The commenters suggested that the following language was clear and should stand as the entire policy here: "A physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the Clinical Laboratory Fee Schedule (CLFS); however, it must be evident, in accordance with regulations at § 410.32(d)(2) and (3), that the physician ordered the services."

Response: We appreciate the commenters' viewpoint. However, for

the reasons discussed previously, we are finalizing our proposal, without modification, to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS.

Comment: The commenters suggested that a pre-printed physician signature or letterhead showing the physician's name should serve in the place of a "signature."

Response: A pre-printed signature or letterhead cannot be construed as a document, the contents of which a physician or NPP has affirmed. In order to discourage fraud and abuse, and to affirm that a medical service was ordered by a medical practitioner who currently works in the practice, a signature is required.

Comment: The commenters stated that the services are transcribed from the medical record onto the requisition by office staff, not written and signed by the physician. The commenters seemed to indicate that the medical record that would be maintained in the physician's office, but not necessarily the requisition, would be signed or annotated in some way.

Response: It seems that the commenters believe that a physician or his/her representative has no problem providing a signature or annotation for the medical record. In addition, some commenters consider the "requisition" to be the medical record and use it for a dual purpose—as the beneficiary's file and as the request for services.

After careful consideration of all the comments received, we are finalizing our proposed policy without modification to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS. This policy does not affect physicians or NPPs who choose not to use requisitions to request clinical diagnostic laboratory tests paid under the CLFS. Such physicians or NPPs can continue to request such tests by other means, such as by using the annotated medical records, documented telephonic requests, or electronically. We will make changes to our manuals to reflect this final policy.

D. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2-years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current Medicare coverage for chiropractic services is limited to manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act. The

demonstration expanded Medicare coverage to include "A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; B) and diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided" and was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that "the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented."

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated BN would be assessed by determining the change in costs based on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate budget neutrality. In the "All Neuromusculoskeletal Analysis," which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration to Medicare was a \$114 million increase in

costs. In the "Chiropractic User Analysis," which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration to Medicare was a \$50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the "Chiropractic User Analysis" because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, including those who did not use chiropractic services and who may not have become users of chiropractic services even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup \$50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping \$10 million for each such year through adjustments to the chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

We are continuing the implementation of the required budget neutrality adjustment by recouping \$10 million in CY 2011. Our Office of the Actuary estimates chiropractic expenditures in CY 2011 to be approximately \$524 million based on actual Medicare spending for chiropractic services for the most recent available year. To recoup \$10 million in CY 2011, the payment amount under the PFS for the chiropractic CPT codes (that is, CPT codes 98940, 98941, and 98942) will be reduced by approximately 2 percent. We are reflecting this reduction

only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the relative value units (RVUs). Avoiding an adjustment to the RVUs would preserve the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

We received no comments on this policy and we will continue the implementation of the required budget neutrality adjustment in CY 2011 by reducing the payment amount under the PFS for chiropractic codes (that is, CPT codes 98940, 98941, and 98942) by approximately 2 percent resulting in a \$10 million recoupment. This is the second year of an adjustment which is required in order to satisfy the budget neutrality requirement in section 651 of MMA and that is being made over a 5-year period to recoup the costs of a demonstration that expanded Medicare coverage for chiropractic services. This reduction will only be reflected in the payment files used by Medicare contractors to process Medicare claims and not through an adjustment to the RVUs.

E. Provisions Related to Payment for Renal Dialysis Services Furnished by End-Stage Renal Disease (ESRD) Facilities

Subsequent to the July 13, 2010 publication of the CY 2011 PFS proposed rule (75 FR 40040) we published in the **Federal Register**, on August 12, 2010 a final rule entitled "End-Stage Renal Disease Prospective Payment System" (75 FR 49030). In that rule, we established a case-mix adjusted bundled PPS for renal dialysis services furnished beginning January 1, 2011, in accordance with the statutory provisions set forth in section 153(b) of MIPPA. The ESRD PPS is mandated to replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

As explained in the ESRD PPS final rule (75 FR 49162), section 1881(b)(14)(E)(i) of the Act requires a 4-year transition (phase-in) from the current composite payment system to the ESRD PPS, and section 1881(b)(14)(E)(ii) of the Act allows ESRD facilities to make a one-time election to be excluded from the transition. Electing to be excluded from the 4-year transition means that the ESRD facility receives payment for renal dialysis services based on 100 percent of the payment rate established under the ESRD PPS, rather than a blended rate for each year of the transition based in part on the payment rate under the current

payment system and in part on the payment rate under the ESRD PPS.

For renal dialysis services furnished during CY 2011, ESRD facilities that elect to go through the ESRD PPS the transition would be paid a blended amount that will consist of 75 percent of the basic case-mix adjusted composite payment system and the remaining 25 percent would be based on the ESRD PPS payment. Thus, we must continue to update the basic case-mix adjusted composite payment system during the ESRD PPS 4-year transition (CYs 2011 through 2013).

For a historical perspective of the basic case-mix adjusted composite rate payment system for ESRD facilities that furnish outpatient dialysis services, see the following PFS final rules with comment period:

- CY 2005 (69 FR 66319 through 66334).
- CY 2006 (70 FR 70161 through 70171).
- CY 2007 (71 FR 69681 through 69688).
- CY 2008 (72 FR 66280 through 66285).
- CY 2009 (73 FR 69754 through 69761).
- CY 2010 (74 FR 61921 through 61926).

In the CY 2011 PFS proposed rule (75 FR 40165 through 40168), we outlined the proposed updates to the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act, which included updates to the drug add-on, as well as the wage index values used to adjust the labor component of the composite rate. Specifically, as described in more detail below in this section, we proposed the following:

- A zero growth update to the drug add-on, resulting in a proposed 14.7 percent add-on adjustment to the composite rate for 2011 required by section 1881(b)(12)(F) of the Act to maintain a \$20.33 per treatment drug add-on amount.
- An update to the wage index adjustment to reflect the latest available wage data, including a revised budget neutrality (BN) adjustment factor of 1.056929.
- A reduction to the ESRD wage index floor from 0.6500 to 0.6000.

We received very few comments on our proposals. The ESRD payment related comments are discussed below in this section.

1. Update to the Drug Add-on Adjustment to the Composite Rate

In the CY 2011 PFS proposed rule (75 FR 40165), we described the drug payment methodology used to update

the drug add-on adjustment to the composite rate. Since we now have 4 years of drug expenditure data based on ASP pricing, we proposed to continue estimating growth in drug expenditures based on the trends in available data.

We did not receive any comments objecting to the drug add-on update methodology, and therefore, we used the proposed update methodology to compute the drug add-on adjustment for CY 2011. We used trend analysis from drug expenditure data to update the per treatment drug add-on adjustment. We then removed growth in enrollment for the same time period from the expenditure growth, so that the residual reflects per patient expenditure growth (which includes price and utilization combined).

To estimate drug expenditure growth using trend analysis, we looked at the average annual growth in total drug expenditures between 2006 and 2009. First, we estimated the total drug expenditures for all ESRD facilities in CY 2009. For this final rule, we used the final CY 2006 through CY 2009 ESRD claims data with dates of service for the same timeframe updated through June 30, 2010 (that is, claims with dates of service from January 1 through December 31, 2009, that were received, processed, paid, and passed to the National Claims History File as of June 30, 2010).

Using the full-year 2009 drug expenditure figure, we calculated the average annual change in drug expenditures from 2006 through 2009. This average annual change showed an increase of 1.9 percent for this timeframe. We used this 1.9 percent increase to project drug expenditures for both CY 2010 and CY 2011.

2. Estimating Per Patient Growth

Once we had the projected growth in drug expenditures from 2010 to 2011 (1.9 percent), to calculate the per patient expenditure growth between CYs 2010 and 2011, we removed the enrollment component by using the estimated growth in enrollment data between CY 2010 and CY 2011, which was approximately 3.6 percent. Specifically, we divided the total drug expenditure factor between 2010 and 2011 (1.019) by enrollment growth of 3.6 percent (1.036) for the same timeframe. The result is a per patient growth factor equal to 0.984 (1.019/1.036=0.984). Thus, we are projecting a 1.6 percent decrease in per patient growth in drug expenditures between 2010 and 2011.

3. Update to the Drug Add-on Adjustment

As previously discussed, we estimate a 1.9 percent increase in drug expenditures between CY 2010 and CY 2011. Combining this reduction with a 3.6 percent increase in enrollment, as described above, we are projecting a 1.6 percent decrease in per patient growth of drug expenditures between CY 2010 and CY 2011. A 1.6 percent decrease in the per patient drug add-on of \$20.33 would result in a decrease of 33 cents (.016*20.33=.33). Hence a decrease of 33 cents in the drug add-on would result in negative update equal to 0.2 percent (.33/138.53, 138.53 is the 2011 base composite rate). Therefore, we are projecting that the combined growth in per patient utilization and pricing for CY 2011 would result in a negative update equal to 0.2 percent. However, as we have done previously, we proposed a zero update to the drug add-on adjustment. We believe this approach is consistent with the language under section 1881(b)(12)(F) of the Act which states in part that "the Secretary shall annually increase" the drug add-on amount based on the growth in expenditures for separately billed ESRD drugs. Our understanding of the statute contemplates "annually increase" to mean a positive or zero update to the drug add-on.

Also, as required by section 1881(b)(14)(F), as amended by section 3401(h) of the Affordable Care Act, a 2.5 percent ESRD market basket increase, as established in the ESRD PPS final rule (75 FR 49161), is applied to the current basic case-mix adjusted composite rate portion of the blended payment amount, resulting in a CY 2011 composite rate of \$138.53 (\$135.15*1.025). This 2.5 percent market basket increase does not apply to the drug add-on adjustment to the composite rate. Since the drug add-on is calculated as a percentage of the composite rate, we note that the drug add-on percentage would be reduced from 15.0 to 14.7 as a result of the increase to the composite rate in CY 2011.

Comment: Several commenters agreed with CMS' decision to apply a zero update to the drug add-on adjustment.

Response: We appreciate the commenters' support that we continue with a zero update to the drug add-on adjustment.

Accordingly, after a review of the public comments, we are finalizing the proposed policy decisions to apply a zero update to the drug add-on, maintain a \$20.33 per treatment drug add-on amount, as well as apply a 14.7 percent add-on adjustment to the

composite rate for CY 2011. Also, as previously discussed a 2.5 percent ESRD market basket increase is applied to the current basic case-mix adjusted composite rate portion of the blended payment amount, resulting in a CY 2011 composite rate of \$138.53 (\$135.15*1.025).

Comment: One commenter agreed with our decision to continue to use the ASP+6 percent methodology for separately billable drugs.

Response: This comment is out of the scope of the proposed ESRD provisions, however, we appreciate the commenters' support of our use of the ASP+6 percent methodology.

4. Update to the Geographic Adjustments to the Composite Rate

In the CY 2011 PFS proposed rule (75 FR 40165), we proposed to update the wage index adjustment to reflect the latest available wage data. The purpose of the wage index is to adjust the composite rates for differing wage levels covering the areas in which ESRD facilities are located. The wage indexes are calculated for each urban and rural area. In addition, we generally have followed wage index policies used under the inpatient hospital prospective payment system (IPPS), but without regard to any approved geographic reclassification authorized under sections 1886(d)(8) and (d)(10) of the Act or other provisions that only apply to hospitals paid under the IPPS (70 FR 70167). Therefore, for purposes of the ESRD wage index methodology, the hospital wage data we use is pre-classified, pre-floor hospital data and unadjusted for occupational mix.

5. Updates to Core-Based Statistical Area (CBSA) Definitions

In the CY 2006 PFS final rule with comment period (70 FR 70167), we announced our adoption of the OMB's CBSA-based geographic area designations to develop revised urban/rural definitions and corresponding wage index values for purposes of calculating ESRD composite rates. The CBSA-based geographic area designations are described in OMB Bulletin 03-04, originally issued June 6, 2003, and is available online at <http://www.whitehouse.gov/omb/bulletins/b03-04.html>. In addition, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We note that this and all subsequent ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index used to determine the

current ESRD wage index. The OMB bulletins may be accessed online at <http://www.whitehouse.gov/omb/bulletins/index.html>.

6. Updated Wage Index Values

In the CY 2007 PFS proposed rule (71 FR 69685), we proposed to update the ESRD wage index values annually. The ESRD wage index values for CY 2011 were developed from FY 2007 wage and employment data obtained from the Medicare hospital cost reports. As we indicated, the ESRD wage index values are calculated without regard to geographic classifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that is unadjusted for occupational mix.

Comment: One commenter wanted CMS to consider the wage index policies that are adopted under the IPPS and that similar wage index policies should be developed for ESRD facilities.

Response: We appreciate the commenters concern as to how ESRD are geographically classified and although we did not propose a change in the geographic reclassification for ESRD facilities at this time, we will take the commenters suggestions into consideration in future rulemaking.

Comment: MedPAC commented that the statutory update to the composite rate for CY 2011 will benefit both rural and urban facilities, and they urge CMS to monitor access to dialysis care especially in rural areas.

Response: We agree with MedPAC's recommendation and we plan to continue to monitor access to dialysis care in rural areas and the impact or influence these effects may have for the ESRD basic case-mix adjusted composite payment rate system wage index.

7. Wage Index Values for Areas With No Hospital Data

In the CY 2011 PFS proposed rule (75 FR 40167), we proposed to use the methodology established in CY 2006 for wage index values for areas with no hospital data. While adopting the CBSA designations, we identified a small number of ESRD facilities in both urban and rural geographic areas where there are no hospital wage data from which to calculate ESRD wage index values. The affected areas were rural Puerto Rico, rural Massachusetts (Barnstable Town, MA (CBSA 12700), and Providence-New Bedford-Fall River, RI-MA (CBSA 39300)), and the urban area of Hinesville, GA (CBSA 25980). As with prior years, for CY 2011, we calculated the ESRD wage index values for those areas as follows:

- For the urban area of Hinesville-Fort Stewart, GA (CBSA 25980), which is an urban area without specific hospital wage data, we applied the same methodology used to impute a wage index value that we used in CY 2010. Specifically, we used the average wage index value for all urban areas within the State of Georgia.

- For rural Massachusetts, we adopted an alternative methodology we used for CY's 2008, 2009 and 2010, which we proposed to use to determine the wage index value for rural Massachusetts for CY 2011. Specifically, for rural areas without hospital wage data, we proposed to use the average wage index values from all contiguous CBSAs as a reasonable proxy for that rural area. In determining the imputed rural wage index, we interpreted the term "contiguous" to mean sharing a border. In the case of Massachusetts, the entire rural area consists of Dukes and Nantucket Counties. We determined that the borders of Dukes and Nantucket counties are contiguous with CBSA 12700, Barnstable Town, MA, and Providence-New Bedford-Fall River, RI-MA. For purposes of rural Massachusetts, we proposed to use the same methodology for CY 2011.

- For rural Puerto Rico, because all geographic areas in Puerto Rico were subject to the wage index floor in CY 2011, we proposed to apply the ESRD wage index floor to rural Puerto Rico as well. For CY 2011, the ESRD wage index floor is 0.60. Therefore, we proposed to apply the ESRD wage index floor to 0.60 to facilities that are located in rural Puerto Rico. We note, however, that there are currently no ESRD facilities located in rural Puerto Rico.

We received no comments on our proposals for the wage areas as previously discussed with no hospital data. Therefore, we are finalizing our policies for wage areas with no hospital data. Also, we will continue to evaluate existing hospital wage data and possibly wage data from other sources such as the Bureau of Labor Statistics, to determine if other methodologies might be appropriate for imputing wage index values for areas without hospital wage data for CY 2010 and subsequent years. To date, no data from other sources, superior to that currently used in connection with the IPPS wage index has emerged. Therefore, for ESRD purposes, we continue to believe this is an appropriate policy. Also, the wage index values associated with these areas are located in the addenda section of this final rule.

Also, in the CY 2011 PFS proposed rule (75 FR 40167), we reported an additional urban area—Anderson, SC

(CBSA 11340)—with no hospital data. For this urban area, we proposed to use the same methodology we have used for the other urban area with no hospital data, that is, Hinesville-Fort Stewart, GA (CBSA 25980). However, since the publication of the CY 2011 PFS proposed rule, we have received hospital wage data for this area, and therefore, the methodology we proposed no longer applies.

8. Reduction to the ESRD Wage Index Floor

In the PFS proposed rule (75 FR 40167), we proposed to continue to reduce the wage index floor to the composite rate portion of the blend during the transition. For CY 2011, we proposed that the ESRD wage index floor would be reduced from 0.65 to 0.60. We believe maintaining the wage index floor provides some relief for ESRD facilities going through the transition that have low wage index values.

For CY 2011, all urban areas in Puerto Rico that have a wage index are eligible for the ESRD wage index floor of 0.60. Currently there are no ESRD facilities located in rural Puerto Rico, however, should any facilities open in rural Puerto Rico, as previously discussed, we intend to apply the CY 2011 wage index floor of 0.60 to these rural facilities.

We received no comments on our proposal regarding the reduction to the ESRD wage index floor with regard to the composite rate portion of the blend during the transition. Therefore, we are finalizing our policy to reduce the wage index floor as proposed.

9. Budget Neutrality Adjustment

We have previously interpreted the statute as requiring that the geographic adjustment be made in a budget neutral manner. Given our application of the ESRD wage index, this means that aggregate payments to ESRD facilities in CY 2011 would be the same as aggregate payments that would have been made if we had not made any changes to the geographic adjustments. We note that this BN adjustment only addresses the impact of changes in the geographic adjustments. A separate BN adjustment was developed for the case-mix adjustments required by the MMA.

Since we did not propose any changes to the case-mix measures for basic case-mix adjusted payment system for CY 2011, the current case-mix BN adjustment of 0.9116 would remain in effect for CY 2011. Consistent with prior rulemaking, for CY 2011, we will apply the wage-index BN adjustment factor of 1.056929 directly to the ESRD wage index values to the composite rate

portion of the blend. Because the ESRD wage index is only applied to the labor-related portion of the composite rate, we computed the BN adjustment factor based on that proportion (53.711 percent).

To compute the CY 2011 wage index BN adjustment factor, we used the FY 2007 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data to compute the wage index values, 2009 outpatient claims (paid and processed as of June 30, 2010), and geographic location information for each facility which may be found through Dialysis Facility Compare Web page on the CMS Web site at <http://www.cms.hhs.gov/DialysisFacilityCompare/>. The FY 2011 hospital wage index data for each urban and rural locale by CBSA may also be accessed on the CMS Web site at <http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp>. The wage index data are located in the section entitled, "FY 2011 Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA."

Using treatment counts from the 2009 claims and facility-specific CY 2010 composite rates, we computed the estimated total dollar amount each ESRD provider would have received in CY 2010. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2011. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD wage index for CY 2011. The total of these payments becomes the new CY 2011 amount of wage-adjusted composite rate expenditures for all ESRD facilities.

After comparing these two dollar amounts (target amount divided by the new CY 2011 amount), we calculated an adjustment factor that, when multiplied by the applicable CY 2011 ESRD wage index value, would result in aggregate payments to ESRD facilities that would remain within the target amount of composite rate expenditures. When making this calculation, the ESRD wage index floor value of 0.60 is applied whenever appropriate. The wage BN adjustment factor for CY 2011 is 1.056929.

To ensure BN, we also must apply the BN adjustment factor to the wage index floor 0.60, which results in an adjusted wage index floor of 0.6342 (0.6000 x 1.056929) for CY 2011. This budget neutrality factor is not applied to the wage index values for the ESRD PPS portion of the blend.

10. ESRD Wage Index Tables

The CY 2011 ESRD final wage index tables are located in Addenda K and L

of this final rule with comment period. Also, we indicated in the ESRD PPS final rule (75 FR 49117), we would finalize the CY 2011 ESRD PPS wage index tables in this final rule. The wage index tables lists two separate columns of wage index values. The first column lists the wage index values will be applied under the composite rate portion and includes the budget neutrality adjustment of 1.056929. The second column lists the wage index values that will be applied under the ESRD PPS beginning January 1, 2011.

F. Issues Related to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

1. Section 131: Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

a. Program Background and Statutory Authority

Section 101 of Division B of the Tax Relief and Health Care Act of 2006—the Medicare Improvements and Extension Act of 2006 (Pub. L. 109-432) (MIEA-TRHCA), which was enacted on December 20, 2006, required us to implement a physician quality reporting system in 2007, which we named the Physician Quality Reporting Initiative (PQRI). The Physician Quality Reporting System is a quality reporting program that provides an incentive payment to identified eligible professionals who satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. Under section 1848(k)(3)(B) of the Act, the term "eligible professional" means any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C); (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist.

The PQRI was extended and further enhanced as a result of the MMSEA, which was enacted on December 29, 2007, and the MIPPA, which was enacted on July 15, 2008. Changes to the PQRI as a result of these laws, as well as information about the PQRI in 2007, 2008, 2009, and 2010, are discussed in detail in the CY 2008 PFS proposed and final rules (72 FR 38196 through 38204 and 72 FR 66336 through 66353, respectively), CY 2009 PFS proposed and final rules (73 FR 38558 through 38575 and 73 FR 69817 through 69847, respectively), and CY 2010 PFS proposed and final rules (74 FR 33559 through 33600 and 74 FR 61788 through 61861, respectively). Further detailed information, about the PQRI program, related laws, and help desk resources, is

available on the CMS Web site at <http://www.cms.gov/PQRI>.

The ACA makes a number of changes to the PQRI, including the following: Authorizing incentive payments through 2014; requiring a payment adjustment beginning in 2015 for eligible professionals who do not satisfactorily report data on quality measures in the applicable reporting period for the year; requiring timely feedback to participating eligible professionals; requiring the establishment of an informal appeals process whereby eligible professionals may seek a review of the determination that an eligible professional did not satisfactorily submit data on quality measures for purposes of qualifying for a PQRI incentive payment; making available an additional incentive payment for those eligible professionals satisfactorily reporting data on quality measures for a year and having such data submitted on their behalf through a Maintenance of Certification Program and participating in a Maintenance of Certification Program practice assessment more frequently than is required to qualify for or maintain board certification status; requiring the establishment of a Physician Compare Web site; and requiring the development of a plan to integrate reporting on quality measures relating to the meaningful use of electronic health records (EHRs). Whereas in the past we only had the authority to continue the PQRI incentive payments for a specified period of time, we believe the changes authorized by the ACA (particularly the fact that the payment adjustments are authorized for 2015 and each subsequent year) lend permanency to the PQRI. To reflect this transition from the PQRI being a temporary initiative to a permanent quality reporting program, we are hereafter referring to the PQRI as the "Physician Quality Reporting System." We will be updating our documents and the relevant Web sites to reflect this name change over time.

In the CY 2011 PFS proposed rule (75 FR 40162) we proposed to add § 414.90 to title 42 of the Code of Federal Regulations to implement the provisions of the Physician Quality Reporting System.

We received several comments from the public on the CY 2011 PFS proposed rule related to the Physician Quality Reporting System. General comments about the Physician Quality Reporting System are addressed as follows.

Comment: We received positive feedback supporting the Physician Quality Reporting System program as a whole, particularly efforts that encourage eligible professional

reporting through registries, Maintenance of Certification Programs, and EHRs. We also received positive feedback regarding our proposals for providing timely feedback and the establishment of an informal appeals process.

Response: We appreciate the commenters' positive feedback. We believe that these options provide eligible professionals with greater flexibility.

Comment: We received one comment expressing dissatisfaction with the Physician Quality Reporting System program as a whole. The commenter stated that while they have been reporting Physician Quality Reporting System data for the past few years, they have not received the incentive payment. As a result, the commenter feels that their clinical professionalism and patient service is not improved by the program and that it diminishes the time they spend on direct patient care.

Response: We are sorry that the commenter has not received a Physician Quality Reporting System incentive. We are hopeful that the improvements that we are making to the Physician Quality Reporting System will make it easier for eligible professionals to participate satisfactorily. We recommend that all participating eligible professionals review their Physician Quality Reporting System feedback report. In addition to providing performance information, eligible professionals who are not incentive eligible will be able to use their feedback report to determine why they did not qualify for an incentive payment. We encourage any eligible professional who has questions about the information contained in their feedback report to contact the QualityNet Help Desk at 866-288-8912 or qnet-support@sdps.org. The Help Desk is available from 7 a.m. to 7 p.m. Central Time to answer a variety of questions about the Physician Quality Reporting System from general program questions to feedback report availability and access. The help desk can provide detailed information about the reasons that an eligible professional failed to earn an incentive as well.

Comment: Some commenters urged us to aggressively provide additional Physician Quality Reporting System education and training opportunities. One commenter requested we provide more "hands-on" Physician Quality Reporting System education and training opportunities at the local level by the state/regional contractors.

Response: We appreciate the commenters' valuable input. We will continue to work with national and regional stakeholder organizations to

educate their members on Physician Quality Reporting System program requirements. We also expect to continue to host monthly national provider calls in which we would provide guidance on specific topics and provide updated educational materials and resources. To augment our portfolio of educational materials and resources, we also anticipate providing a series of educational videos to help educate eligible professionals on Physician Quality Reporting System program requirements.

Comment: One commenter expressed disappointment with the exclusion of eligible professionals in institutional settings. Other commenters urged us to identify and adopt a Physician Quality Reporting System reporting mechanism that could apply to all eligible professionals in all settings, including eligible therapists providing services in CORFs, SNFs Part B, and outpatient departments of a hospital.

Response: As we stated in the CY 2010 PFS final rule with comment period (74 FR 61791), for professionals who practice in an institutional setting where the provider of service is an institution and not a physician or other professional paid under the PFS or where claims submission does not identify the professional by his or her NPI, we are unable to make the determination of satisfactory reporting and calculate earned incentive payment amounts at the individual eligible professional level without extensive modifications to the claims processing systems of CMS and providers, which would represent a material administrative burden to us and to providers. It would also require modifications to the industry standard claims formats, which would require substantial time to effect through established processes and structures that we do not maintain or control. We have also found that most institutions that employ eligible professionals do not tie the individual professional to the service rendered to an individual patient. In this case, there are no individual provider identifiers available to use in processing these claims.

Comment: One commenter was concerned that one of the analytical changes that was made to facilitate satisfactory Physician Quality Reporting System reporting may have had an unintended consequence on radiologists by overly inflating their eligible cases, or reporting denominator. Specifically, the commenter is requesting that, for radiology, we look at the CPT/ICD-9 combinations only for the specific line item in which the CPT/ICD-9

combination is present rather than across any dates of service.

Response: We are aware of this issue and are currently analyzing the impact. We believe there are only a handful of measures where this is a concern because the measure specifications tie a procedure to a diagnosis. We are working with the appropriate measure developers/owners to analyze the specifications for these measures to see if they can be changed for 2011 to lessen the impact.

Comment: One commenter encouraged us to consider strategies to move the Physician Quality Reporting System toward a more robust role in quality improvement. Individual clinicians and smaller group practices' self-selection of measures, the small number of measures required to be reported, and variations in the required sample sizes make the measures less meaningful than they could be if the program was more structured and rigorous.

Response: The commenter brings up a number of valid points. As the program matures and we phase out the incentives for satisfactory reporting and phase in payment adjustments for failing to satisfactorily report, we envision continuing to make further refinements to the program to address the commenter's concerns. Any such changes would be described in notice and comment rulemaking prior to implementation.

Comment: Another commenter urged us to transition to rewarding performance, not just reporting. Changes made now should lay the groundwork for moving towards this goal.

Response: As we noted in the CY 2011 PFS proposed rule (75 FR 40114 through 40115), section 3007 of the ACA requires the Secretary to apply a separate, budget-neutral payment modifier to the PFS PFS payment formula. The payment modifier, which will be phased in beginning January 1, 2015 through January 1, 2017, will provide for differential payment under the fee schedule to a physician or groups of physicians, and later, possibly to other eligible professionals, based upon the relative quality and cost of care of their Medicare beneficiaries.

Comment: One commenter was concerned that eligible professionals would not decide to participate in the Physician Quality Reporting System. The commenter was concerned that given the current status of the industry in trying to meet 5010/ICD10 regulations and incentive requirements for achieving the meaningful use of EHR adoption, the additional reporting

requirements will serve as a disincentive.

Response: We are unclear what additional reporting requirements the commenter is referring to nor are we clear on how they relate to the 5010/ICD10 regulations and the incentive requirements for achieving the meaningful use of EHR adoption. However, if the commenter is concerned that eligible professionals may not be motivated to participate in the Physician Quality Reporting System in light of other quality programs and/or requirements, we agree that this is a valid concern.

Upon consideration of the comments, we are finalizing our proposal to add § 414.90 to title 42 of the Code of Federal Regulations to implement the provisions of the Physician Quality Reporting System as discussed in this section. We made certain technical changes to § 414.90 as appropriate to reflect the change in the name of the PQRI to "Physician Quality Reporting System," to eliminate the unnecessary use of acronyms, and to add cross-references to relevant statutory or regulatory provisions where appropriate, to specify the particular program year addressed in this rulemaking, and to make other technical changes as noted.

b. Incentive Payments for the 2011 Physician Quality Reporting System

For years 2011 through 2014, section 3002(a) of the ACA extends the opportunity for eligible professionals to earn a Physician Quality Reporting System incentive payment for satisfactorily reporting Physician Quality Reporting System quality measures. For the 2011 Physician Quality Reporting System, section 1848(m)(2)(B) of the Act, as amended by section 3002(a) of the ACA, authorizes a 1.0 percent incentive, and for 2012 through 2014, a 0.5 percent incentive, for qualified eligible professionals who satisfactorily submit Physician Quality Reporting System quality measures data.

The following is a summary of the comments we received regarding the 2011 Physician Quality Reporting System incentive payment amount.

Comment: One commenter expressed support for the extension of the Physician Quality Reporting System incentives through 2014 for eligible professionals who satisfactorily report.

Response: We appreciate the commenters' positive feedback.

Comment: Some commenters expressed concern that the incentive payment is too small to motivate eligible professionals to report Physician Quality Reporting System measures,

even if they are providing quality care in their practice, or to drive quality. The commenters stated that added administrative cost and time should be considered when setting the incentive and disincentive rates, in an effort to better reflect the financial incentive to begin utilizing the measures and financial disincentives to maintain such practice. Commenters were specifically concerned that the incentives are not commensurate with the burden of reporting.

Response: While we understand commenters' concerns with the costs and burdens associated with satisfactory reporting under the Physician Quality Reporting System, we have neither the authority to change the basis for calculation of the incentive payment nor the authority to change the incentive amount. We continue to seek ways to minimize impact on eligible professionals, such as by continuing to offer multiple reporting options in order to give eligible professionals the flexibility to choose the option that best fits their practice. Furthermore, we note that under section 1848(a)(8) of the Act, beginning 2015, eligible professionals who do not satisfactorily report Physician Quality Reporting System measures will be subject to a payment adjustment. Eligible professionals who participate in the Physician Quality Reporting System prior to 2015 receive the added benefit of familiarizing themselves with the Physician Quality Reporting System prior to the implementation of the payment adjustment. Moreover, beginning 2015, eligible professionals who satisfactorily report under the Physician Quality Reporting System will avoid the payment adjustment.

Comment: One commenter requested clarification and examples on how the incentive payment calculations are determined and an explanation of what is meant by "allowable."

Response: As stated in the CY 2011 PFS proposed rule (75 FR 40169), the Physician Quality Reporting System incentive payment amount is calculated using estimated Medicare Part B PFS allowed charges for all covered professional services, not just those charges associated with the reported quality measures. "Allowed charges" refers to total charges, including the beneficiary deductible and coinsurance, and is not limited to the 80 percent paid by Medicare or the portion covered by Medicare where Medicare is secondary payer. Amounts billed above the PFS amounts for assigned and non-assigned claims will not be included in the calculation of the incentive payment amount. In addition, since, by definition

under section 1848(k)(3)(A) of the Act, "covered professional services" are limited to services for which payment is made under, or is based on, the PFS and which are furnished by an eligible professional, other Part B services and items that may be billed by eligible professionals, but are not paid under or based upon the Medicare Part B PFS, are not included in the calculation of the incentive payment amount.

Therefore, eligible professionals and group practices that satisfactorily report quality data under the 2011 Physician Quality Reporting System will qualify for an incentive payment equal to 1.0 percent of their total estimated Medicare Part B PFS allowed charges for the all covered professional services furnished by the eligible professional during the applicable 2011 Physician Quality Reporting System reporting period. For satisfactory reporting at the individual level in 2011, 1.0 percent of allowed charges will be paid at the TIN/NPI level. For satisfactory reporting at the group practice level in 2011, 1.0 percent of allowed charges will be paid at the TIN level.

c. 2011 Reporting Periods for Individual Eligible Professionals

Under section 1848(m)(6)(C) of the Act, the "reporting period" for the 2008 Physician Quality Reporting System and subsequent years is defined to be the entire year, but the Secretary is authorized to revise the reporting period for years after 2009 if the Secretary determines such revision is appropriate, produces valid results on measures reported, and is consistent with the goals of maximizing scientific validity and reducing administrative burden. For the 2011 Physician Quality Reporting System, we proposed the following reporting periods: (1) 12-Month reporting period for claims-based reporting and registry-based reporting (that is, January 1, 2011 through December 31, 2011); (2) 12-month reporting period for EHR-based reporting (that is, January 1, 2011 through December 31, 2011); and (3) 6-month reporting period for claims-based reporting and registry-based reporting (that is, July 1, 2011 through December 31, 2011). Additionally, we proposed the 12-month reporting period for the group practice reporting option (GPRO) for both the Physician Quality Reporting System and the Electronic Prescribing (eRx) Incentive Program Prescribing Incentive Program (January 1, 2011 through December 31, 2011).

The following is a summary of the comments we received regarding the proposed reporting periods.

Comment: We received comments generally supporting the proposed reporting periods as well as comments specifically supporting the 6-month reporting period for registry-based reporting.

Response: We appreciate the commenters' positive feedback. As these comments support our proposed reporting periods and for the reasons discussed, we are finalizing the reporting periods, as proposed.

Comment: One commenter was opposed to the elimination of the 6-month reporting period for claims-based reporting as this would create an unnecessary obstacle for the reporting mechanism that is available to nearly all eligible professionals.

Response: We agree with the commenter's urging of the preservation of the 6-month reporting period for 2011, and, as such, we did not propose to eliminate the 6-month reporting period for claims-based reporting. In an effort to encourage participation by eligible professionals who may not be ready to do so at the beginning of the year, for the 2011 Physician Quality Reporting System, there will continue to be both a 12-month and 6-month reporting period for all reporting options except for EHR reporting and the group practice reporting option.

Comment: Another commenter requested that we consider a 6-month reporting period for registry-based reporting.

Response: We proposed a 6-month reporting period for registry-based reporting in the CY 2011 PFS proposed rule (75 FR 40169). As previously stated, for the 2011 Physician Quality Reporting System, there will continue to be a 12-month and 6-month reporting period for all reporting options except for EHR reporting and the group practice reporting option.

Comment: One commenter requested that we consider providing both 6-month and 12-month EHR-based reporting options, consistent with the 6-month reporting period options available for the claims-based and registry-based reporting mechanisms.

Response: As we stated in the CY 2010 PFS final rule with comment period (74 FR 61794), we may consider including a 6-month reporting period for EHR reporting in future years once we have additional experience with EHR reporting in the Physician Quality Reporting System. At this time, no data has yet been collected from EHRs for the Physician Quality Reporting System. EHR data submission for the 2010 Physician Quality Reporting System will not occur until early 2011. Therefore, we are not adding a 6-month

reporting period for EHR-based reporting at this time.

Comment: One commenter opposed tying the incentive amount to the reporting period in which the eligible professional satisfactorily reports.

Response: Section 1848(m)(1)(A) of the Act specifies that the incentive payment is based on the covered professional services furnished during the reporting period for which the eligible professional or group practice satisfactorily reports. Therefore, we are obligated to tie the incentive amount to the reporting period in which the eligible professional satisfactorily reports. We note, however, the incentive is not limited to the charges for the services associated with the measures being reported. Rather the incentive is calculated based on all of covered professional services furnished during the applicable reporting period.

Upon consideration of the comments received, we will finalize the 2011 reporting periods as proposed. As discussed previously, if an eligible professional only satisfactorily reports for the 6-month reporting period, then the professional's incentive payment will be calculated based on the eligible professional's charges for covered professional services furnished between July 1, 2011 and December 31, 2011 only. Services furnished prior to July 1, 2011 would not be included in the professional's incentive payment calculation.

We are also deleting the definition for the term "quality reporting period" proposed at § 414.90(b) since the reporting period is defined at § 414.90(g)(1).

d. 2011 Physician Quality Reporting System Reporting Mechanisms for Individual Eligible Professionals

For the 2011 Physician Quality Reporting System, we proposed to retain the claims-based, registry-based, and EHR-based reporting mechanism from 2010 and invited comments on other options that could be included in the 2011 Physician Quality Reporting System. We also discussed in the CY 2011 PFS proposed rule that we continue to consider significantly limiting the claims-based mechanism of reporting clinical quality measures in future program years (75 FR 40170).

The following is a summary of the comments received with regard to the proposed 2011 Physician Quality Reporting System reporting mechanisms and our intent to lessen reliance on the claims-based reporting mechanism beyond 2011.

Comment: Several commenters supported the proposed reporting

mechanisms for the 2011 Physician Quality Reporting System, including strong support for the continuation of claims-based reporting and continued availability of multiple reporting mechanisms. Many commenters noted that claims-based reporting is the only reporting mechanism available to all eligible professionals. One commenter believes claims-based reporting may be a more accurate reporting method overall and that it would be unduly burdensome and costly to force practitioners into changing their established reporting methods. Another commenter thought CMS should not totally discontinue claims-based reporting as some practitioners, such as radiologists, work at several different locations where they may not consistently have access to a registry or EHR. One commenter noted that many small practices may not yet be linked to EHR systems. Commenters also noted that registry reporting frequently requires additional costs, which adds another burden on eligible professionals who wish to participate in the Physician Quality Reporting System. Another commenter stated that in the transition to payment adjustments beginning in 2015, where it is crucial to encourage greater participation, it would be premature to eliminate claims-based reporting. Other commenters urged us to delay eliminating or lessening our reliance on claims-based reporting until eligible professionals can demonstrate that they understand how to use and capture quality data via EHRs or registers and can consistently and successfully do so. Finally, another commenter encouraged us to provide a one or two year transition period if we want to proceed with eliminating claims-based reporting in future years.

Response: We appreciate the commenters' positive feedback. We agree with some of the reasons cited by commenters for retaining claims-based reporting and/or retaining multiple reporting mechanisms. For these reasons and in the discussion that follows, we are retaining, for 2011, the three 2010 Physician Quality Reporting System reporting mechanisms for individual eligible professionals, including claims-based reporting.

Comment: While a majority of commenters requested that we delay or reconsider lessening our reliance on claims-based reporting after 2011, some commenters recommended that the claims-based reporting option be phased out with the expectation that registry-based and EHR-based reporting will become the mainstay of the program, especially as EHR adoption increases. Commenters noted that claims-based

reporting has been problematic for eligible professionals and that transitioning the Physician Quality Reporting System away from claims-based reporting would maximize the potential of registries and EHRs for quality measurement reporting. One commenter requested clarification around the timing for phasing out claims-based reporting in order to assist eligible professionals' decision-making around how and when to implement various parts of an EHR or registry.

Response: In addition to the reasons offered by commenters, our ability to lessen our reliance on the claims-based reporting mechanism is dependent on there being an adequate number and variety of registries available and/or EHR reporting options. We believe that it would be premature to eliminate the claims-based reporting mechanism for 2011 and doing so would create a barrier to participation. For 2009, approximately 75 percent of eligible professionals used claims-based reporting. We do not anticipate phasing out claims-based reporting while it continues to be actively used by eligible professionals.

Comment: One commenter requested that we allow certified registered nurse anesthetists (CRNAs) to submit Physician Quality Reporting System data through an EHR-based reporting mechanism.

Response: CRNAs are not precluded from reporting via a qualified Physician Quality Reporting System EHR. However, CRNAs may find the current measures available for Physician Quality Reporting System EHR reporting to be beyond their scope of practice. Additionally, CRNAs tend to collect the majority of their data in operating rooms and may require specific EHR products which, due to their specialization, may have Physician Quality Reporting System qualification later on their timeline.

Comment: One commenter expressed support for the use of registries as a recognized instrument to leverage existing clinical data collection efforts.

Response: We appreciate the supportive comment and agree that registries may be able to augment data collection efforts, particularly for measures that are more difficult to collect and require longer time horizons to get complete data information.

Comment: One commenter expressed concern about the discrepancy between claims-based reporting and registry reporting. Physician Quality Reporting System analysis for 2007 and 2008 showed that providers who did registry reporting had a 90 percent success rate for earning a Physician Quality

Reporting System bonus and claims-based reporting had a 50 percent success rate. Due to this large discrepancy, the commenter believed that it will be very important to know which reporting method results in actual performance improvement based on patient outcomes and whether methods are subject to manipulation. The commenter encouraged us to ensure the processes and resulting data of the reporting methods are reliable and not susceptible to manipulation.

Response: We understand the commenter's concerns about the differences in the registry results compared to the claims results. We are continually assessing the accuracy and reliability of all data submitted under the Physician Quality Reporting System. We compare the data that is submitted to us from registries against claims data and are exploring reasons for any discrepancies found.

Comment: Some commenters, in the spirit of harmonization, noted that several aspects of the Physician Quality Reporting System are different from the Hospital Inpatient Quality Reporting Program, formerly known as the Reporting Hospital Quality Data Annual Payment Update Program (RHQDAPU). One commenter stated that while we are moving away from claims-based quality measures for eligible professionals, they are moving toward claims-based quality measures for hospitals. The commenter strongly encouraged us to harmonize their programs and make this same conclusion for the Hospital Inpatient Quality Reporting Program.

Response: We understand the commenters' desire for harmonization of our various quality reporting programs and we attempt to do so when practical and feasible. We note, however, that the Physician Quality Reporting System and the Hospital Inpatient Quality Reporting Program are separate and distinct programs. The two programs apply to two different types of providers, have different goals, and are governed by different laws and requirements.

Claims-based submission for the Physician Quality Reporting System provides a means to submit additional data, using QDCs, beyond what is required for billing. Claims as used for hospital quality reporting does not require the submission of additional QDCs to be added to applicable patient claims.

Based upon consideration of the comments received and for the reasons previously explained, we are retaining the claims, registry, and EHR reporting mechanisms for use by individual eligible professionals for the 2011 Physician Quality Reporting System. As

in previous years, depending on which Physician Quality Reporting System individual quality measures or measures groups an eligible professional selects, one or more of the 2011 reporting mechanisms may not be available for reporting a particular 2011 Physician Quality Reporting System individual quality measure or measures group. In addition, while eligible professionals can attempt to qualify for a Physician Quality Reporting System incentive under multiple reporting mechanisms, an eligible professional must satisfy the 2011 criteria for satisfactory reporting with respect to a single reporting mechanism to qualify for a 2011 incentive. For example, an eligible professional who starts submitting individual Physician Quality Reporting System measures via claims in January 2011 and then switches to registry-based reporting for services furnished after April 2011 would be able to qualify for a 2011 Physician Quality Reporting System incentive based on a 12-month reporting period only if he or she satisfies the appropriate reporting criteria for either claims-based reporting or registry-based reporting for this reporting period. We will not combine data submitted via multiple reporting mechanisms to determine incentive eligibility.

(1) Final Requirements for Individual Eligible Professionals Who Choose the Claims-Based Reporting Mechanism

For eligible professionals who choose to participate in the 2011 Physician Quality Reporting System by submitting data on individual quality measures or measures groups through the claims-based reporting mechanism, we proposed the eligible professional would be required to submit the appropriate Physician Quality Reporting System quality data codes (QDCs) on the professionals' Medicare Part B claims. QDCs for the eligible professional's selected individual Physician Quality Reporting System quality measures or measures group may be submitted to CMS at any time during 2011. However, as required by section 1848(m)(1)(A) of the Act, all claims for services furnished between January 1, 2011 and December 31, 2011, would need to be processed by no later than February 28, 2012, to be included in the 2011 Physician Quality Reporting System analysis.

We did not receive any comments specific to the requirements for individual eligible professionals who choose claims-based reporting. Therefore, we are finalizing the requirements as proposed (75 FR 40171) and previously discussed. Eligible professionals should refer to the "2011

Physician Quality Reporting System Implementation Guide" to facilitate satisfactory reporting of QDCs for 2011 Physician Quality Reporting System individual measures on claims and to the "Getting Started with 2011 Physician Quality Reporting System Reporting of Measures Groups" to facilitate satisfactory reporting of QDCs for 2011 Physician Quality Reporting System measures groups on claims. By no later than December 31, 2010, both of these documents will be posted on the Physician Quality Reporting System section of the CMS Web site at <http://www.cms.gov/pqri>.

(2) Final Requirements for Individual Eligible Professionals Who Choose the Registry-Based Reporting Mechanism

We proposed that in order to report quality data on the 2011 Physician Quality Reporting System individual quality measures or measures groups through a qualified clinical registry, an eligible professional must enter into and maintain an appropriate legal arrangement with a qualified 2011 Physician Quality Reporting System registry. Such arrangements would provide for the registry's receipt of patient-specific data from the eligible professional and the registry's disclosure of quality measures results and numerator and denominator data on Physician Quality Reporting System quality measures or measures groups on behalf of the eligible professional to CMS. Thus, the registry would act as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA) Business Associate and agent of the eligible professional. Such agents are referred to as "data submission vendors." The "data submission vendors" would have the requisite legal authority to provide clinical quality measures results and numerator and denominator data on individual quality measures or measures groups on behalf of the eligible professional for the Physician Quality Reporting System.

We proposed that the registry, acting as a data submission vendor, would submit CMS-defined registry-derived measures information to our designated database for the Physician Quality Reporting System, using a CMS-specified record layout, which would be provided to the registry by CMS. Similarly, we proposed that eligible professionals choosing to participate in the Physician Quality Reporting System through the registry-based reporting mechanism for 2011 would need to select a qualified Physician Quality Reporting System registry and submit information on Physician Quality

Reporting System individual quality measures or measures groups to the selected registry in the form and manner and by the deadline specified by the registry.

In addition to meeting the proposed requirements specific to registry-based reporting, we proposed that eligible professionals who choose to participate in the Physician Quality Reporting System through the registry-based reporting mechanism would need to meet the relevant criteria proposed for satisfactory reporting of individual measures or measures groups that all eligible professionals must meet in order to satisfactorily report for the Physician Quality Reporting System 2011.

We did not receive any comments specific to the requirements for individual eligible professionals who choose registry-based reporting. Therefore, we are finalizing the requirements for individual eligible professionals who choose the registry-based reporting mechanism as proposed (75 FR 40171 through 40173) and previously discussed.

We will post a list of qualified registries for the 2011 Physician Quality Reporting System on the Physician Quality Reporting System section of the CMS Web site at <http://www.cms.gov/pqri>, which will include the registry name, contact information, and the 2011 measures and/or measures group and eRx reporting (if qualified) for which the registry is qualified and intends to report. However, we do not anticipate making this list available prior to the start of the 2011 program year as we had proposed. We proposed to post the names of the 2011 Physician Quality Reporting System qualified registries in 3 phases starting with a list of those registries qualified for the 2011 Physician Quality Reporting System based on: (1) Being a qualified registry for a prior Physician Quality Reporting System program year that successfully submitted 2008 and/or 2009 Physician Quality Reporting System quality measures results and numerator and denominator data on the quality measures; (2) having received a letter indicating their continued interest in being a Physician Quality Reporting System registry for 2011 by October 31, 2010; and (3) the registry's compliance with the 2011 Physician Quality Reporting System registry requirements. As discussed further in section VII.F.1.j. of this final rule with comment period, we proposed and are finalizing new requirements for the 2011 Physician Quality Reporting System registries. Since there are new requirements that did not apply to previously qualified

registries, we will need to ensure that the previously qualified registries meet the new requirements for 2011. While we fully expect all of the previously qualified registries to meet the new registry requirements for the 2011 Physician Quality Reporting System, we do not expect to be able to determine previously qualified registries' compliance with these new registry requirements for 2011 until the middle of 2011. Thus, by Summer 2011, we expect to post a list of registries (this list will include both registries that were previously qualified and those that self-nominate to be newly qualified for 2011) that are conditionally qualified to submit numerator and denominator data on 2011 Physician Quality Reporting System measures and measures groups and Physician Quality Reporting System measure results. After we receive a test file from the registries, we will finalize the list of 2011 Physician Quality Reporting System registries. We anticipate finalizing the list of 2011 Physician Quality Reporting System registries by Fall 2011.

An eligible professional's ability to report Physician Quality Reporting System quality measures results and numerator and denominator data on Physician Quality Reporting System quality measures or measures groups using the registry-based reporting mechanism should not be impacted by the list of qualified registries for the 2011 Physician Quality Reporting System being made available after the start of the reporting period. First, registries will not begin submitting eligible professionals' Physician Quality Reporting System quality measures results and numerator and denominator data on the quality measures or measures groups to CMS until 2012. Second, if an eligible professional decides that he or she is no longer interested in submitting quality measures results and numerator and denominator data on Physician Quality Reporting System individual quality measures or measures groups through the registry-based reporting mechanism after the complete list of qualified registries becomes available, this does not preclude the eligible professional from attempting to meet the criteria for satisfactory reporting through another 2011 Physician Quality Reporting System reporting mechanism.

In any event, even though a registry is listed as "qualified," we cannot guarantee or assume responsibility for the registry's successful submission of the required Physician Quality Reporting System quality measures results or measures group results or

required data elements submitted on behalf of a given eligible professional.

(3) Final Requirements for Individual Eligible Professionals Who Choose the EHR-Based Reporting Mechanism

For 2011, in addition to meeting the criteria for satisfactory reporting of at least 3 individual measures, we proposed the following requirements associated with EHR-based reporting: (1) Selection of a Physician Quality Reporting System qualified EHR product; and (2) submission of clinical quality data extracted from the EHR to a CMS clinical data warehouse in the CMS-specified manner and format (75 FR 40172). Similar to the 2010 Physician Quality Reporting System, a test of quality data submission from eligible professionals who wish to report 2011 quality measure data directly from their qualified EHR product will be required and is anticipated to occur in early 2012 immediately followed by the submission of the eligible professional's actual 2011 Physician Quality Reporting System data. This entire final test/production 2011 data submission timeframe is expected to be January 2012 through March 2012. As discussed in the CY 2010 PFS final rule with comment period (74 FR 61801 through 61802), we are currently vetting newly self-nominated EHR vendor products for possible qualification for the 2011 Physician Quality Reporting System program year. We expect to list any additional Physician Quality Reporting System qualified EHR products by January 2011. It is expected that these newly qualified products would be able to submit 2011 Physician Quality Reporting System data in early 2012.

The following is a summary of the comments we received regarding the proposed requirements for individual eligible professionals who choose the EHR-based reporting mechanism for the 2011 Physician Quality Reporting System.

Comment: One commenter recommended that we consider accepting measure rates from EHRs rather than just numerator and denominator data. Rates generated within the system will be more readily available for local quality improvement purposes and timely feedback to eligible professionals and office staff. Timely feedback has been and will continue to be a problem for this program. System characteristics that promote and facilitate local improvement efforts should be designed in from the outset.

Response: We agree that an EHR's ability to calculate measure results locally will provide useful and timely

information to eligible professionals who are participating in the Physician Quality Reporting System. However, receiving individual data elements allows us to ensure that measure results are calculated in a more standardized fashion across eligible professionals. Individual data elements can also more readily be combined with other data from other sources. Additionally, if measure specifications change, there would be no need to recode the EHR to account for these specification changes. Rather we can make one change to the measures engine to obviate the need for a change to the EHR itself.

Comment: One commenter finds problematic the definition of a qualified EHR as one incorporating eRx functionality. Such functionality is unnecessary and costly for eligible professionals who do not prescribe. As a result, the current proposed definition of EHR could disenfranchise practitioners lacking prescriptive authority by automatically denying them the opportunity to use EHRs for reporting performance measures. Another commenter requested clarification on whether the electronic prescription function is E-Prescribing, which requires the patient's pharmacy benefits information, or E-Prescription Writing, which does not.

Response: We believe the commenters are referring to the eRx functionality required of a certified EHR for the EHR Incentive Program, which is beyond the scope of this final rule with comment period. This final rule is limited to the use of EHRs in the Physician Quality Reporting System and eRx Incentive Programs as one of multiple reporting mechanisms available to eligible professionals to report on Physician Quality Reporting System measures and/or the electronic prescribing quality measure.

Upon consideration of the comments and for the reasons we highlighted based on our experience thus far with EHR-based reporting, eligible professionals who choose the EHR-based reporting mechanism for the 2011 Physician Quality Reporting System will be required to (in addition to meeting the appropriate criteria for satisfactory reporting of individual measures):

- Have a Physician Quality Reporting System qualified EHR product;
- Have access to the identity management system specified by CMS (such as, but not limited to, the Individuals Authorized Access to CMS Computer Systems, or IACS) to submit clinical quality data extracted from the EHR to a CMS clinical data warehouse;

- Submit a test file containing real or dummy clinical quality data extracted from the EHR to a CMS clinical data warehouse via an identity management system specified by CMS during a timeframe specified by CMS;

- Submit a file containing the eligible professional's 2011 Physician Quality Reporting System clinical quality data extracted from the EHR for the entire reporting period (that is, January 1, 2011 through December 31, 2011) via the CMS-specified identify management system during the timeframe specified by CMS in early 2012.

Measures groups reporting continues to not be an option for EHR-based reporting of quality measures for the 2011 Physician Quality Reporting System.

We also cannot assume responsibility for the successful submission of data from eligible professionals' EHRs. Any eligible professional who chooses to submit Physician Quality Reporting System data extracted from an EHR should contact the EHR product's vendor to determine if the product is qualified and has been updated to facilitate 2011 Physician Quality Reporting System quality measures data submission. Such professionals also should begin attempting submission soon after the opening of the clinical data warehouse in order to assure the professional has a reasonable period of time to work with his or her EHR and/or its vendors to correct any problems that may complicate or preclude successful quality measures data submission through that EHR.

The specifications for the electronic transmission of the 2011 Physician Quality Reporting System measures identified in Tables 81 and 82 of this final rule with comment period as being available for EHR-based reporting in 2011 are posted in the Alternative Reporting Mechanisms page of the Physician Quality Reporting System section of the CMS Web site. The requirements that an EHR vendor must meet in order for one or more of its products to be considered qualified for purposes of an eligible professional submitting 2011 Physician Quality Reporting System data extracted from the EHR product(s) were described in the CY 2010 PFS final rule with comment period (74 FR 61800 through 61802) and are posted on the Alternative Reporting Mechanisms page of the Physician Quality Reporting System section of the CMS Web site. We expect to post the names of the EHR vendors and the specific product(s) and version(s) that are qualified for the 2011 Physician Quality Reporting System on the Alternative Reporting Mechanisms

page of the Physician Quality Reporting System section of the CMS Web site by January 2011.

(4) Final Qualification Requirements for Registries

For the 2011 Physician Quality Reporting System, we proposed to require a self-nomination process for registries wishing to submit 2011 Physician Quality Reporting System quality measures or measures groups on behalf of eligible professionals for services furnished during the applicable reporting periods in 2011 (75 FR 40173). To be considered a qualified registry for purposes of submitting individual quality measures and measures groups on behalf of eligible professionals who choose this reporting mechanism, we proposed that both registries new to the Physician Quality Reporting System and those previously qualified must:

- Be in existence as of January 1, 2011;
- Have at least 25 participants by January 1, 2011;
- Provide at least 1 feedback report per year to participating eligible professionals;
- Not be owned and managed by an individual locally-owned single-specialty group (in other words, single-specialty practices with only 1 practice location or solo practitioner practices would be prohibited from self-nominating to become a qualified Physician Quality Reporting System registry);
- Participate in ongoing 2011 Physician Quality Reporting System mandatory support conference calls hosted by CMS (approximately 1 call per month), including an in-person registry kick-off meeting to be held at CMS headquarters in Baltimore, MD. Registries that miss more than one meeting will be precluded from submitting Physician Quality Reporting System data for the reporting year (2011);
- Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures in the 2011 Physician Quality Reporting System (according to the posted 2011 Physician Quality Reporting System Measure Specifications);
- Be able to calculate and submit measure-level reporting rates or the data elements needed to calculate the reporting rates by TIN/NPI;
- Be able to calculate and submit, by TIN/NPI, a performance rate (that is, the percentage of a defined population who receive a particular process of care or achieve a particular outcome) for each measure on which the TIN/NPI reports

or the data elements needed to calculate the reporting rates;

- Be able to separate out and report on Medicare Part B FFS patients;
- Provide the name of the registry;
- Provide the reporting period start date the registry will cover;
- Provide the reporting period end date the registry will cover;
- Provide the measure numbers for the Physician Quality Reporting System quality measures on which the registry is reporting;
- Provide the measure title for the Physician Quality Reporting System quality measures on which the registry is reporting;
- Report the number of eligible instances (reporting denominator);
- Report the number of instances of quality service performed (numerator);
- Report the number of performance exclusions;
- Report the number of reported instances, performance not met (eligible professional receives credit for reporting, not for performance);
- Be able to transmit this data in a CMS-approved XML format.
- Comply with a CMS-specified secure method for data submission, such as submitting the registry's data in an XML file through an identity management system specified by CMS or another approved method such as over the NHIN (national health information network) if technically feasible;
- Submit an acceptable "validation strategy" to CMS by March 31, 2011. A validation strategy ascertains whether eligible professionals have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method;
- Perform the validation outlined in the strategy and send the results to CMS by June 30, 2012 for the 2011 reporting year's data;
- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the registry's receipt of patient-specific data from the eligible professionals, as well as the registry's disclosure of quality measure results and numerator and denominator data on behalf of eligible professionals who wish to participate in

the Physician Quality Reporting System program;

- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the registry has authorized the registry to submit quality measures and numerator and denominator data to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the registry to submit Physician Quality Reporting System quality measures data to the registry and must meet any applicable laws, regulations, and contractual business associate agreements;

- Provide CMS access (if requested for validation purposes) to review the Medicare beneficiary data on which 2011 Physician Quality Reporting System registry-based submissions are founded or provide to CMS a copy of the actual data (if requested);

- Provide the reporting option (reporting period and reporting criteria) that the eligible professional has satisfied or chosen; and

- Provide CMS a signed, written attestation statement via mail or e-mail which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.

For registries that intend to report on 2011 Physician Quality Reporting System measures groups, we proposed that both registries new to the Physician Quality Reporting System and those previously qualified must:

- Indicate the reporting period chosen for each eligible professional who chooses to submit data on measures groups;

- Base reported information on measures groups only on patients to whom services were furnished during the 12-month reporting period of January through December 2011 or the 6-month reporting period of July 1, 2011 through December 31, 2011;

- Agree that the registry's data may be inspected or a copy requested by CMS and provided to CMS under our oversight authority;

- Be able to report data on all applicable measures in a given measures group on either 30 or more Medicare Part B FFS patients from January 1, 2011 through December 31, 2011, or on 80 percent of applicable Medicare Part B FFS patients for each eligible professional (with a minimum of 15 patients during the January 1, 2011, through December 31, 2011, reporting period or a minimum of 8 patients

during the July 1, 2011, through December 31, 2011, reporting period).

Although these proposed qualification requirements for 2011 registries are similar to those in previous years, we noted that registries would no longer be permitted to include non-Medicare patients for measures group reporting. Additionally, in an effort to reduce the variation in measures results across registries and better allow eligible professional comparisons, we also proposed that all current and future registries would have to meet the following new requirements:

- Use Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. CMS will provide registries a standard set of logic to calculate each measure and/or measures group they intend to report in 2011.

- Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the registry intends to calculate. The registries will be required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format.

- Provide us the individual data elements used to calculate the measures if so requested by CMS for validation purposes, if aggregated data submission is still the selected method of data collection. Registries that are subject to validation will be asked to send discrete data elements for a measure (determined by CMS) in the required data format for us to recalculate the registries' reported results. Validation will be conducted for several measures at a randomly selected sample of registries in order to validate their data submissions.

We also invited comments on an alternative considered in which registries would be required to send CMS beneficiary-level data provided to the registry by the eligible professional and CMS would use the data to calculate the eligible professional's measure results (that is, reporting and performance rates).

The following is a summary of the comments we received regarding the proposed qualification requirements and self-nomination process for registries for the 2011 Physician Quality Reporting System.

Comment: One commenter supported the CMS proposal to limit registries based on size and sophistication. The intent of allowing registry reporting was

to allow physicians to benefit from an infrastructure that could enable real time reporting and comparison with other groups. A registry from a single physician practice does not meet the intent of why registry reporting was allowed and should not be allowed for registry reporting.

Response: We believe that the costs (time and money) associated with creating and testing a registry for Physician Quality Reporting System qualification are not insignificant. This and the increased potential for individual practices to "game" Physician Quality Reporting System has influenced our decision to require registries to report on larger numbers of eligible professionals or be third party vendors.

Comment: One commenter indicated that it is not clear if reporting needs to be at both the TIN and NPI level or the TIN or NPI level and recommended that all quality reporting be required to include NPI information and feedback at that level.

Response: Reporting from registries is to be submitted at the individual TIN/NPI level. Feedback is available at the individual NPI level as well as a TIN's rolled-up NPI report, that is, all NPIs under a particular TIN. For reporting 2011 measures groups via a registry, we will no longer accept data from non-Medicare beneficiaries. This will allow a better comparison of registry-submitted data and measure calculations to ensure accurate reporting and meaningful feedback reports to eligible professionals.

Comment: Some commenters supported the proposal that registries would no longer use their own measure calculation logic or measure flows to calculate measure results but instead use a CMS-specified standard set of logic for calculating measures. Some commenters supported the proposal based on the fact that registry data results have been inconsistent in the past, and the results do not yield reliable information for eligible professionals to analyze their performance results for practice improvement.

Response: We agree with the commenter and plan to provide registries with a calculation flow diagram for each measure they intend to report and also provide the registry with a use case. As part of their qualification process, registries will need to calculate the measure reporting and performance rates and send this information to CMS or our contractor in the specified XML format.

Comment: One commenter, while supporting the use of a CMS-specified

measure calculation logic, suggested that at least three months be provided to account for the development time necessary to convert measures to use CMS's algorithms. The actual development effort for a registry, however, would be proportionate to the quantity of measures supported by a registry.

Response: We respect and appreciate the time requirements of registries as they attempt qualification. We try to balance the needs of the registries with the importance of letting eligible professionals know which registries are qualified so they can begin selecting and reporting to their registry of choice.

Comment: Another commenter who supported the use of a CMS-specified measure calculation logic, suggested that we make the logic public prior to implementation in order to determine the best logic and calculations for measure results.

Response: We do not believe that public input for measure logic calculation beyond what is already allowed for measure development and endorsement is prudent. We attempt to use the measures as the developer intended and only make changes when necessary for implementation purposes or as required by Medicare policy.

Comment: Some commenters opposed the proposal for registries to use a CMS-specified logic to calculate measure results. One commenter stated they do not believe requiring registries to use a CMS-specified measure calculation logic will lessen the observed variation in measure results. The commenter believes the rate calculation from the numerator and denominator data involves simple arithmetic and is unlikely to be the cause of the observed variation. The more likely cause is a variation in how the data is collected or defined within the system. Another commenter was concerned that a CMS-developed logic might not accurately calculate measure reporting or performance rates in all instances for all eligible professionals since it will likely be based on claims and may not be appropriate to examine the data that is submitted to registries.

Response: We appreciate these comments and agree that a CMS-specified logic may not eliminate all of the data variations or inconsistencies but believe providing a specific logic calculation will help reduce these data differences.

Comment: One commenter believes that registries should have reasonable latitude in interpreting the measure flows or logic provided by us to account for variability in the ways that data are collected by the registries.

Response: While this may seem like a good idea on the surface, this proposal would allow too much data variation and prevent us and outside stakeholders from comparing an eligible professional's performance. This is contrary to our desire to increase standardization in the way registries calculate measure reporting and performance rates.

Comment: A few commenters did not support the alternative approach in which registries would be required to send us discrete data elements and we would calculate the results for eligible professionals.

Response: We do not intend to adopt this method of registry data submission for the 2011 Physician Quality Reporting System.

Comment: One commenter requested that we publish the list of registries and EHR products qualified for purposes of submitting Physician Quality Reporting System data prior to the beginning of the reporting year.

Response: We strive to qualify registries and EHRs in as timely a manner as is possible, however while we do not guarantee successful submission of data by an EHR or a given registry, we want to be as thorough as possible in vetting these systems to increase the likelihood of successful data submission. To date, we have not had any qualified registries who have not successfully reported data to us. We do try to post a partial list of qualified registries (based on successful participation in a prior year) prior to the start of the next reporting period.

Comment: One commenter urged us to include additional information related to the registries such as the physician participants' success rate, the number of participants and the cost.

Response: We agree that providing cost information may be helpful to eligible professionals as they choose a qualified registry. There has been considerable objection by the registries to listing this information on our Web site as the registries report that comparison of their fees is misleading since some of the registries solely report Physician Quality Reporting System information on behalf of eligible professionals to us while others provide additional information and tools to their participants.

Upon considering the comments received, we are finalizing the 2011 qualification requirements as proposed (75 FR 40173 through 40175), including the new requirements for registries to:

- Use Physician Quality Reporting System measure specifications and a standard set of measure calculation logic provided by CMS to calculate

reporting rates or performance rates unless otherwise stated;

- Provide a calculated result using the CMS-supplied logic and XML file for each measure that the registry intends to calculate; and
- Provide us the individual data elements used to calculate the measures if so requested by CMS for validation purposes.

We intend to post the final 2011 Physician Quality Reporting System registry requirements on the Physician Quality Reporting System section of the CMS Web site at <http://www.cms.gov/PQRI> by November 15, 2010 or shortly thereafter. We anticipate that new registries that wish to self-nominate for 2011 would be required to do so by January 31, 2011.

Similar to the 2010 Physician Quality Reporting System, registries that were "qualified" for 2010 and wish to continue to participate in 2011 will not need to be "re-qualified" for 2011 but instead demonstrate that they can meet the new 2011 data submission requirements. For technical reasons, however, we do not expect to be able to complete this vetting process for the new 2011 data submission requirements until mid-2011. Therefore, we will not be able to post the names of registries that are qualified for the 2011 Physician Quality Reporting System until we have determined the previously qualified registries that wish to be qualified for the 2011 Physician Quality Reporting System are in compliance with the new registry requirements.

Nevertheless, registries "qualified" for 2010, who were successful in submitting 2010 Physician Quality Reporting System data, and wish to continue to participate in 2011 will need to indicate their desire to continue participation for 2011 by submitting a letter to CMS indicating their continued interest in being a Physician Quality Reporting System registry for 2011 and their compliance with the 2011 Physician Quality Reporting System registry requirements by no later than October 31, 2010. Additionally, registries that are unsuccessful submitting 2010 Physician Quality Reporting System data (that is, fail to submit 2010 Physician Quality Reporting System data per the 2010 Physician Quality Reporting System registry requirements) will need to go through a full self-nomination vetting process for 2011.

Similar to the 2010 Physician Quality Reporting System, if a qualified 2010 Physician Quality Reporting System registry fails to submit 2010 Physician Quality Reporting System data per the 2010 Physician Quality Reporting

System registry requirements, the registry will be considered unsuccessful at submitting 2010 Physician Quality Reporting System data and will need to go through the full self-nomination process again to participate in the 2011 Physician Quality Reporting System. By March 31, 2011, registries that are unsuccessful at submitting quality measures results and numerator and denominator data for 2010 will need to be able to meet the 2011 Physician Quality Reporting System registry requirements and go through the full vetting process again. This would include CMS receiving the registry's self-nomination by March 31, 2011. As discussed in another section of this final rule with comment period, the aforementioned registry requirements will also apply for the purpose of a registry qualifying to submit the electronic prescribing measure for the 2011 Electronic Prescribing Incentive Program.

(5) Final Qualification Requirements for EHR Vendors and Their Products

The EHR vendor qualification process for the 2011 Physician Quality Reporting System was finalized in the 2010 PFS final rule with comment period (74 FR 61800 through 61802) and is currently underway. We anticipate the 2011 EHR vendor vetting process will be complete in early 2011, at which point those EHR products meeting all of the 2011 vendor requirements will be listed on the Physician Quality Reporting System section of the CMS Web site as a "qualified" Physician Quality Reporting System EHR product.

During 2011, we proposed to use the same self-nomination process described in the "Requirements for Electronic Health Record (EHR) Vendors to Participate in the 2011 Physician Quality Reporting System EHR Testing Program" posted on the Physician Quality Reporting System section of the CMS Web site at http://www.cms.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage, to qualify additional EHR vendors and their EHR products to submit quality data extracted from their EHR products to the CMS clinical quality data warehouse for the 2012 Physician Quality Reporting System. Specifically, we proposed that the 2011 Physician Quality Reporting System EHR test vendors, who, if their testing is successful, may report 2012 Physician Quality Reporting System data to CMS, must meet the following requirements:

- Be able to collect and transmit all required data elements according to the 2012 EHR Specifications.

- Be able to separate out and report on Medicare Part B FFS patients only.
- Be able to include TIN/NPI information submitted with an eligible professional's quality data.
- Be able to transmit this data in the CMS-approved format.
- Comply with a secure method for data submission.
- Not be in a beta test form.
- Have at least 25 active users.

Additionally, we proposed that previously qualified Physician Quality Reporting System EHR vendors and 2012 EHR test vendors must participate in ongoing Physician Quality Reporting System mandatory support conference calls hosted by CMS (approximately one call per month). These requirements would apply not only for the purpose of a vendor's EHR product being qualified so that the product's users may submit data extracted from the EHR for the 2012 Physician Quality Reporting System in 2013, but also for the purpose of a vendor's EHR product being qualified so that the product's users may electronically submit data extracted from the EHR for the electronic prescribing measure for the 2012 eRx Incentive Program in 2013. We proposed that if a vendor misses more than one mandatory support call or meeting, the vendor and their product would be disqualified for the Physician Quality Reporting System reporting year, which is covered by the call.

We proposed that previously qualified vendors and new vendors will need to incorporate any new EHR measures (that is, electronically-specified measures) added to the Physician Quality Reporting System for the reporting year they wish to maintain their Physician Quality Reporting System qualification, as well as update their electronic measure specifications and data transmission schema should either or both change.

The following is a summary of the comments received regarding the proposed 2012 EHR vendor qualification requirements and/or process.

Comment: We received a comment disagreeing that an EHR should be required to support all new measures. The commenter noted that an EHR might not collect all the necessary data points for all measures and that this is not required for the EHR Incentive Program.

Response: While the commenter makes a valid point, selecting an appropriate EHR can be challenging for eligible professionals. As such, we are requiring qualified EHRs to be able to report all Physician Quality Reporting System measures with electronic

specifications. We believe that this will lessen the burden on eligible professionals in deciding which system to purchase. That is, either the EHR is qualified for the Physician Quality Reporting System (completely) or not at all.

Upon consideration of these comments, we are finalizing the 2012 EHR vendor qualification requirements that will be used to vet EHR vendors in 2011 for 2012 Physician Quality Reporting System data submission in 2013 as proposed in the CY 2011 PFS proposed rule (75 FR 40175 through 40176). Any EHR vendor interested in having one or more of their EHR products "qualified" to submit quality data extracted from their EHR products to the CMS clinical quality data warehouse for the 2012 Physician Quality Reporting System will be required to submit their self-nomination letter by January 31, 2011. Instructions for submitting the self-nomination letter will be provided in the 2012 EHR vendor requirements, which we expect to post in the 4th quarter of CY 2010. Specifically, for the 2012 Physician Quality Reporting System, only EHR vendors that self-nominate to participate in the 2012 EHR Test Program will be considered qualified EHR vendors for the 2012 Physician Quality Reporting System.

e. Criteria for Satisfactory Reporting of Individual Quality Measures for Individual Eligible Professionals

Section 1848(m)(3)(A) of the Act established the criteria for satisfactorily submitting data on individual quality measures as at least 3 measures in at least 80 percent of the cases in which the measure is applicable. If fewer than 3 measures are applicable to the services of the professional, the professional may meet the criteria by submitting data on 1 or 2 measures for at least 80 percent of applicable cases where the measures are reportable. For years after 2009, section 1848(m)(3)(D) of the Act provides additional authority to the Secretary, in consultation with stakeholders and experts, to revise the criteria for satisfactorily reporting data on quality measures. Based on this authority and the input we have previously received from stakeholders, we proposed (75 FR 40176), for 2011, the following 2 criteria for claims-based reporting of individual measures by individual eligible professionals:

- Report on at least 3 measures that apply to the services furnished by the professional; and
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom

services were furnished during the reporting period to which the measure applies.

To the extent that an eligible professional has fewer than 3 Physician Quality Reporting System measures that apply to the eligible professional's services, we proposed the eligible professional would be able to meet the criteria for satisfactorily reporting data on individual quality measures by meeting the following 2 criteria:

- Report on all measures that apply to the services furnished by the professional (that is 1 to 2 measures); and
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We also proposed for 2011 the requirement that an eligible professional who reports on fewer than 3 measures through the claims-based reporting mechanism may be subject to the Measure Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. This process was applied in prior years. Under the proposed MAV process, when an eligible professional reports on fewer than 3 measures, we propose to review whether there are other closely related measures (such as those that share a common diagnosis or those that are representative of services typically provided by a particular type of eligible professional). We further proposed that if an eligible professional who reports on fewer than 3 measures in 2011 reports on a measure that is part of an identified cluster of closely related measures and did not report on any other measure that is part of that identified cluster of closely related measures, then the eligible professional would not qualify as a satisfactory reporter in the 2011 Physician Quality Reporting System or earn an incentive payment. In 2011, we proposed that these criteria for satisfactorily reporting data on fewer than 3 individual quality measures would apply for the claims-based reporting mechanism only.

For the 2011 Physician Quality Reporting System, we proposed the following 2 criteria for satisfactorily reporting of data on individual Physician Quality Reporting System quality measures for registry-based and EHR-based reporting:

- Report on at least 3 measures that apply to the services furnished by the professional; and

- Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We also proposed, in 2011, not to count measures that are reported through a registry or EHR that have a zero percent performance rate. That is, if the recommended clinical quality action is not performed on at least 1 patient for a particular measure or measures group reported by the eligible professional via a registry or EHR, we will not count the measure (or measures groups) as a measure (or measures group) reported by an eligible professional. We proposed to disregard measures (or measures groups) that are reported through a registry or EHR that have a zero percent performance rate in the 2011 Physician Quality Reporting System because we are assuming that the measure was not applicable to the eligible professional and was likely reported from EHR-derived data (or from data mining) and was unintentionally submitted from the registry or EHR to CMS. We also seek to avoid the possibility of intentional submission of spurious data solely for the purpose of receiving an incentive payment for reporting.

The following is a summary of the comments received regarding the criteria for satisfactory reporting of individual quality measures for individual eligible professionals.

Comment: We received several comments in support of the proposal to decrease the reporting sample from 80 percent to 50 percent of applicable cases where the measures are reportable as this would encourage greater Physician Quality Reporting System participation. One commenter expressed support for the lower percentage due to the errors and complexity seen to date with claims-based reporting in the Physician Quality Reporting System. Other commenters noted that a less restrictive requirement is a step forward in decreasing the costs and burdens associated with Physician Quality Reporting System participation.

Response: We appreciate the commenters' positive feedback. In lowering the reporting threshold for claims-based reporting from 80 percent to 50 percent, we are, as indicated by a commenter, acknowledging the complexity of claims-based reporting. As stated in the CY 2011 PFS proposed rule (75 FR 40176), a major reason that eligible professionals who participate in the Physician Quality Reporting System via claims-based reporting fail to do so satisfactorily is that they fail to report at

the required 80 percent. As shown in the quarterly QDC Error Reports that we post on the CMS Physician Quality Reporting System Web site at <http://www.cms.gov/PQRI>, eligible professionals often do not report QDCs on claims that are eligible for inclusion in a measure's denominator or report QDCs on claims that are not eligible for inclusion in a measure's denominator. When an eligible professional fails to report QDCs on eligible cases, it negatively impacts their reporting rate for that measure or measures group. When an eligible professional reports QDCs on ineligible cases, it neither improves nor negatively impacts their reporting rate for that measure or measures group. Thus, while lowering the reporting threshold may decrease the number of cases on which an eligible professional is required to report, it is still crucial that eligible professionals carefully review and understand the measure specifications for each measure or measures group they intend to report in order to be able to properly identify eligible cases.

Comment: A few commenters supportive of the proposal to reduce the reporting sample requirement from 80 percent to 50 percent recommended we also use our existing authority to apply the new 50 percent threshold retrospectively to the 2010 Physician Quality Reporting System.

Response: We finalized the 2010 Physician Quality Reporting System criteria for satisfactory reporting by individual eligible professionals in the CY 2010 PFS final rule with comment (74 FR 61802 through 61807). Therefore, we are not applying the 50 percent threshold retrospectively to the 2010 Physician Quality Reporting System. Any eligible professional who would have participated in the 2010 Physician Quality Reporting System had they known that we were lowering the reporting threshold for claims-based reporting to 50 percent would be disadvantaged. Such eligible professionals are not likely to be able to start participating in the 2010 Physician Quality Reporting System and meet the 2010 criteria for satisfactory reporting in the time between publication of this final rule with comment period and December 31, 2010.

Comment: A couple of commenters requested that the threshold for registry-based and EHR-based reporting also be reduced to 50 percent in order to facilitate overall participation via an EHR or registry.

Response: As we stated in the CY 2011 PFS proposed rule (75 FR 40177), we do not believe that reducing the reporting sample to 50 percent for

registry-based reporting and EHR-based reporting would substantially impact the portion of participating eligible professionals who qualify for the Physician Quality Reporting System incentive. Over 90 percent of eligible professionals submitting data through registries were incentive eligible. The level of effort for EHR-reporting should be the same regardless of whether the reporting threshold is 50 percent, 80 percent, or 100 percent since the EHR could theoretically be programmed to submit data on all eligible cases to CMS.

Comment: A few commenters opposed the proposal to weaken the standard for claims-based reporting from 80 percent to 50 percent. The commenters stated it was unclear why we would suggest that we want to move toward more meaningful reporting mechanisms such as registries and EHRs, while at the same time lowering the bar for claims-based reporting. Another commenter suggested that we strengthen the reporting requirements.

Response: In light of the Physician Quality Reporting System payment adjustments that are required by section 1848(a)(8) of the Act beginning in 2015 for eligible professionals who do not satisfactorily report and the fact that claims-based reporting still remains the only reporting mechanism that is available to all eligible professionals, we believe that it is important to take steps to facilitate Physician Quality Reporting System reporting where feasible. As we have seen from Physician Quality Reporting System results from prior years, meeting the 80 percent reporting threshold for claims-based reporting is challenging because of the multiple billing codes as specified by the measure developer, that can place patients in the denominator of a measure combined with the inability to resubmit claims solely for the purpose of adding a QDC. Thus far, we have not experienced the same issues with other reporting mechanisms. As we stated in the CY 2011 PFS proposed rule (75 FR 40176), we believe that lowering the

reporting threshold for claims-based reporting will encourage greater participation in the Physician Quality Reporting System without increasing the likelihood that professionals will selectively report based on whether the performance expectation of a measure is met for that particular patient. Once a substantial proportion of eligible professionals begin participating in the Physician Quality Reporting System, we envision that we will gradually strengthen the reporting requirements.

Comment: A few commenters recommended we remove the restriction on registry reporting for those eligible professionals that cannot report 3 measures, especially given that our results show that those who report via a registry are roughly twice as successful as those who report via claims.

Response: We have received similar comments to this effect in the past. We continue to maintain that permitting an eligible professional to report fewer than 3 measures through the registry-based reporting mechanism (if fewer than 3 measures apply to him or her) would be inefficient. It would be analytically difficult in that if an eligible professional submits fewer than 3 measures via registries, we would not know whether the eligible professional did so because only 2 measures applied to him or her or because the registry only accepts data for 2 of the professional's measures and he or she is reporting the third measure via claims. We also look for the most favorable method of reporting (that is, did the eligible professional report via a different method for a longer reporting period as well as whether an eligible professional satisfactorily reported under a different reporting option if he or she did not satisfactorily report for a particular reporting period. Accepting fewer than 3 measures from registries would increase the amount of cross-checking already required, which would impact the timeline for paying incentives.

Comment: Some commenters recommended we change the reporting requirements for individual eligible professionals with respect to increasing the number of required measures and/or requiring reporting on a standard cluster of measures. One commenter recommended that we create a standard, risk-adjusted list of Physician Quality Reporting System quality measures for all eligible professionals that we would update annually. Similarly, another commenter suggested that we assign a core set of measures that applies across eligible professions. The commenter also suggested that we assign sets of measures for individual and small group practice participants for high-volume conditions, based on services provided to their patient population. Additional recommendations for strengthening the reporting requirements include, requiring eligible professionals to stratify measures by patient race, ethnicity, preferred language and gender, constructing composites for the current measures groups, using a reliability threshold of 0.70 in lieu of, or in conjunction with, a minimum sample size, increasing the sample size for larger group practices, and maintaining the reporting threshold of 80 percent for claims-based reporting.

Response: We appreciate the constructive feedback and agree with the potential benefit of core measures, moving to more sets or groups of measures, and being more specific as to which measures eligible professionals should report in order to achieve more consistency of reporting across eligible professionals in the future.

After consideration of the comments and for the reasons we previously explained, the final 2011 criteria for satisfactory reporting of data on individual Physician Quality Reporting System quality measures for individual eligible professionals are summarized in Table 73 and are arranged by reporting mechanism and reporting period.

TABLE 73—2011 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES, BY REPORTING MECHANISM AND REPORTING PERIOD

Reporting mechanism	Reporting criteria	Reporting period
Claims-based reporting	<ul style="list-style-type: none"> Report at least 3 PQRI measures, or 1–2 measures if less than 3 measures apply to the eligible professional; and Report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. 	January 1, 2011–December 31, 2011.
Claims-based reporting	<ul style="list-style-type: none"> Report at least 3 PQRI measures, or 1–2 measures if less than 3 measures apply to the eligible professional; and Report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. 	July 1, 2011–December 31, 2011.

TABLE 73—2011 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES, BY REPORTING MECHANISM AND REPORTING PERIOD—Continued

Reporting mechanism	Reporting criteria	Reporting period
Registry-based reporting	<ul style="list-style-type: none"> • Report at least 3 PQRI measures (measures with a 0% performance rate will not be counted); and • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. 	January 1, 2011–December 31, 2011.
Registry-based reporting	<ul style="list-style-type: none"> • Report at least 3 PQRI measures (measures with a 0% performance rate will not be counted); and • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. 	July 1, 2011–December 31, 2011.
EHR-based reporting	<ul style="list-style-type: none"> • Report at least 3 PQRI measures (measures with a 0% performance rate will not be counted); and • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. 	January 1, 2011–December 31, 2011.

For the 2011 Physician Quality Reporting System, we are finalizing a total of 5 reporting options, or ways, in which an eligible professional may meet the criteria for satisfactory reporting on individual measures. Each reporting option consists of the criteria for satisfactory reporting such data and results on individual quality measures relevant to a given reporting mechanism and reporting period. Eligible professionals must meet the requirements for at least 1 of these 5 reporting options using a single reporting mechanism in order to qualify for a 2011 Physician Quality Reporting System incentive for satisfactorily reporting individual measures. CMS will not combine data received via different reporting mechanisms to determine whether the reporting criteria are met. It is possible, however, for eligible professionals to potentially qualify as satisfactorily reporting individual quality measures under more than one of the reporting criteria, reporting mechanisms, and/or for more than one reporting period. In this case, only one incentive payment will be made to an eligible professional based on the longest reporting period for which the eligible professional satisfactorily reports.

f. Criteria for Satisfactory Reporting Measures Groups for Individual Eligible Professionals

For the 2011 Physician Quality Reporting System, we proposed that individual eligible professionals have the option to report measures groups instead of individual quality measures to qualify for the 2011 Physician Quality Reporting System incentive, using claims or registries. The criteria that we proposed for 2011 for satisfactory reporting of measures groups through claims-based or registry-based reporting

for either the 12-month or 6-month reporting period are as follows: (1) For claims-based reporting, the reporting of at least 1 measures group for at least 50 percent of patients to whom the measures group applies, during the reporting period; or (2) for registry-based reporting, the reporting of at least 1 measures group for at least 80 percent of patients to whom the measures group applies during the reporting period. Eligible professionals, for both claims-based and registry-based reporting under these criteria, would be required to submit data on a minimum of 15 unique Medicare Part B FFS patients for the 12-month reporting period and a minimum of 8 Medicare Part B FFS patients for the 6-month reporting period.

Additionally for 2011, we proposed to retain the criteria, available only for the 12-month reporting period, based on reporting on at least 1 measures group for at least 30 unique patients for whom services were furnished between January 1, 2011, and December 31, 2011, to whom the measures group applies. As in previous years, we proposed that for 2011, the patients; for claims-based reporting, would be limited to Medicare Part B FFS patients. Finally, for registry-based reporting in 2011, in contrast to prior program years, we proposed to require that the minimum patient numbers or percentages must be met by Medicare Part B FFS patients exclusively and not non-Medicare Part B FFS patients.

The following is a summary of the comments received regarding the proposed criteria for reporting measures groups for individual eligible professionals.

Comment: One commenter strongly supported the proposed Physician Quality Reporting System measures group reporting option for claims-based

and registry reporting, especially the change in the reporting threshold for claims-based reporting from 80 percent to 50 percent.

Response: We appreciate the commenter's positive feedback.

Comment: A few commenters supported the proposal that for registry reporting of measures groups for 2011 that the minimum patient numbers or percentages must be met by Medicare Part B FFS patients exclusively and exclude data on non-Medicare Part B FFS patients. It is thought that this will reduce the difficulty of analyzing the data we received from registries where patients other than Medicare Part B FFS patients are included. Another commenter was concerned that this change eliminates any benefit that eligible professionals had for using the registry more broadly than just for Medicare patients. The commenter also noted that registries are most useful for improved patient care when all patients in the practice with a particular condition are included in the system.

Response: We appreciate the supportive comment. We believe that limiting the reporting sample for registry-based reporting of measures groups to Medicare Part B FFS patients will facilitate validation of registry-submitted data against the Medicare claims data.

Comment: One commenter supported our proposal to eliminate the requirement for reporting on consecutive patients for registry-based reporting of measures groups.

Response: We appreciate the commenter's support. We assume that the commenter is referring to a requirement in the 2008 and 2009 Physician Quality Reporting System where eligible professionals were required to report on patients seen consecutively by date of service. We

note that we removed the requirement for reporting on consecutive patients for registry-based reporting of measures groups for the 2010 Physician Quality Reporting System. We did not propose nor are we requiring eligible

professionals to report on consecutive patients when reporting measures groups for the 2011 Physician Quality Reporting System.

Based on the comments, the final 2011 criteria for satisfactory reporting of

data on measures groups are summarized in Table 74 and are arranged by reporting mechanism and reporting period.

TABLE 74—2011 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS, BY REPORTING MECHANISM AND REPORTING PERIOD

Reporting mechanism	Reporting criteria	Reporting period
Claims-based reporting	<ul style="list-style-type: none"> Report at least 1 PQRI measures group; Report each measures group for at least 30 Medicare Part B FFS patients. 	January 1, 2011–December 31, 2011.
Claims-based reporting	<ul style="list-style-type: none"> Report at least 1 PQRI measures group; Report each measures group for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; and Report each measures group on at least 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. 	January 1, 2011–December 31, 2011.
Claims-based reporting	<ul style="list-style-type: none"> Report at least 1 PQRI measures group; Report each measures group for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; and Report each measures group on at least 8 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. 	July 1, 2011–December 31, 2011.
Registry-based reporting	<ul style="list-style-type: none"> Report at least 1 PQRI measures group (measures groups with a 0% performance rate will not be counted); Report each measures group for at least 30 Medicare Part B FFS patients. 	January 1, 2011–December 31, 2011.
Registry-based reporting	<ul style="list-style-type: none"> Report at least 1 PQRI measures group (measures groups with a 0% performance rate will not be counted); Report each measures group for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; and Report each measures group on at least 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. 	January 1, 2011–December 31, 2011.
Registry-based reporting	<ul style="list-style-type: none"> Report at least 1 PQRI measures group (measures groups with a 0% performance rate will not be counted); Report each measures group for at least 80% of the EP's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; and Report each measures group on at least 8 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. 	July 1, 2011–December 31, 2011.

As illustrated in Table 74, there are a total of 6 reporting options, or ways in which eligible professionals may meet the criteria for satisfactory reporting of measures groups for the 2011 Physician Quality Reporting System. As we stated previously, eligible professionals may potentially qualify as satisfactorily reporting for the 2011 Physician Quality Reporting System on measures groups under more than one of the reporting criteria, reporting mechanisms, and/or for more than one reporting period; however, only one incentive payment will be made to an eligible professional based on the longest reporting period for which the eligible professional satisfactorily reports. In addition,

although an eligible professional could submit data under multiple reporting mechanisms, CMS will not combine data received from different reporting mechanisms to determine whether the eligible professional satisfactorily reported. Similarly, an eligible professional could also potentially qualify for the Physician Quality Reporting System incentive payment by satisfactorily reporting both individual measures and measures groups. However, only one incentive payment will be made to the eligible professional based on the longest reporting period for which the eligible professional satisfactorily reports.

g. Reporting Option for Satisfactory Reporting on Quality Measures by Group Practices

(1) Background and Authority

Section 1848(m)(3)(C)(i) of the Act required the Secretary to establish and have in place a process by January 1, 2010 under which eligible professionals in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures under the Physician Quality Reporting System if, in lieu of reporting measures under the Physician Quality Reporting System, the group practice reports measures determined appropriate by the Secretary, such as

measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time specified by the Secretary. Section 1848(m)(3)(C)(ii) of the Act requires that this process provide for the use of a statistical sampling model to submit data on measures, such as the model used under the Medicare Physician Group Practice (PGP) demonstration project under section 1866A of the Act. A group practice reporting option (GPRO) was established for the 2010 Physician Quality Reporting System in the CY 2010 PFS final rule with comment period (74 FR 61807 through 61811).

For the 2011 Physician Quality Reporting System, we proposed to continue to allow a group practice, as a whole (that is, for the TIN(s)), to participate in the 2011 Physician Quality Reporting System and to submit Physician Quality Reporting System quality measures for 2011 and qualify to earn an incentive (75 FR 40178–40183). If, however, an individual eligible professional is affiliated with a group practice participating in the GPRO and the group practice satisfactorily reports under the GPRO, the eligible professional will be considered as satisfactorily reporting Physician Quality Reporting System quality measures data at the individual level under that same TIN (that is, for the same TIN/NPI combination).

(2) Definition of “Group Practice”

As stated previously, section 1848(m)(3)(C)(i) of the Act authorized the Secretary to define “group practice.” For purposes of determining whether a group practice satisfactorily submits Physician Quality Reporting System quality measures data, we proposed that for the 2011 Physician Quality Reporting System a “group practice” would consist of a physician group practice, as defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) who have reassigned their billing rights to the TIN. This proposed definition for group practice is different from the 2010 Physician Quality Reporting System definition of group practice in that we proposed to change the minimum group size from 200 to 2 to enable more group practices to participate in the Physician Quality Reporting System GPRO in 2011.

As our intent is to build on an existing quality reporting program with which group practices may already be familiar, we proposed to be consistent with the PGP demonstration and use one GPRO process, which we refer to as “GPRO I” that would be available only

to similar large group practices. For group practices that have fewer than 200 members, we proposed, if technically feasible, an alternative GPRO process which we refer to as “GPRO II”.

In order to participate in the 2011 Physician Quality Reporting System through the GPRO, we proposed to require group practices to complete a self-nomination process and to meet certain technical and other requirements. For 2011, we proposed that group practices must participate in the Physician Quality Reporting System group practice reporting option in order to be eligible to participate in the eRx group practice reporting option for the 2011 Physician Quality Reporting System. As this is the current requirement under the 2010 Physician Quality Reporting System and eRx Incentive Program, we proposed that a group practice wishing to participate in both the Physician Quality Reporting System group practice reporting option and the electronic prescribing group practice reporting option must notify CMS of its desire to do so at the time that it self-nominates to participate in the Physician Quality Reporting System group practice reporting option.

In addition, we proposed that group practices that are participating in Medicare demonstration projects, as approved by the Secretary, would also be considered group practices for purposes of the 2011 Physician Quality Reporting System GPRO. Specifically, for the 2011 Physician Quality Reporting System we proposed to deem group practices participating in the PGP, Medicare Care Management Performance (MCMP), and EHR demonstrations to be participating in the Physician Quality Reporting System GPRO since many of the measures being reported under these demonstration programs are similar to Physician Quality Reporting System measures. As a result, such practices do not need to separately self-nominate to participate in the Physician Quality Reporting System GPRO, although it would be necessary for such groups to meet the requirements for incentive qualification under their respective approved demonstration project. For example, the MCMP demonstration sites would be required to meet the requirements for earning a Physician Quality Reporting System incentive specified under the MCMP demonstration.

For purposes of the 2011 eRx Incentive Program, however, we proposed that group practices participating in CMS-approved demonstration projects previously discussed would be required to meet the discussed 2011 eRx Incentive Program

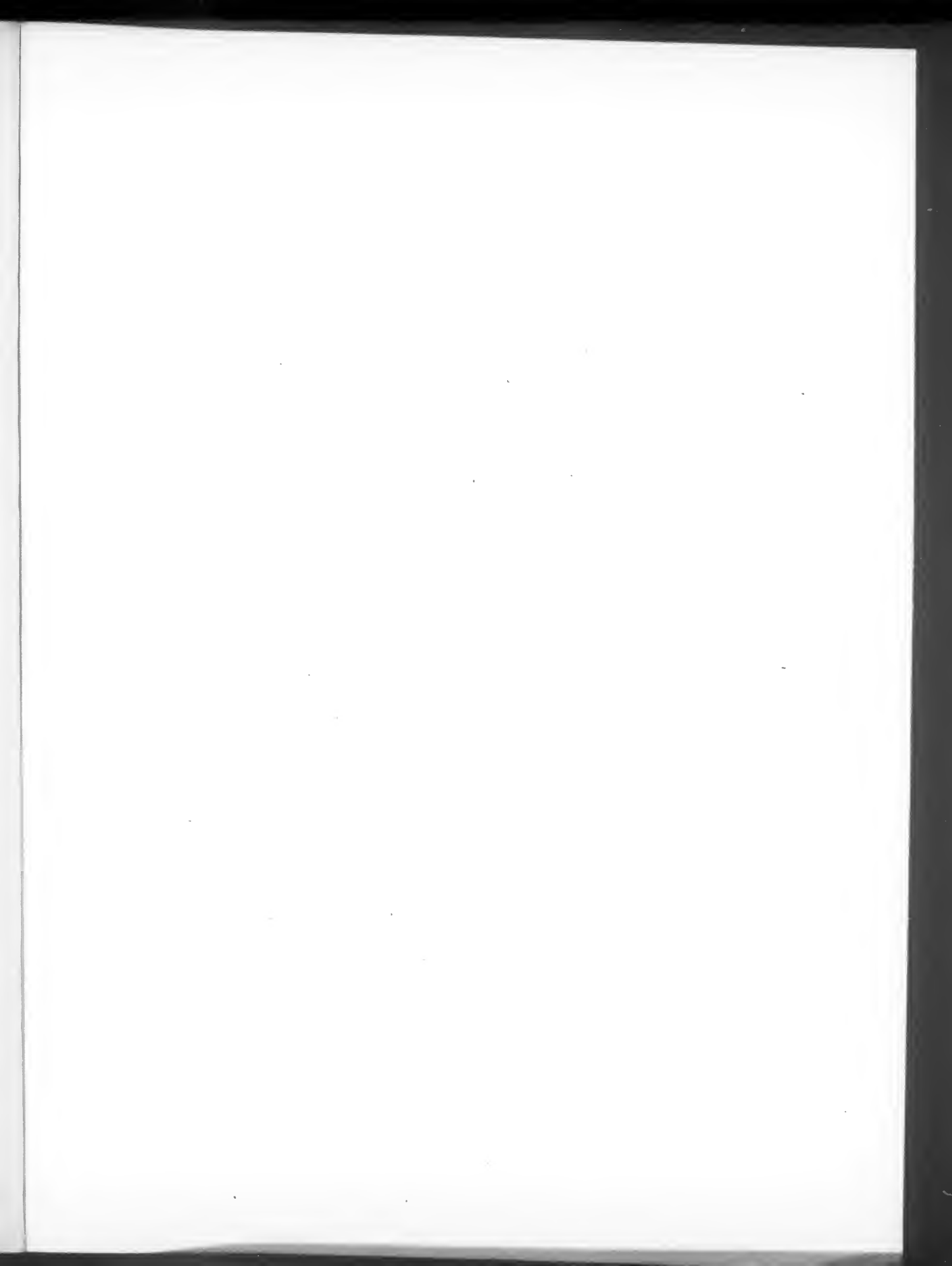
GPRO requirements or the proposed 2011 eRx Incentive Program requirements for individual eligible professionals in order to qualify for a 2011 eRx incentive. Such group practices would not be able to qualify for a 2011 eRx incentive via participation in an approved demonstration project since there is no eRx requirement under these demonstrations.

We also sought comment on alternatives for expanding GPRO in 2011. One option that we considered was to expand GPRO I to include smaller group practices. Specifically, we considered allowing groups of 100 or more eligible professionals to participate in the Physician Quality Reporting System under GPRO using the same reporting mechanism and reporting criteria required under the 2010 Physician Quality Reporting System GPRO and proposed for the 2011 Physician Quality Reporting System GPRO I. We also considered modifying the definition of “group practice” to include groups that have and use multiple TINs.

The following is a summary of the comments received regarding the proposed definition of “group practice” and the alternatives that were considered.

Comment: Several commenters expressed support for the proposed 2011 definition of a group practice as 2 or more individual eligible professionals who have reassigned their billing rights to the appropriate TIN, as opposed to a group practice with 200 or more individual eligible professionals as was the case in 2010. Commenters believed that this will greatly expand the opportunities for participation in the group practice reporting option and aligns with the current environment.

Response: We agree that our proposed definition of “group practice” will expand opportunities to participate in the group practice reporting option. To allow for expanded use of the group practice reporting option, we are finalizing our proposal to define “group practice” as 2 or more individual eligible professionals. However, as noted in the discussed that follows, we are modifying the definition of “group practice” with respect to group practices participating in Medicare demonstration projects approved by the Secretary.” Rather than including such group practices in the definition of “group practice” at § 414.90(b), we are indicating that such practices are deemed to be participating in the Physician Quality Reporting System at § 414.90(g)(1).





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